STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v. **CASE NO. 2019-10611**

GUILLERMO E. SALAS, R.PH.,

RESPONDENT.
_____/

AMENDED ADMINISTRATIVE COMPLAINT

COMES NOW, Petitioner, Department of Health, by and through its undersigned counsel, and files this Amended Administrative Complaint before the Board of Pharmacy against Respondent, Guillermo E. Salas, R.Ph., and in support thereof alleges:

1. Petitioner is the state agency charged with regulating the practice of pharmacy pursuant to section 20.43, Florida Statutes; chapter 456, Florida Statutes; and chapter 465, Florida Statutes.

2. At all times material to this Administrative Complaint, Respondent was a licensed pharmacist within the state of Florida, having been issued license number PS42755.

3. Respondent's address of record is 3701 North Country Club Drive, Apartment 1505, Aventura, Florida 33180.

4. On or about June 9, 2019, in the Eleventh Judicial Circuit Court, in and for Miami-Dade County, Florida, Respondent entered a plea of guilty to one count of grand theft, a third-degree felony in violation of section 812.014(2)(c), Florida Statutes (2018).

5. On or about June 11, 2019, in the Eleventh Judicial Circuit Court, in and for Miami-Dade County, Florida, Respondent entered a plea of nolo contendere to one count of grand theft, a third-degree felony in violation of section 812.014(2)(c), Florida Statutes (2018).

6. Respondent did not report to the Board of Pharmacy in writing within 30 days after he entered a plea of nolo contendere to grand theft.

7. Section 456.072(1)(x), Florida Statutes (2018-2019), provides that failing to report to the board, or the department if there is no board, in writing within 30 days after the licensee has been convicted or found guilty of, or entered a plea of nolo contendere to, regardless of adjudication, a crime in any jurisdiction constitutes grounds for disciplinary action.

8. Respondent failed to report to the Board of Pharmacy in writing within 30 days after entering a plea of nolo contendere to grand theft.

9. Based on the foregoing, Respondent violated section 456.072(1)(x).

WHEREFORE, the Petitioner respectfully requests that the Board of Pharmacy enter an order imposing one or more of the following penalties: permanent revocation or suspension of Respondent's license, restriction of practice, imposition of an administrative fine, issuance of a reprimand, placement of the Respondent on probation, corrective action, refund of fees billed or collected, remedial education and/or any other relief that the Board deems appropriate.

[*Signature on Next Page.*]

SIGNED this _____ day of _____ 2020.

Scott A. Rivkees, M.D.
State Surgeon General

_____

Alejandro Camacho
Assistant General Counsel
FDOH Prosecution Services Unit
4052 Bald Cypress Way, Bin #C-65
Tallahassee, Florida 32399-3265
Florida Bar Number 1018880
(P) (850) 558-9839
(F) (850) 245-4662
(E) alejandro.camacho@flhealth.gov

Original PCP Meeting: November 21, 2019
Original PCP Members: Weizer & Mesaros

Amendment PCP Meeting:
Amendment PCP Members:

NOTICE OF RIGHTS

Respondent has the right to request a hearing to be conducted in accordance with section 120.569 and 120.57, Florida Statutes, to be represented by counsel or other qualified representative, to present evidence and argument, to call and cross-examine witnesses and to have subpoena and subpoena duces tecum issued on his or her behalf if a hearing is requested.

A request or petition for an administrative hearing must be in writing and must be received by the Department within 21 days from the day Respondent received the Administrative Complaint, pursuant to rule 28-106.111(2), Florida Administrative Code. If Respondent fails to request a hearing within 21 days of receipt of this Administrative Complaint, Respondent waives the right to request a hearing on the facts alleged in this Administrative Complaint pursuant to rule 28-106.111(4), Florida Administrative Code. Any request for an administrative proceeding to challenge or contest the material facts or charges contained in the Administrative Complaint must conform to rule 28-106.2015(5), Florida Administrative Code.

Please note that mediation under section 120.573, Florida Statutes, is not available to resolve this Administrative Complaint.

NOTICE REGARDING ASSESSMENT OF COSTS

Respondent is placed on notice that Petitioner has incurred costs related to the investigation and prosecution of this matter. Pursuant to section 456.072(4), Florida Statutes, the Board shall assess costs related to the investigation and prosecution of a disciplinary matter, which may include attorney hours and costs, on the Respondent in addition to any other discipline imposed.

MEMORANDUM FOR RECONSIDERATION

TO:	Probable Cause Panel — Board of Pharmacy
FROM:	Alejandro Camacho, Assistant General Counsel
RESPONDENT:	Guillermo E. Salas, R.Ph.
CASE NO.:	2019-10611
DATE:	July 28, 2020

On November 21, 2019, the Probable Cause Panel found probable cause that Respondent had violated section 456.072(1)(x), Florida Statutes (2018–2019), by failing to report in writing, within 30 days, to the Board after entering a plea of guilty to grand theft on June 9, 2019. On November 22, 2019, an Administrative Complaint was filed against Respondent.

On July 19, 2020, Respondent presented new information in response to the Administrative Complaint. Respondent alleged that he notified the Board of the charges brought against him for grand theft on April 19, 2019. The alleged notice by Respondent was left on a Saturday at a closed Investigative Services Unit office in Doral, Florida, nearly two months before his plea to the charge of grand theft and specified that he pled not guilty to the charges.

The Department reviewed the information provided by Respondent. There is no record that the Department or the Board received any correspondence from Respondent regarding his plea to grand theft prior to his response to the Administrative Complaint. If the notice was received on April 19, 2019, Respondent's notice was nonetheless faulty because it represented Respondent would plead not guilty and section 456.072(1)(x) expressly requires that notice be provided after a triggering event. Upon review of the court records in Respondent's criminal case, the Department found Respondent later changed his plea to nolo contendere to the charge of grand theft. Therefore, the Department recommends that the Panel uphold its previous finding of probable cause and authorize the filing of the Amended Administrative Complaint.

Statement of Guillermo Salas R.Ph

Date July 2, 2020

Name Guillermo Salas R.Ph
3701 N. Country Club Drive, Apt 1505
Aventura, Florida 33180

Case No. 2019-10611

Phone 305-984-0812

Board members I Guillermo Salas did not failed to report to the Florida Board of Pharmacy both in writing and via telephone of my situation. On March 28, 2019 I was arrested at Nordstrom Store in Aventura Mall due to a Wrongful incident. According to the police report I conceal $ 678.00 worth of merchandise in a blue shopping bag. I did inform the Board via phone at 305-470-5800 the inspector (Elizabeth) from the Board of Pharmacy informed me I had to do it via mail I asked for the address or online. I wrote the letter attached with the police report and personally drop it at 8350 NW 52 Ter, Suite 400 in Doral it was a Saturday at approximately 1:30 pm a security officer informed me they are closed I left the letter under the door. I called back on Monday they informed me that it was received and wait. I did informed the Board of my situation within 30 days.

Sincerely

PS42755

This person is produced the following identification: FL Driver License

Subscribed and sworn to or affirmed before me this 2nd day of July 2020
NOTARY STATE SEAL:

Notary Public State of Florida
Beatriz Carreon
My Commission GG 931361
Expires 11/12/2023

Notary Public Name

11/12/2023
My Commission Expires

April 13, 2019

Attn: Florida Board of Pharmacy
8350 Nw 52 Terrace Suit 400
Doral, FL 33176

COPY

Re: Rph Guillermo Salas -PS42755
3701 N Country Club Dr Apt 1505
Aventura FL 33180

Dear Florida Board of Pharmacy Members:

I am writing this letter in order to notify you according to Florida Board of Pharmacy Statutes that on 03/28/2019 I was arrested at Nordstrom Store locate on Aventura Mall due to a wrongful incident.

Unfortunately, at this time due to this incident I have been charge with Grand Theft 3er Degree, but I already have a Criminal Attorney that will represent me for this issue with the Miami-Dade County Clerk of the Courts for my Courts Defense hearings.

Also, Please find enclosed with this letter a copy of the Police arrest Report, the Notice of Appearance from my Attorney and Plea of not guilty, that my attorney filed with the clerk of Court on my behalf.

If you need any additional information, please do not hesitate to contact me.

Respectfully

Guillermo Salas
FL Board No. PS42755
3701 N Country Club Dr Apt 1505
Aventura FL 33180
Ph No.: 305-9840812

C.c : Ivan Abrams Esq

COMPLAINT/ARREST AFFIDAVIT

COMPLAINT/ARREST AFFIDAVIT - COURT COPY

OBTS NUMBER	ARMED FORCES	BWC	POLICE CASE NO.
1301373297	NO	NO	19001504

SPECIAL OPERATION: [X] FELONY [ ] MISD [ ] TRAFFIC [ ] JUV [ ] DV [ ] MOVES [ ] CIV INF — FUGITIVE WARRANT: [ ] In State [ ] Out State — [X] WARRANT

JAIL NO.	PMHD	COURT CASE NO.
190133466	NO	F19006243

IDS NO.	AGENCY CODE	MUNICIPAL P.D. DEF. ID NO.	MDPD RECORDS AND ID NO	STUDENT ID NO.	GANG RELATED	FRAUD RELATED
3276734	085		1197259		NO	NO

DEFENDANT'S NAME (LAST, FIRST, MIDDLE): SALAS, GUILLERMO ENRIQUE

ALIAS and / or STREET NAME:

SIGNAL:

DOB (MM/DD/YYYY)	AGE	RACE	SEX	HISPANIC / ETHNICITY	HEIGHT	WEIGHT	HAIR COLOR	HAIR LENGTH	HAIR STYLE	EYES	GLASSES	FACIAL HAIR	TEETH
01/13/1967	52	W	M	NO / VEN	5'07	200	BRO	SHT	STR	BRO	NO	CLN	NOR

SCARS, TATTOOS, UNIQUE PHYSICAL FEATURES (Location, Type, Description):

PLACE OF BIRTH (City, State/Country): VZ

LOCAL ADDRESS:

PHONE:

CITIZENSHIP: VZ

PERMANENT ADDRESS (Street, Apt. Number): 3701 N COUNTRY CLUB DR

(City): AVENTURA (State): FL (Country): US (Zip): 33180

PHONE: (305) 384-0813

OCCUPATION: PHARMACY

SCHOOL OR BUSINESS ADDRESS (Street, Apt. Number):

(City): (State): (Country): (Zip):

PHONE:

ADDRESS SOURCE: DL

DRIVER'S LICENSE NUMBER/STATE	SOCIAL SECURITY NO.	WEAPON SEIZED	Defendant/CONCEALED WEAPON PERMIT	INDICATION OF:
FL-S420285670131	XXX-XX-XXXX	NO	NONE	Alcohol Influence: N Drug Influence: N

ARREST DATE	ARREST TIME	ARREST LOCATION	GRID
03/28/2019	19:25	NORDSTROMS 19507 BISCAYNE BLVD AVENTURA, FL 33180	

CO-DEFENDANT NAME	DOB			
		[ ] IN CUSTODY [ ] AT LARGE	[ ] FELONY [ ] DV	[ ] JUVENILE [ ] MISDEMEANOR
CO-DEFENDANT NAME	DOB			
		[ ] IN CUSTODY [ ] AT LARGE	[ ] FELONY [ ] DV	[ ] JUVENILE [ ] MISDEMEANOR
CO-DEFENDANT NAME	DOB			
		[ ] IN CUSTODY [ ] AT LARGE	[ ] FELONY [ ] DV	[ ] JUVENILE [ ] MISDEMEANOR

JUV only	Relation	Name	Street	Zip	Phone	Contacted?

CHARGES	CHARGE AS:	CNTS	FL STATUTE NUMBER	VIOL OF SECT.	CODE OF	UCR	DV	WARRANT TYPE OR TRAFFIC CITATION
1. F/3-GRAND THEFT 3RD DEGREE	F.S.	1	812.014(2)(C)			0006230C	N	
2.								
3.								
4.								

The undersigned certifies and swears that he/she has just and reasonable grounds to believe, and does believe that the above named Defendant committed the following violation of law:

On the 28 day of MARCH, 2019 at 18:54 at (NORDSTROMS) 19507 BISCAYNE BLVD. AVENTURA, FL, 33180

ON 3-28-2019 AT 1809 HOURS, THE DEF WAS OBSERVED BY LISTED LOSS PREVENTION OFFICER ENTER THE NORDSTROM'S DEPT STORE LOCATED AT 19507 BISCAYNE BLVD VIA CCTV. AFTER THE DEF ENTERED THE STORE, THE LISTED LP OFFICER OBSERVED THE DEF CONCEAL $678.00 WORTH OF MERCHANDISE IN A BLUE SHOPPING BAG. THE DEF THEN EXITED THE STORE AT 1854 HOURS MAKING NO ATTEMPT TO PAY FOR THE CONCEALED ITEMS AFTER PASSING ALL POINTS OF SALE.

ONCE THE DEF EXITED THE STORE VIA THE SECOND FLOOR NORTH PARKING GARAGE EXIT HE WAS DETAINED BY LISTED LP AND APD WAS CALLED. UPON MY ARRIVAL TO THE LP OFFICE, I VIEWED THE CCTV FOOTAGE OF THE DEF... [Continued on Next Page]

HOLD FOR OTHER AGENCY VERIFIED BY:

[ ] HOLD FOR BOND HEARING. DO NOT BOND OUT (Officer Must Appear at Bond Hearing).

[ ] I understand that should I willfully fail to appear before the court as required by this notice to appear that I may be held in contempt of court and a warrant for my arrest shall be issued. Furthermore, I agree that notice concerning the time, date and place of all court hearings should be sent to the above address. I agree that it is my responsibility to notify Clerk of the Court (Juveniles notify Juvenile Division) anytime that my address changes.

[ ] You need not appear in court, but must comply with the instructions on the reverse side hereof.

I SWEAR THAT THE ABOVE STATEMENT IS TRUE AND CORRECT.

BONVILLE, C: Court ID: 085-00110

SWORN TO AND SUBSCRIBED BEFORE ME, THE UNDERSIGNED AUTHORITY THIS 28 DAY OF MARCH, 2019

HOWELL, A: Court ID: 085-00195

1100419130

OBTS NUMBER	COMPLAINT/ARREST AFFIDAVIT CONTINUATION	POLICE CASE NO.
1301373297		19001504

JAIL NO.	COURT CASE NO.
190133466	F19006243

SPECIAL OPERATION:		JAIL NO.	PNHD	COURT CASE NO.
	[X] FELONY [ ] MISD [ ] TRAFFIC [ ] JUV [ ] DV [ ] MOVES [ ] CIV INF [ ] WARRANT FUGITIVE WARRANT: [ ] In State [ ] Out State	190133466	NO	F19006243

DEFENDANT'S NAME (LAST, FIRST, MIDDLE)	DOB (MM/DD/YYYY)
SALAS, GUILLERMO ENRIQUE	01/13/1967

CO-DEFENDANT NAME	DOB			
		[ ] IN CUSTODY [ ] AT LARGE	[ ] FELONY [ ] DV	[ ] JUVENILE [ ] MISDEMEANOR
CO-DEFENDANT NAME	DOB			
		[ ] IN CUSTODY [ ] AT LARGE	[ ] FELONY [ ] DV	[ ] JUVENILE [ ] MISDEMEANOR

CHARGES	CHARGE AS:	CNTS	FL STATUTE NUMBER	VIOL OF SECT.	CODE OF	UCR	DV	WARRANT TYPE OR TRAFFIC CITATION
5.								
6.								
7.								
8.								

COMPLAINT/ARREST AFFIDAVIT CONT.

CONCEALING THE MERCHANDISE AND EXITING THE STORE. AFTER VIEWING THE VIDEO, THE DEF WAS PLACED UNDER ARREST AND TRANSPORTED TO TGK.

ALL MERCHANDISE WAS RECOVERED BY LP AND RETURNED. THE CCTV FOOTAGE OF THE THEFT WAS BURNED ONTO A DVD AND WILL BE PROVIDED TO THE MIAMI-DADE ASA AT PREFILE.

HOLD FOR OTHER AGENCY VERIFIED BY	[ ] HOLD FOR BOND HEARING. DO NOT BOND OUT (Officer Must Appear at Bond Hearing).	[ ] I Understand that should I willfully fail to appear before the court as required by this notice to appear that I may be held in contempt of court and a Warrant for my arrest shall be issued. Furthermore, I agree that notice concerning the time, date and place of all court hearings should be sent to the stores address. I agree that it is my responsibility to notify Clerk of the Court (juveniles notify Juvenile Division) anytime that my address changes.
I SWEAR THAT THE ABOVE STATEMENT IS TRUE AND CORRECT. BONVILLE, C: Court ID: 085-00110	SWORN TO AND SUBSCRIBED BEFORE ME, THE UNDERSIGNED AUTHORITY THIS 28 DAY OF MARCH, 2019 HOWELL, A: Court ID: 085-00195	[ ] You need not appear in court, but must comply with the instructions on the reverse side hereof.

IN THE CIRCUIT COURT OF THE ELEVENTH JUDICIAL CIRCUIT
IN AND FOR MIAMI-DADE COUNTY, FLORIDA

STATE OF FLORIDA,

Plaintiff,

v.

GUILLERMO SALAS,

Defendant.
_____/

CASE NO.: F19-6243

JUDGE: DE LA O

NOTICE OF APPEARANCE

TO THE CLERK OF THIS COURT:

YOU ARE HEREBY NOTIFIED that the undersigned attorney does hereby enter his appearance as attorney of record for the Defendant, **GUILLERMO SALAS**, in the above styled cause, and you are hereby requested to furnish said attorney with copies of all future Court dates, Motions, Orders, etc., in this cause.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing has been furnished by the e-filing portal to: Miami- Dade Clerk of the Court and to the Office of the State Attorney this ___11th___ day of April, 2019.

/s/ Ivan Abrams
IVAN ABRAMS, ESQ.
ABRAMS JUSTICE
8950 SW 74th Court
Suite 2201
Miami, Florida 33156
Office: (305) 709-0880
Fax: (305) 402-2888
Florida Bar # 72441

IN THE CIRCUIT COURT OF THE ELEVENTH JUDICIAL CIRCUIT
IN AND FOR MIAMI-DADE COUNTY, FLORIDA

STATE OF FLORIDA,

Plaintiff,

v.

GUILLERMO SALAS,

Defendant.
_____/

CASE NO: F19-6243

JUDGE: DE LA O

WRITTEN PLEA OF NOT GUILTY

COMES NOW, the Defendant, **GUILLERMO SALAS**, by and through his undersigned counsel and informs the Court that:

1. The above-named Defendant enters a plea of not guilty
2. The above-named Defendant hereby stands mute, requests a TRIAL by Jury, hereby waives formal arraignment and requests fifteen (15) days for the filing of appropriate defensive motions.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing has been furnished by the e-filing portal to: Miami- Dade Clerk of the Court and to the Office of the State Attorney this ___11th___ day of April, 2019.

/s/ **Ivan Abrams**
IVAN ABRAMS, ESQ.
8950 SW 74th Court
Suite 2201
Miami, Florida 33156
Office: (305) 709-0880
Fax: (305) 402-2888
Florida Bar # 72441

IN THE CIRCUIT COURT OF THE ELEVENTH JUDICIAL CIRCUIT
IN AND FOR MIAMI-DADE COUNTY, FLORIDA

STATE OF FLORIDA,

Plaintiff,

v.

GUILLERMO SALAS,

Defendant.
_____/

CASE NO.: F19-6243

JUDGE: DE LA O

NOTICE OF DISCOVERY

The Defendant, **GUILLERMO SALAS,** by and through his undersigned counsel, notifies the State of Florida of his intention to participate in discovery and pursuant to Rule 3.220 for the Florida Rules of Criminal Procedure, to disclose to counsel for the defendant and permit said counsel to inspect, copy, test and photograph the following material within the State's actual or constructive possession or control:

1. A complete list of the names and addresses of all persons known to the prosecutor to have information which may be relevant to the offense charged, and to any defense with respect thereto, regardless of whether the State intends to call said person at the time of trial or any hearings in the instant case.

2. The " statement" of any person whose name is furnished in compliance with the preceding paragraph, as said term is defined by Rule 3.220 and case decisions interpreting said Rule. The Defendant specifically demands disclosure of all statements, affidavits, transcripts and/or writings of testimony under oath upon which the above-styled Indictment or Information is based and upon which the probable cause for the detention of the Defendant has been determined.

3. Any written or recorded statements and the substance of any oral statements made by the Defendant and known to the prosecutor or any state witness, including any statements made in police reports, to loss prevention officers, or report summaries, together with the name and address for each witness to the statements.

4. Any written or recorded statements and the substance of any oral statements made by any purported witnesses in this case.

5. Any tangible papers or objects which were obtained from or belonged to the Defendant.

6. Whether there has been any electronic surveillance at the incident location which is in the possession of the State of Florida, including wire-tapping, of the premises of the Defendant, **the Nordstrom surveillance video mentioned in the (A-form),** or of conversations to which the Defendant was a party; and, any documents relating thereto:

a. Please disclose the contents of said conversations and please provide a copy of the Nordstrom surveillance videotape. Please ensure that if a body worn camera was used by the arresting officer, that is preserved for use at trial, and a copy is provided to the defense forthwith.

7. Whether there has been any search and seizure and any documents relating thereto:

a. Please disclose when, where, and under what circumstances the search and seizure was conducted.

b. Please disclose any documents relating thereto, including but not limited to, offense incident reports and affidavits and exhibits in support thereof, consent forms, miranda forms, property receipts and inventories reflecting material seized, and police reports relating to the performance of the search and seizure, as well as the preservation and disclosure of any police radio dispatch communication regarding this incident.

8. Any tangible papers or objects including photographs which the prosecuting attorney intends to use in the hearing or trial and which were not obtained from or belonged to the Defendant.

10. Any and all material now known to the State of Florida, or which through due diligence may be learned from the investigating officers or the witnesses or persons having knowledge of this case, that is favorable to the accused or may lead to favorable material or might serve to mitigate the punishment, including any material impeaching or contradicting testimony of state witnesses or instructions to state witnesses not to speak with or discuss the facts of the case with defense counsel. *Brady v. Maryland, 373 U.S. 83 S.Ct. 1194, 10 L.Ed.2d 215 (1963).* The favorable material sought includes but is not limited to the following items:

a) Any and all material relating to the guilt or punishment of the accused;

b) Any and all material that impeaches prosecution as to witnesses;

c) Any and all material consisting of prior inconsistent statements of a state witness.

d) Any and all material consisting of information as to pending charges, prior charges, or prior convictions of a state witness;

e) Any and all material consisting of information regarding a state or government witness, interest, motives, prejudices, hostilities, means of obtaining knowledge, or power of memory;

f) Any and all material consisting of information that either of the alleged victims were the aggressor in the alleged incident.

11. Please disclose to and permit defense counsel to inspect and copy or photograph certain records which are in the possession of the State of Florida, or to which the State of Florida has access, to-wit:

a. The police arrest report and incident report filed by all police officers who participated in the arrest of the Defendant in this case.

b. The police complaint form filed by the police officer who received the original complaint of the alleged crime from any complaining witness in this case.

c. The arrest and/or crime conviction records, if any, of the witnesses that the State of Florida intends to call at the trial in this case.

d. The police booking sheet indicating the exact date, time, charge and other relevant data contained therein with reference to the arrest of the Defendant in this case.

The Defendant respectfully requests that copies of the written material and information demanded pursuant to the foregoing paragraphs be attached to the State's discovery response as said method of disclosure should be mutually agreeable to defense counsel and the prosecutor.

The Defendant requests the State to file and serve defense counsel with a written discovery responsewhich specifically, individually and completely responds to each of the aforementioned discovery requests.

All of this Documentary Evidence shall be furnished prior to any depositions should there be any, of the witnesses involved in this cause. It shall be presumed that the aforementioned discovery will be provided by U.S. mail from the prosecutor to the defense counsel absent objection from the prosecutor within (15) days of service of this written notice by the Defendant's attorney.

Should the State claim reasonable grounds, exceptions or privileges, that authorize non-disclosure, same should be specifically stated and the factual basis professed so that issues may be clearly joined for future litigation.

Respectfully Submitted,

/s/ Ivan Abrams

Ivan Abrams, Esq.

Attorney for Defendant

Florida Bar #72441

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing has been furnished by the e-filing portal to: Miami- Dade Clerk of the Court and through e-service to the Office of the Miami-Dade State Attorney this ___11th___ day of April, 2019.

/s/ Ivan Abrams
IVAN ABRAMS, ESQ.
ABRAMS JUSTICE
8950 SW 74th Court
Suite 2201
Miami, Florida 33156
Office: (305) 709-0880
Fax: (305) 402-2888
Florida Bar # 72441

Statement of Guillermo Salas R.Ph

Date July 2, 2020

Name Guillermo Salas R.Ph
3701 N. Country Club Drive, Apt 1505
Aventura, Florida 33180

Case No. 2019-10611

Phone 305-984-0812

Board members I Guillermo Salas did not failed to report to the Florida Board of Pharmacy both in writing and via telephone of my situation. On March 28, 2019 I was arrested at Nordstrom Store in Aventura Mall due to a Wrongful incident. According to the police report I conceal $ 678.00 worth of merchandise in a blue shopping bag. I did inform the Board via phone at 305-470-5800 the inspector (Elizabeth) from the Board of Pharmacy informed me I had to do it via mail I asked for the address or online. I wrote the letter attached with the police report and personally drop it at 8350 NW 52 Ter, Suite 400 in Doral it was a Saturday at approximately 1:30 pm a security officer informed me they are closed I left the letter under the door. I called back on Monday they informed me that it was received and wait. I did informed the Board of my situation within 30 days.

Sincerely

This person is produced the following identification: _____

Subscribed and sworn to or affirmed before me this ____ day of _____2020
NOTARY STATE SEAL:

_____

Notary Public Name

My Commission Expires

CONFIDENTIAL AND EXEMPT MATERIALS

One or more pages have been removed from this document for security reasons

Scroll down to see the available pages or advance to the next document if all pages have been removed.

SOME OR ALL PAGES IN THIS DOCUMENT ARE PATIENT RECORDS AND/OR DOCUMENTS THAT IDENTIFY THE PATIENT BY NAME AND ARE EXEMPT FROM PUBLIC RECORDS LAWS.

456.057 - Ownership and control of patient records; report or copies of records to be furnished.—

10)(a)All patient records obtained by the department and any other documents maintained by the department which identify the patient by name are confidential and exempt from s. 119.07(1) and shall be used solely for the purpose of the department and the appropriate regulatory board in its investigation, prosecution, and appeal of disciplinary proceedings. The records shall not be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the department or the appropriate board.

IN THE CIRCUIT COURT OF THE ELEVENTH JUDICIAL CIRCUIT IN AND FOR MIAMI-DADE COUNTY, FLORIDA 388	CLOCK IN
CRIMINAL DIVISION — **FINDING OF GUILT AND ORDER OF WITHHOLDING ADJUDICATION/SPECIAL CONDITIONS**	
THE STATE OF FLORIDA **VS.** GUILLERMO ENRIQUE SALAS **PLAINTIFF** **DEFENDANT**	
CASE NUMBER: **F19006243**	

FILED FOR RECORD
2019 NOV 21 PM 1:16
CLERK OF THE CIRCUIT & COUNTY COURTS
MIAMI-DADE COUNTY, FLORIDA

IT APPEARING UNTO THE COURT that the defendant being personally before the court accompanied by his/her attorney, IVAN ABRAMS, PA has been found guilty of the charge of

COUNT	CRIME	DEGREE
1	GRAND THEFT 3RD DEGREE	3/F

by the court upon the entry of a nolo contendere plea
and it appearing unto the court, upon a hearing of the matter, that the defendant is not likely to engage in a criminal course of conduct and the ends of justice and welfare of society do not require that the defendant shall presently suffer the penalty imposed by law, and the Court being fully advised in the premises, it is thereupon ORDERED and ADJUDGED that an adjudication of guilt be, and the same is hereby stayed and withheld.

IT IS FURTHER ORDERED AND ADJUDGED that:

The defendant is placed on PROBATION in a separate Order entered herein.

SPECIAL CONDITIONS

Costs
DNA previously taken
PROBATION

IT IS ORDERED THAT the defendant be fingerprinted pursuant to Florida Statute 921.241(1).

BOOK 31518 PAGE 1942 CFN: 20190427702 DATE:07/10/2019 01:13:50 PM Pgs 1942-1944 Mia-Dade Cty, FL

IN THE CIRCUIT COURT OF THE ELEVENTH JUDICIAL CIRCUIT IN AND FOR MIAMI-DADE COUNTY, FLORIDA		
CRIMINAL DIVISION	**CHARGES/COSTS/FEES**	**CASE NUMBER: F19006243**
THE STATE OF FLORIDA	**VS.** GUILLERMO ENRIQUE SALAS	
PLAINTIFF	**DEFENDANT**	

The Defendant is hereby ordered to pay the following sum indicated:

$50.00	Pursuant to Florida Statute 938.03(4) (Crimes Compensation Trust Fund).
$20.00	Pursuant to Florida Statute 938.06 (Crime Stopper's Programs).
$3.00	Pursuant to Florida Statute 938.19 (Teen Courts).
$50.00	Pursuant to Florida Statute 775.083(2) (Crime Prevention Programs).
$65.00	Pursuant to Florida Statute 939.185(1)(a) (Assessment of Additional Court Costs as Adopted by Ordinance 04-116).
$85.00	Pursuant to Florida Statute 939.185(1)(b) (Surcharge as adopted by Ordinance 05-123).
$100.00	Cost of prosecution Florida Statute 938.27(8)
$225.00	Additional cost fine and forfeiture Florida Statute 938.05

$598.00 TOTAL

STAY DUE DATE: 7/11/2019

DONE AND ORDERED in Open Court in Miami-Dade County, Florida this 11th day of June, 2019.

JUDGE MIGUEL M DE LA O DIV. F005

ELECTION OF RIGHTS

I received the Administrative Complaint on the following date: _____

Persons seeking a hearing on an Administrative Complaint must file a petition for hearing with the agency within 21 days of receipt of written notice of the Administrative Complaint pursuant to Rule 28-106.111(2), Florida Administrative Code.

Any person who receives written notice of an Administrative Complaint and who fails to file a written request for a hearing within 21 days waives the right to request a hearing on such matters pursuant to Rule 28-106.111(4), Florida Administrative Code.

PLEASE SELECT ONLY 1 OF THE 2 OPTIONS.

OPTION 1. _____ **I <u>do not</u> dispute the allegations** of material fact in the Administrative Complaint. I request a hearing be conducted pursuant to Section 120.57(2), Florida Statutes, where I will be permitted to appear, if I so choose, and submit oral and/or written evidence in mitigation of the complaint to the Board.

OPTION 2. ✓ **I <u>do</u> dispute the allegations** of material fact contained in the Administrative Complaint and request this to be considered a petition for formal hearing, pursuant to Sections 120.569(2)(a) and 120.57(1), Florida Statutes, before an Administrative Law Judge appointed by the Division of Administrative Hearings. **Pursuant to the requirement of Uniform Rule 28-106.2015(5), Florida Administrative Code, I specifically dispute the following material facts (identified by paragraph number and fact disputed) in the Administrative Complaint:**

I Guillermo Salas Dispute the allegations on April 13, 2019 a Saturday left a letter explaining the incident. The address is the following 7350 W 52 Ter, Suit 400, Doral FL 33166 they have a Security that walked me directly to the office and I left the letter.

<u>PLEASE NOTE</u>: If the Department does not receive your completed election of rights within 21 days of your receipt of the Administrative Complaint, your request for hearing will be denied.

✓ _____

Respondent's Signature
Address: _____

_____

Lic. No.: PS 42755
Phone No.: 305-934-0812 Fax No.: 305-477-6578
Email: Guillermo@hotmail.com .

STATE OF FLORIDA
COUNTY OF Dade

Notary Public State of Florida
Beatriz Carreon
My Commission GG 931361
Expires 11/12/2023

_____

Attorney/Qualified Representative*
Address: _____

_____

Phone No.: _____
Fax No.: _____
Email: _____

***Qualified Representatives must file written requests to appear as such pursuant to Rule 28-106.106, Uniform Rules of Procedure.**

PLEASE MAIL AND/OR FAX COMPLETED FORM TO: Hannah Phillips, Esquire, Assistant General Counsel, DOH, Prosecution Services Unit, 4052 Bald Cypress Way, Bin C-65, Tallahassee, Florida 32399-3265. Telephone Number: (850) 558-9824; FAX (850) 245-4662; TDD 1-800-955-877

STATE OF FLORIDA

DEPARTMENT OF HEALTH

INVESTIGATIVE REPORT

Office: Miami ISU	Date of Complaint: 7/3/19	Case Number: 2019-10611
Subject: GUILLERMO E. SALAS, RPh 3701 N. Country Club Dr., Apt 1505 Aventura, FL 33180 305 984-0812		Source: FLORIDA DEPARTMENT OF HEALTH- CONSUMER SERVICES UNIT
Profession: Pharmacist		License Number and Status: 42755, Clear, Active
Related Case(s): 201926421, 201939585		Period of Investigation and Type of Report: 5/8/2020 - 6/23/2020, Supplemental 1
Alleged Violation: See final report		

Synopsis: This supplemental report is based on a request from DOH attorney ALEJANDRO CAMACHO requesting that an Administrative Complaint (AC) packet be hand-served to SALAS.

On 6/18/2020 DOH Investigator, ANA CALVO hand-served the AC packet to SALAS at his residence at 3701 N. Country Club Dr., Apt 1505, Aventura, FL 33180.

Exhibit page

S1-1 PSU Request Form.....2

S1-2 Affidavit of Service.....3

Investigator/Date:	Approved By/Date:
Robert Radin, MQA Investigator, 6/23/20	Carlos Suarez, MQA Supervisor 6/23/2020

PSU REQUEST FORM

FROM: Alejandro Camacho, Esq.	TO: ISU Miami
Date: May 8, 2020	TO: CSU
Phone #: 850-558-9839	CC:

Case Number: **2019-10611** Board: **Pharmacy**
Subject: **Guillermo Salas, R.Ph.** HL Code:**hll162b** Status: **87**
Requested Completion Date: 06/08/2020

(PSU) TYPE OF REQUEST: (describe details below)

☒ Process Service* (**Activity Code 160**)

☐ Additional Information Requested (**Activity Code 145**)

☐ Deficiency in Investigative Work (**Activity Code 150**)

Details: Please hand deliver AC pack to Respondent; he was detained by ICE and is currently at:
Krome North SPC Detention Facility, 18201 S.W. 12th St., Miami, FL 33194
Visitor Phone: 305-207-2001

*The following additional information is needed for each service request:
Last Known Address: 18201 S.W. 12th St. Miami, FL 33194
Last Known Name & Phone Number: Guillermo Salas 305-984-0812
Last Known Place of Employment & Address if Known:
Has Contact Been Made With This Individual? YES ☐ No☒; If Yes, When?

Was this case originally worked by CSU or in an area office different from where this service request is being sent? YES ☐** No ☐ NOTE: All process service requests need to be sent to appropriate field office.
****IF YES, please send a copy of the original Investigative Report without attachments.**

(ISU/CSU) RESPONSE:
☒ Process Service Completed (Activity Code 161) ☐ Process Service NOT Completed (Activity Code 162)

☐ Additional Info Sent to Legal (Activity Code 156)

☐ Supp. Investigation Request Cancelled (Activity Code 157)

Email to:
Pensacola | Tallahassee | Alachua | Jacksonville | St. Pete | Tampa | Orlando | Ft. Myers | Jupiter | Ft. Lauderdale | Miami
Consumer Services

Rev. 01/2020

AFFIDAVIT OF SERVICE OR DILIGENT SEARCH

DEPARTMENT OF HEALTH
Petitioner

vs

Case No. 2019-10611

Guillermo E. Salas, R.PH.,
Respondent

COMES NOW, the affiant, who first being duly sworn, deposes and states:
1) Affiant is an Investigator/Inspector employed by the DEPARTMENT OF HEALTH, State of Florida.

2) That on _____, Affiant made a diligent effort to locate Respondent, to serve XX Administrative Complaint and related papers; _ Order compelling examination(s); Subpoena(s); _____Final order; _____Notice to cease and desist; _____ ESO/ERO and related papers.

3) Check applicable answer below:

XX Affiant made personal service on Guillermo E. Salas, Respondent, on 6/18/2020 at 3701 N. Country Club Dr., Apt 1505, Aventura, FL 33180, where Guillermo E. Salas resides.

____Affiant was unable to make service after searching for Respondent at: (a) all addresses for Respondent shown in the DOH investigation of the case; (b) all official addresses for Respondent shown in his licensing records on the computer terminal or Board office; (c) Local telephone company for the last area Respondent was known to frequent; (d) Division of Drivers Licenses; and (e) Utilities (electric, cable, etc.); any others: _____

Affiant

State Of Florida
County Of Miami-Dade
Before me, personally appeared Ana Maria Calvo whose identity is known to me by Person _____ (type of identification) and who, acknowledges that his/her signature appears above.

Sworn to or affirmed by Affiant before me this 18 day of June 2020.

Notary Public-State of Florida

My Commission Expires

ROBERT RADIN
Commission # GG 286364
Expires January 14, 2023
Bonded Thru Troy Fain Insurance 800-385-7019

Robert Radin

Type or Print Name

Florida Department of Health
Division of Medical Quality Assurance
8350 NW 52 Terrace, Ste 400• Miami, FL 33166-7709
PHONE: 305 470-5896 • FAX 305 499-2090
FloridaHealth.gov
INV FORM 321, Revised 8/14

PHAB Accredited Health Department
Public Health Accreditation Board

Exhibit S1-2

STATE OF FLORIDA

DEPARTMENT OF HEALTH

INVESTIGATIVE REPORT

Office: Consumer Services Unit	Date of Complaint: 7/3/19	Case Number: 201910611

Subject: GUILLERMO E. SALAS 3701 N. Country Club Dr. Apt 1505 Aventura, FL 33180 305-984-0812	Source: FLORIDA DEPARTMENT OF HEALTH- Consumer Services Unit
Profession: Pharmacist	License Number and Status: 42755/ Clear, Active
Related Case(s): none	Period of Investigation and Type of Report: 7/10/19- 7/10/19 FINAL

Alleged Violation: S.S. 456.072(1)(c)(k)(x)(dd), 465.016(1)(f)(r), F.S.

Synopsis: This investigation is predicated on the receipt of an internally generated complaint generated complaint stating SALAS retained fingerprints matched a recent arrest record. Review of the Criminal History Database indicates SALAS was arrested on 3/28/19 in Miami-Dade County and was charged with GRAND THEFT 3RD DEGREE 812.014(2)(C) (felony). SALAS plead guilty and adjudication was withheld on 6/11/19. SALAS has not reported this violation within the required time frame.

☒ Yes ☐ No Subject Notification Completed?
☐ Yes ☒ No Subject responded?
☐ Yes ☒ No Patient Notification Completed?
☒ Yes ☐ No Above referenced licensure checked in database/LEIDS?
☐ Yes ☒ No Board certified? Name of Board: Date:
Specialty:

Law Enforcement
☐ Notified Date:
☒ Involved Agency: Miami-Dade County

☐ Yes ☒ No Subject represented by an attorney?
Attorney information:

Investigator/Date: 7/10/19 Aliza Hopkins Government Analyst I	Approved By/Date: Rachel Beam Senior Management Analyst II 7/10/2019

Distribution: CSU/PSU

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** Exhibits contain information which identifies patient(s) by name and are sealed pursuant to section 456.057(9)(a) Florida Statute.

***This exhibit contains confidential records concerning reports of abuse, neglect or exploitation of the vulnerable adult, including reports made to the central abuse hotline, and is sealed pursuant to section 415.107(1), Florida Statutes

INVESTIGATIVE DETAILS

STATEMENT OF FLORIDA DEPARTMENT OF HEALTH- Consumer Services Unit– Source

This investigation is predicated on the receipt of an internally generated complaint generated complaint stating SALAS retained fingerprints matched a recent arrest record. Review of the Criminal History Database indicates SALAS was arrested on 3/28/19 in Miami-Dade County and was charged with GRAND THEFT 3RD DEGREE 812.014(2)(C) (felony). SALAS plead guilty and adjudication was withheld on 6/11/19. SALAS has not reported this violation within the required time frame.

STATEMENT OF GUILLERMO E SALAS – Subject

SALAS' response will be forwarded to the Prosecution Services Unit upon receipt.

CASE SUMMARY

CONFIDENTIAL

Case No: 201910611
Please use this number in all correspondence with the Department concerning this matter.

RESPONDENT INFORMATION

License: 42755 Profession: 2201 Pharmacist
Name: GUILLERMO E SALAS
Address: 3701 N COUNTRY CLUB DR APT 1505
AVENTURA, FL 33180
Home Phone: 305-984-0812

SOURCE OF INFORMATION

Name: Department Of Health/Consumer Services Unit
Address:

Home Phone:

REPORTED INFORMATION

Receive Date: 07/03/2019 Source Code: 79 Form Code: 1
Responsible Party: ha165 Status Code: 10
Classification Code: Incident Date: 06/11/2019

Patient Name:

Possible Code(s): 18, 12, 15, 37

Summary:
Possible Violation S.S. 456.072(1)(c)(k)(x)(dd), 465.016(1)(f)(r), F.S. Convicted of crime related to practice, Violate Statute/ Rule of Board, Failure to report violation, Failure to perform legal obligation. Received internally generated complaint stating the Subject's retained fingerprints matched a recent arrest record. Review of the Criminal History Database indicates Subject was arrested on 3/28/19 in Miami-Dade County and was charged with GRAND THEFT 3RD DEGREE 812.014(2)(C) (felony). Subject plead guilty and adjudication was withheld on 6/11/19. Subject has not reported this violation within the required time frame.
Analyzed by Aliza Hopkins HA165

Aliza Hopkins HA165

DOH-Form200

MEMORANDUM

TO: **Consumer Services Unit**

FROM: **Consumer Services Unit**

DATE: **7/3/2019**

RE: **Guillermo E Salas, PS42755**

Received a print hit indicating Guillermo E Salas matched an arrest record.

2019-10611
hales

Harvey Ruvin

CLERK OF THE CIRCUIT AND COUNTY COURTS
Miami-Dade County, Florida

☐ CRIMINAL COURTS DIVISION
☐ TRAFFIC/MISDEMEANOR
Richard E. Gerstein Justice Building
1351 N.W. 12th Street
Suite # _____
Miami, Florida 33125
Telephone: (305) 275-1155

DOH Consumer Services

JUL 0 3 2019

Date: 6/27/19

Dear Sir/Madam:

Enclosed are the documents/information you requested from our office. If you need any further assistance, please contact our office at (305) 275-1155 between the hours of 9:00 a.m. to 4:00 p.m., or direct your inquiries to the Clerk of Courts, 1351 N.W. 12th Street, Miami, Fl. 33125, Suite 9000 or 8100 attention Research and Correspondence. Please refer to the items checked below for any further information concerning your request.

☑ Copies of Information, Judgment & Sentence, arrest form and clerk's minutes enclosed.
☐ The document(s) you requested is (are) not available through our office.
☐ The document(s) you requested has (have) been supplied to your attorney.
☐ The document(s) you requested was (were) previously supplied to you on _____.
☑ Other Order of probation

Sincerely,

Harvey Ruvin
Clerk of Courts

By: _____ Deputy Clerk

Deputy Clerk of the Circuit Court of the Eleventh Judicial Circuit of Florida, ...d for Miami-Dade County

Central Depository • Civil Division • Clerk of the Board • Code Enforcement • Comptroller/Auditor • County Recorder Criminal Division • District Courts Division • Family Courts Division • Human Resources / Administrative Services • Juvenile Division Marriage License • Parking Violations • Records /Archives Management • Technical Services Division • Traffic Division • V.A.B.

Mission:
To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.

Florida HEALTH

Vision: To be the **Healthiest State** in the Nation

Ron DeSantis
Governor

June 17, 2019

Miami-Dade County Clerk of Court
73 W. Flagler Street, Suite 242
Miami, FL 33130

PLEASE RETURN THIS LETTER
WITH YOUR RESPONSE

RECEIVED JUN 24 2019

Subject: Guillermo E Salas
Social Security Number: xxx-xx-4465
Date of Birth: 01/13/1967
DOH Reference Number: 201910611
Court Case Number: 132019CF0062430001XX

Dear Miami-Dade Clerk of Court:

The above healthcare practitioner was convicted of a crime in your court that may be related to the practice of Pharmacist in Florida. The Department of Health is required to investigate possible violations of the laws and rules regulating this practitioner's profession.

We need the following information so that the department can review this matter and take appropriate action. Please submit a ***certified copy*** of:

- the warrant;
- the Bill of Indictment or Information
- the Judgment or Conviction;
- the Arrest Report; and
- any additional public information that may relate to this practitioner's professional practice.

If there is a charge for these certified copies, please send an itemized invoice with your **Federal Employer Identification number**, the amount per page, and the total number of pages.

Pursuant to Section 28.345 F.S. Exemption from court-related fees and charges.- Notwithstanding any other provision of this chapter or law to the contrary, judges and those court staff acting on behalf of judges, state attorneys, guardians ad litem, public guardians, attorney ad litem, court-appointed private counsel, criminal conflict and civil regional counsel, and public defenders, acting in their official capacity, and state agencies, are exempt from all court-related fees and charges assessed by the clerks of the circuit courts.

The mission of the Department of Health is to protect, promote & improve the health of all people in Florida through integrated state, county, & community efforts. If you have any questions, please call the Consumer Services Unit at (850) 245-4339.

Sincerely,

Aliza Hopkins
Government Analyst I

Florida Department of Health
Division of Medical Quality Assurance• Bureau of Enforcement
4052 Bald Cypress Way, Bin C-75 • Tallahassee, FL 32399-3275
PHONE: (850) 245-4339 • FAX : (850) 488-0796

PHAB Accredited Health Department
Public Health Accreditation Board

1100419138

COMPLAINT/ARREST AFFIDAVIT

COMPLAINT/ARREST AFFIDAVIT - COURT COPY

OBTS NUMBER	ARMED FORCES	BWC	POLICE CASE NO.
1301373297	NO	NO	19001504

SPECIAL OPERATION:	FELONY / WARRANT	MISD	TRAFFIC	JUV	DV	MOVES	CIV INF	JAIL NO.	PMHD	COURT CASE NO.
	X					FUGITIVE WARRANT: In State / Out State		190133466	NO	F19006243

IDS NO.	AGENCY CODE	MUNICIPAL P.D. DEF. ID NO.	MDPD RECORDS AND ID NO.	STUDENT ID NO.	GANG RELATED	FRAUD RELATED
3276734	085		1197259		NO	NO

DEFENDANT'S NAME (LAST, FIRST, MIDDLE)	ALIAS and / or STREET NAME	SIGNAL:
SALAS, GUILLERMO ENRIQUE		

DOB (MM/DD/YYYY)	AGE	RACE	SEX	HISPANIC: NO / ETHNICITY: VEN	HEIGHT	WEIGHT	HAIR COLOR	HAIR LENGTH	HAIR STYLE	EYES	GLASSES	FACIAL HAIR	TEETH
01/13/1967	52	W	M		5'07	200	BRO	SHT	STR	BRO	NO	CLN	NOR

SCARS, TATTOOS, UNIQUE PHYSICAL FEATURES (Location, Type, Description)	PLACE OF BIRTH (City, State/Country)
	VZ

LOCAL ADDRESS	PHONE	CITIZENSHIP
		VZ

PERMANENT ADDRESS (Street, Apt. Number)	(City)	(State)	(Country)	(Zip)	PHONE	OCCUPATION
3701 N COUNTRY CLUB DR	AVENTURA	FL	US	33180	(305) 384-0813	PHARMACY

SCHOOL OR BUSINESS ADDRESS (Street, Apt. Number)	(City)	(State)	(Country)	(Zip)	PHONE	ADDRESS SOURCE
						DL

DRIVER'S LICENSE NUMBER/STATE	SOCIAL SECURITY NO.	WEAPON SEIZED	Defendant/CONCEALED WEAPON PERMIT	INDICATION OF:
FL-S420285670131	XXX-XX-XXXX	NO	NONE	Alcohol Influence: N Drug Influence: N

ARREST DATE	ARREST TIME	ARREST LOCATION	GRID
03/28/2019	19:25	NORDSTROMS 19507 BISCAYNE BLVD AVENTURA, FL 33180	

CO-DEFENDANT NAME	DOB	IN CUSTODY / AT LARGE	FELONY / DV	JUVENILE / MISDEMEANOR
CO-DEFENDANT NAME	DOB	IN CUSTODY / AT LARGE	FELONY / DV	JUVENILE / MISDEMEANOR
CO-DEFENDANT NAME	DOB	IN CUSTODY / AT LARGE	FELONY / DV	JUVENILE / MISDEMEANOR

JUV only	Relation	Name	Street	Zip	Phone	Contacted?

CHARGES	CHARGE AS:	CNTS	FL STATUTE NUMBER	VIOL OF SECT.	CODE OF	UCR	DV	WARRANT TYPE OR TRAFFIC CITATION
1. F/3-GRAND THEFT 3RD DEGREE	F.S.	1	812.014(2)(C)			0006230C	N	
2.								
3.								
4.								

STATE OF FLORIDA, COUNTY OF MIAMI DADE
I HEREBY CERTIFY that the foregoing is a true and correct copy of the original on file in this office.
JUN 27 2019
HARVEY RUVIN, CLERK OF COURTS
Deputy Clerk

The undersigned certifies and swears that he/she has just and reasonable grounds to believe, and does believe that the above named Defendant committed the following violation of law:

On the 28 day of MARCH, 2019, at 18:54 at (NORDSTROMS) 19507 BISCAYNE BLVD. AVENTURA, FL, 33180

ON 3-28-2019 AT 1809 HOURS, THE DEF WAS OBSERVED BY LISTED LOSS PREVENTION OFFICER ENTER THE NORDSTROM'S DEPT STORE LOCATED AT 19507 BISCAYNE BLVD VIA CCTV. AFTER THE DEF ENTERED THE STORE, THE LISTED LP OFFICER OBSERVED THE DEF CONCEAL $678.00 WORTH OF MERCHANDISE IN A BLUE SHOPPING BAG. THE DEF THEN EXITED THE STORE AT 1854 HOURS MAKING NO ATTEMPT TO PAY FOR THE CONCEALED ITEMS AFTER PASSING ALL POINTS OF SALE.

ONCE THE DEF EXITED THE STORE VIA THE SECOND FLOOR NORTH PARKING GARAGE EXIT HE WAS DETAINED BY LISTED LP AND APD WAS CALLED. UPON MY ARRIVAL TO THE LP OFFICE, I VIEWED THE CCTV FOOTAGE OF THE DEF... [Continued on Next Page]

HOLD FOR OTHER AGENCY VERIFIED BY	☐ HOLD FOR BOND HEARING. DO NOT BOND OUT (Officer Must Appear at Bond Hearing).	☐ I Understand that should I willfully fail to appear before the court as required by this notice to appear that I may be held in contempt of court and a warrant for my arrest shall be issued. Furthermore, I agree that notice concerning the time, date and place of all court hearings should be sent to the above address. I agree that it is my responsibility to notify Clerk of the Court (Juveniles notify Juvenile Division) anytime that my address changes. ☐ You need not appear in court, but must comply with the instructions on the reverse side hereof.	
I SWEAR THAT THE ABOVE STATEMENT IS TRUE AND CORRECT. BONVILLE, C: Court ID: 085-00110	SWORN TO AND SUBSCRIBED BEFORE ME, THE UNDERSIGNED AUTHORITY THIS 28 DAY OF MARCH, 2019 HOWELL, A: Court ID: 085-00195		

Exhibit 1
008

1100419138

OBTS NUMBER	COMPLAINT/ARREST AFFIDAVIT CONTINUATION	POLICE CASE NO.
1301373297		19001504

JAIL NO.	COURT CASE NO.
190133466	F19006243

SPECIAL OPERATION:		JAIL NO.	PMHD	COURT CASE NO.
	[X] FELONY [ ] MISD [ ] TRAFFIC [ ] JUV [ ] DV [ ] MOVES [ ] CIV INF; [ ] WARRANT FUGITIVE WARRANT: [ ] In State [ ] Out State	190133466	NO	F19006243

DEFENDANT'S NAME (LAST, FIRST, MIDDLE)	DOB (MM/DD/YYYY)
SALAS, GUILLERMO ENRIQUE	01/13/1967

CO-DEFENDANT NAME	DOB	[ ] IN CUSTODY [ ] AT LARGE	[ ] FELONY [ ] DV	[ ] JUVENILE [ ] MISDEMEANOR

CO-DEFENDANT NAME	DOB	[ ] IN CUSTODY [ ] AT LARGE	[ ] FELONY [ ] DV	[ ] JUVENILE [ ] MISDEMEANOR

CHARGES	CHARGE AS:	CNTS	FL STATUTE NUMBER	VIOL OF SECT.	CODE OF	UCR	DV	WARRANT TYPE OR TRAFFIC CITATION
5.								
6.								
7.								
8.								

CONCEALING THE MERCHANDISE AND EXITING THE STORE. AFTER VIEWING THE VIDEO, THE DEF WAS PLACED UNDER ARREST AND TRANSPORTED TO TGK.

ALL MERCHANDISE WAS RECOVERED BY LP AND RETURNED. THE CCTV FOOTAGE OF THE THEFT WAS BURNED ONTO A DVD AND WILL BE PROVIDED TO THE MIAMI-DADE ASA AT PREFILE.

COMPLAINT/ARREST AFFIDAVIT CONT.

HOLD FOR OTHER AGENCY VERIFIED BY	[ ] HOLD FOR BOND HEARING. DO NOT BOND OUT (Officer Must Appear at Bond Hearing).	[ ] I Understand that should I willfully fail to appear before the court as required by this notice to appear that I may be held in contempt of court and a warrant for my arrest shall be issued. Furthermore, I agree that notice concerning the time, date and place of all court hearings should be sent to the above address. I agree that it is my responsibility to notify Clerk of the Court (Juveniles notify Juvenile Division) anytime that my address changes. [ ] You need not appear in court, but must comply with the instructions on the reverse side hereof.
I SWEAR THAT THE ABOVE STATEMENT IS TRUE AND CORRECT. BONVILLE, C: Court ID: 085-00110	SWORN TO AND SUBSCRIBED BEFORE ME, THE UNDERSIGNED AUTHORITY THIS 28 DAY OF MARCH, 2019 HOWELL, A: Court ID: 085-00195	

C SALAS

F19-6243

IN THE CIRCUIT COURT OF THE ELEVENTH JUDICIAL CIRCUIT
IN AND FOR MIAMI- DADE COUNTY, FLORIDA FALL TERM, 2018

THE STATE OF FLORIDA v.

GUILLERMO ENRIQUE SALAS

Defendant(s)

FILED
APR 26 2019
CLERK

INFORMATION FOR

1. GRAND THEFT 3RD DEGREE 812.014(2)(C) FEL. 3D

IN THE NAME AND BY THE AUTHORITY OF THE STATE OF FLORIDA:

KATHERINE FERNANDEZ RUNDLE, State Attorney of the Eleventh Judicial Circuit, prosecuting for the State of Florida, in the County of Miami-Dade, by and through her undersigned Assistant State Attorney, under oath, Information makes that:

PORTMAN,ERROL :sp 04/16/2019
Circuit Court Direct File
Jail No. 190133466 ,Bkd: 3/28/2019 , CIN: 1197259, W/M, DOB: 1/13/1967

F19006243
De La O (F005)

STATE OF FLORIDA, COUNTY OF MIAMI-DADE
I HEREBY CERTIFY that the foregoing is a true and correct copy of the original on file in this office
JUN 27 2019
HARVEY RUVIN, Clerk
Deputy Clerk

CIRCUIT AND COUNTY COURTS FLORIDA

(CC#: F19006243)

COUNT 1

GUILLERMO ENRIQUE SALAS, on or about March 28, 2019, in the County and State aforesaid, did unlawfully and knowingly obtain or use, or endeavor to obtain or use, retail merchandise valued at three hundred dollars ($300.00) or more, but less than five thousand dollars ($5,000.00), the property of Nordstrom and/or Andrew Lara, as owner or custodian, with the intent to either temporarily or permanently deprive said owner or custodian of a right to the property or a benefit therefrom, or appropriate the property to said defendant's own use or to the use of a person not entitled thereto, in violation of s. 812.014(2)(C), Fla. Stat., contrary to the form of the Statute in such cases made and provided, and against the peace and dignity of the State of Florida.

12:12:05 PM

CASE FILE SHEET

04/16/2019

DEFENDANT(S): SALAS, GUILLERMO

COURT CASE #: F19006243

Intake Atty: 10699 PORTMAN,ERROL
21st Day: 04/18/2019 **Arraign:** 04/26/2019

Police #: 19001504
Department: 085 Aventura
Arrest Date: 03/28/2019
Lead Officer: 00110 BONVILLE,CHASE
Dept/Station: 085-
Remarks:

Unit: 001 FSU-Case Screening
DIVISION: De La O

Book Date: 03/28/2019
JailNum: 190133466
PID: RACE: W **Sex:** M
DOB: 01/13/1967
IDS: 3276734 **CIN:** 1197259

PFC Date(s): 04/05/2019
04/12/2019
04/12/2019

Arraignment Action **Date**

Clerk File Date: 03/29/2019
Domestic: N
Lab #:
ME #:

Case Filing Decision **Date**

FF Felony Filed /2019 2:29:26 PM

Propery Release: N
Extradite: 1 Fel-Full extradition unless note
VictimType: 34 Victim-Business, State
Min/Mandatory: 1 Not Charged/Not Filed
Tel/Video Depo: N Normal
Career Criminal:

T	D	CJIS	Description	Charge Filing Decision	Count
F	3	81201402CF3NB	GRAND THEFT 3RD DEG	FF Filed Felony	1

ATTORNEY: _____
Assistant State Attorney

APPROVED: _____
Assistant State Attorney

DATE: _____

DATE: _____

STATE OF FLORIDA
Plaintiff

-VS-

Sarcs, Guillermo Enrique
Defendant

FILED
JUN 11 2019
CLERK

IN THE **ELEVENTH** JUDICIAL CIRCUIT COURT, IN AND FOR **MIAMI-DADE** COUNTY

CASE NUMBER F19006243

DC NUMBER _____

Local Jurisdiction Identification Number _____

☑ **ORDER OF PROBATION** ☐ **DRUG OFFENDER PROBATION** ☐ **COMMUNITY CONTROL**
☐ **COMMUNITY CONTROL/PROBATION** ☐ **COMMUNITY CONTROL/DRUG OFFENDER PROBATION**
☐ **DRUG OFFENDER PROBATION/PROBATION** ☐ **SEX OFFENDER PROBATION**
☐ **COMMUNITY CONTROL/SEX OFFENDER PROBATION**

This cause coming before the Court to be heard, and you, the defendant, being now present before the court, and you having

☑ entered a plea of guilty to
☐ entered a plea of nolo contendere to
☐ been found guilty by jury verdict of
☐ been found guilty by the court trying the case without a jury of

Count I Grand Theft 3rd Deg
Count _____
Count _____
Count _____
Count _____
Count _____
Count _____
Count _____

STATE OF FLORIDA, COUNTY OF MIAMI-DADE
I HEREBY CERTIFY that the foregoing is a true and correct copy of the original as the same appears in the records of this office.
HARVEY RUVIN, Clerk of the Circuit and County Courts
JUN 21 2019
Deputy Clerk

SECTION 1: JUDGMENT OF GUILT

☐ The court hereby adjudges you to be guilty of the above offense(s).

Now, therefore, it is ordered and adjudged that the imposition of sentence is hereby withheld and that you be placed on ☐ Probation, ☐ Community Control ☐ Drug Offender Probation ☐ Sex Offender Probation for a period of _____ under the supervision of the Department of Corrections, subject to Florida law.

SECTION 2: ORDER WITHHOLDING ADJUDICATION

☑ Now, therefore, it is ordered and adjudged that the adjudication of guilt is hereby withheld and that you be placed on ☑ Probation ☐ Community Control ☐ Drug Offender Probation ☐ Sex Offender Probation for a period of one (1) Year under the supervision of the Department of Corrections, subject to Florida law.
Probation

SECTION 3: INCARCERATION DURING PORTION OF SUPERVISION SENTENCE

It is hereby ordered and adjudged that you be:

☐ committed to the Department of Corrections

for a term of _____ prison with credit for _____ jail time, followed by, ☐ Probation ☐ Community Control ☐ Drug Offender Probation ☐ Sex Offender Probation for a period of _____ under the supervision of the Department of Corrections, subject to Florida law.
or

Distribution: White: Office Yellow - Probation Pink - Defendant

(Revised 9/04/15)

Defendant Scalas, Guillermo Enrique Case # F19006243

☐ confined in the County Jail
for a term of _____ with credit for _____ jail time. After you have served _____ of a term, you shall be placed on ☐ Probation ☐ Community Control ☐ Drug Offender Probation ☐ Sex Offender Probation for a period of _____ under the supervision of the Department of Corrections, subject to Florida law.

or

☐ confined in the County Jail
For a term of _____ with credit for _____ jail time, as a special condition of supervision.

IT IS FURTHER ORDERED that you shall comply with the following standard conditions of supervision as provided by Florida law:

(1) You will report to the probation office as directed.

(2) You will pay the State of Florida the amount of $ 50.00 per month, as well as 4% surcharge, toward the cost of your supervision in accordance with s. 948.09, F.S., unless otherwise exempted in compliance with Florida Statutes.

(3) You will remain in a specified place. You will not change your residence or employment or leave the county of your residence without first procuring the consent of your officer.

(4) You will not possess, carry or own any firearm. You will not possess, carry, or own any weapon without first procuring the consent of your officer.

(5) You will live without violating the law. A conviction in a court of law shall not be necessary for such a violation of law to constitute a violation of your probation, community control, or any other form of court ordered supervision.

(6) You will not associate with any person engaged in any criminal activity.

(7) You will not use intoxicants to excess or possess any drugs or narcotics unless prescribed by a physician. Nor will you visit places where intoxicants, drugs or other dangerous substances are unlawfully sold, dispensed or used.

(8) You will work diligently at a lawful occupation, advise your employer of your probation status, and support any dependents to the best of your ability, as directed by your officer.

(9) You will promptly and truthfully answer all inquiries directed to you by the court or the officer, and allow your officer to visit in your home, at your employment site or elsewhere, and you will comply with all instructions your officer may give you.

(10) You will pay restitution, court costs, and/or fees in accordance with special conditions imposed or in accordance with the attached orders.

(11) You will submit to random testing as directed by your officer or the professional staff of the treatment center where he/she is receiving treatment to determine the presence of alcohol or controlled substances.

(12) You will submit a DNA sample to your officer, for DNA analysis as prescribed in ss. 943.325 and 948.014, F.S.

(13) You will submit to the taking of a digitized photograph by the department. This photograph may be displayed on the department's website while you are on supervision, unless exempted from disclosure due to requirements of s. 119.07, F.S.

(14) You will report in person within 72 hours of your release from incarceration to the probation office in Miami, FL County, Florida, unless otherwise instructed by the court or department. (This condition applies only if section 3 on the previous page is checked.) Otherwise, you must report immediately to the probation office located at 3601 NW 167th St Miami, FL 33056

Distribution: White: Office Yellow - Probation Pink - Defendant

(Revised 9/04/15)

Defendant Salas, Guillermo Enrique Case # F19006243

SPECIAL CONDITIONS X

☐ 1. You must undergo a ☐ Drug and Alcohol ☐ Drug ☐ Alcohol ☐ Mental Health ☐ Psycho-sexual ☐ Drug, Alcohol and Mental Health evaluation and, if treatment is deemed necessary, you must successfully complete the treatment, and be responsible for the payment of any costs incurred while receiving said evaluation and treatment, unless waived by the court.
Additional instructions ordered: _____

☐ 2. You will make restitution to the following victim(s), as directed by the court, until the obligation is paid in full:
NAME: _____
TOTAL AMOUNT: $_____
Additional instructions ordered, including specific monthly amount, begin date, due date, or joint & several:
_____

NAME: _____
TOTAL AMOUNT: $_____
Additional instructions ordered, including specific monthly amount, begin date, due date, or joint & several:
_____

☑ 3. You will be required to pay for drug testing unless exempt by the court. $ 30.00

☐ 4. You will enter the Department of Corrections Non-Secure Drug Treatment Program or other residential treatment program/Probation and Restitution Center for a period of successful completion as approved by your officer. You are to remain until you successfully complete said Program and Aftercare. You are to comply with all Rules and Regulations of the Program. ☐ You shall ☐ Shall not be confined in the county jail until placement in said program, and if you are confined in the jail, the Sheriff will transport you to said program.

☐ 5. You will abstain entirely from the use of alcohol and/or illegal drugs, and you will not associate with anyone who is illegally using drugs or consuming alcohol.

☐ 6. You will submit to urinalysis testing on a ☐ monthly ☐ bi-weekly ☐ weekly basis to determine the presence of alcohol or illegal drugs. You will be required to pay for the tests unless exempt by the court.

☐ 7. You will not visit any establishment where the primary business is the sale and dispensing of alcoholic beverages.

☑ 8. You will successfully complete 50 hours of community service at a rate of 5 monthly at a work site approved by your officer.
Additional instructions ordered: _____

☐ 9. You will remain at your residence between 10 p.m. and 6 a.m. due to a curfew imposed, unless otherwise directed by the court.

☐ 10. You will submit to electronic monitoring, follow the rules of electronic monitoring, and pay $_____ per day for the cost of the monitoring service.

☐ 11. You will not associate with _____ during the period of supervision.

☐ 12. You will have no contact (direct or indirect) with the victim or the victim's family during the period of supervision.

☐ 13. You will have no contact (direct or indirect) with _____ during the period of supervision.

☐ 14. You will maintain full time employment or attend school/vocational school full time or a combination of school/work during the term of your supervision.

☐ 15. You will make a good faith effort toward completing basic or functional literacy skills or a high school equivalency diploma.

☐ 16. You will successfully complete the Probation & Restitution Program, abiding by all rules and regulations.

Distribution: White: Office Yellow - Probation Pink - Defendant

(Revised 7/01/14)

Defendant Salas, Guillermo Enrique Case # F19006243

SPECIAL CONDITIONS – CONTINUED

☐ 17. You will attend a support group with a focus on _____ at least monthly, unless otherwise directed by the court.

☐ 18. You must successfully complete ☐ Anger Management ☐ Batterer's Intervention Program ☐ Anger Management / Batterer's Intervention Program and be responsible for the payment of any costs incurred while receiving said treatment, unless waived. If convicted of a Domestic Violence offense, as defined in s. 741.28, F.S., you must attend and successfully complete a batterer's intervention program, unless otherwise directed by the court.
Additional instructions ordered: _____

☐ 19. You will attend an HIV/AIDS Awareness Program consisting of a class of not less than two (2) hours or more than four (4) hours in length, the cost for which will be paid by you.

☐ 20. If you have been found to have committed a crime on or after October 1, 2008 for the purpose of benefitting, promoting, or furthering the interests of a criminal gang, you are prohibited from knowingly associating with other criminal gang members or associates, except as authorized by law enforcement officials, prosecutorial authorities, or the court, for the purpose of aiding in the investigation of criminal activity.

☐ 21. You will successfully complete a Post-adjudicatory treatment-based drug court program, as provided in s. 397.334(3),F.S.

☐ 22. If you are required to register as a sexual predator under s. 775.21 or sexual offender under s. 943.0435, s. 944.606, or s. 944.607, F.S., you will undergo an evaluation, at your expense, by a qualified practitioner to determine whether you need sexual offender treatment. If the qualified practitioner determines that sexual offender treatment is needed and recommended, you must successfully complete and pay for the treatment as provided in s. 948.31, F.S.

☑ 23. Other: Enter and complete Anti Theft course

☐ 24. Other:

☑ 25. Other: 50 CSH @ 5 per month as of July 2019

☐ 26. Other:

☑ 27. Other: Stay away order from Nordstrom in

☑ 28. Other: Aventura, Florida

☑ 29. Other:

☐ 30. Other:

AND, IF PLACED ON DRUG OFFENDER PROBATION, YOU WILL COMPLY WITH THE FOLLOWING CONDITION OF SUPERVISION IN ADDITION TO THE STANDARD CONDITIONS LISTED ABOVE AND ANY OTHER SPECIAL CONDITIONS ORDERED BY THE COURT:

(15) You will participate in a specialized drug treatment program, either as an in-patient or out patient, as recommended by the treatment provider. You will attend all counseling sessions, submit to random urinalysis and, if an in-patient, you will comply with all operating rules, regulations and procedures of the treatment facility. You will pay for all costs associated with treatment and testing unless otherwise directed.
Additional instructions ordered: _____

☐ (16) You will remain at your residence between _____ p.m. and _____ a.m. due to a curfew imposed, unless otherwise directed by the court.

☐ (17) You will successfully complete a Post-adjudicatory treatment based drug court program, as provided in s. 397.334(3), F.S.

AND, IF PLACED ON COMMUNITY CONTROL, YOU WILL COMPLY WITH THE FOLLOWING CONDITIONS, IN ADDITION TO THE STANDARD CONDITIONS LISTED ABOVE AND ANY OTHER SPECIAL CONDITIONS ORDERED BY THE COURT:

(15) You will report to your officer as directed, at least one time a week, unless you have written consent otherwise.

(16) You will remain confined to your approved residence except for one half hour before and after your approved employment, public service work, or any other special activities approved by your officer.

(17) You will maintain an hourly accounting of all your activities on a daily log, which you will submit to your officer on request.

(18) You will successfully complete _____ hours of community service at a rate of _____, at a work site approved by your officer.
Additional instructions ordered: _____

Distribution: White: Office Yellow - Probation Pink - Defendant

(Revised 9/04/15)

☐ (19) You will submit to electronic monitoring, follow the rules of electronic monitoring, and pay $_____ per day for the cost of the monitoring service.

AND, IF PLACED ON PROBATION OR COMMUNITY CONTROL FOR A SEX OFFENSE PROVIDED IN CHAPTER 794, s. 800.04, s. 827.071, s. 847.0135(5), or s. 847.0145, COMMITTED ON OR AFTER OCTOBER 1, 1995 YOU WILL COMPLY WITH THE FOLLOWING STANDARD SEX OFFENDER CONDITIONS, IN ADDITION TO THE STANDARD CONDITIONS LISTED ABOVE AND ANY OTHER SPECIAL CONDITIONS ORDERED BY THE COURT:

(15) A mandatory curfew from 10 p.m. to 6 a.m. The court may designate another 8-hour period if the offender's employment precludes the above specified time, and the alternative is recommended by the Department of Corrections. If the court determines that imposing a curfew would endanger the victim, the court may consider alternative sanctions.

(16) If the victim was under the age of 18, a prohibition on living within 1,000 feet of a school, child care facility, park, playground, or other place where children regularly congregate, as prescribed by the court. The 1,000-foot distance shall be measured in a straight line from the offender's place of residence to the nearest boundary line of the school, child care facility, park, playground, or other place where children congregate. The distance may not be measured by a pedestrian route or automobile route.

(17) Active participation in and successful completion of a sex offender treatment program with qualified practitioners specifically trained to treat sex offenders, at the offender's own expense. If a qualified practitioner is not available within a 50-mile radius of the offender's residence, the offender shall participate in other appropriate therapy.

(18) A prohibition on any contact with the victim, directly or indirectly, including through a third person, unless approved by the victim, the offender's therapist, and the sentencing court.

(19) If the victim was under the age of 18, a prohibition on contact with a child under the age of 18 except as provided in this paragraph. The court may approve supervised contact with a child under the age of 18 if the approval is based upon a recommendation for contact issued by a qualified practitioner who is basing the recommendation on a risk assessment. Further, the sex offender must be currently enrolled in or have successfully completed a sex offender therapy program. The court may not grant supervised contact with a child if the contact is not recommended by a qualified practitioner and may deny supervised contact with a child at any time.

(20) If the victim was under age 18, a prohibition on working for pay or as a volunteer at any place where children regularly congregate, including, but not limited to any school, child care facilities, park, playground, pet store, library, zoo, theme park, or mall.

(21) Unless otherwise indicated in the treatment plan provided by a qualified practitioner in the sexual offender treatment program, a prohibition on viewing, accessing, owning, or possessing any obscene, pornographic, or sexually stimulating visual or auditory material, including telephone, electronic media, computer programs, or computer services that are relevant to the offender's deviant behavior pattern.

(22) A requirement that the offender submit a DNA sample to the Florida Department of Law Enforcement to be registered with the DNA data bank.

(23) A requirement that the offender make restitution to the victim, as ordered by the court under s. 775.089, for all necessary medical and related professional services relating to physical, psychiatric, and psychological care.

(24) Submission to a warrantless search by the community control or probation officer of the offender's person, residence, or vehicle.

EFFECTIVE FOR PROBATIONER OR COMMUNITY CONTROLLEE WHOSE CRIME WAS COMMITTED ON OR AFTER OCTOBER 1, 1997, AND WHO IS PLACED ON COMMUNITY CONTROL OR SEX OFFENDER PROBATION FOR A VIOLATION OF CHAPTER 794, s. 800.04, s. 827.071, s. 847.0135(5) or s. 847.0145, IN ADDITION TO ANY OTHER PROVISION OF THIS SECTION, YOU MUST COMPLY WITH THE FOLLOWING CONDITIONS OF SUPERVISION:

(25) As part of a treatment program, participation at least annually in polygraph examinations to obtain information necessary for risk management and treatment and to reduce the sex offender's denial mechanisms. A polygraph examination must be conducted by a polygrapher who is a member of a national or state polygraph association and who is certified as a post conviction sex offender polygrapher, where available, and at the expense of the offender.

(26) Maintenance of a driving log and a prohibition against driving a motor vehicle alone without the prior approval of the supervising officer.

(27) A prohibition against obtaining or using a post office box without the prior approval of the supervising officer.

(28) If there was sexual contact, a submission to, at the offender's expense, an HIV test with the results to be released to the victim and/or the victim's parent or guardian.

(29) Electronic monitoring when deemed necessary by the probation officer and supervisor, and ordered by the court at the recommendation of the Department of Corrections. If you are placed on electronic monitoring you must pay the Department for the cost of the electronic monitoring service.

Defendant Salas, Guillermo Enrique Case # F19006243

(30) **Effective for an offender whose crime was committed on or after July 1, 2005, and who are placed on supervision for violation of chapter 794, s. 800.04, s. 827.071, s. 847.0135(5), or s. 847.0145,** a prohibition on accessing the Internet or other computer services until a qualified practitioner in the offender's sex offender treatment program, after a risk assessment is completed, approves and implements a safety plan for the offender's accessing or using the Internet or other computer services.

(31) **Effective for offenders whose crime was committed on or after September 1, 2005,** there is hereby imposed, in addition to any other provision in this section, mandatory electronic monitoring as a condition of supervision for those who:

- Are placed on supervision for a violation of chapter 794, s. 800.04(4), (5), or (6), s. 827.071, or s. 847.0145 and the unlawful sexual activity involved a victim 15 years of age or younger and the offender is 18 years of age or older; or
- Are designated as a sexual predator pursuant to s 775.21; or
- Has previously been convicted of a violation of chapter 794, s. 800.04(4), (5), or (6), s. 827.071, or s 847.0145 and the unlawful sexual activity involved a victim 15 years of age or younger and the offender is 18 years of age or older.

You are hereby placed on notice that should you violate your probation or community control, and the conditions set forth in s. 948.063(1) or (2) are satisfied, whether your probation or community control is revoked or not revoked, you shall be placed on electronic monitoring in accordance with F.S. 948.063.

(32) **Effective for offenders who are subject to supervision for a crime that was committed on or after May 26, 2010,** and who has been convicted at any time of committing, or attempting, soliciting, or conspiring to commit, any of the criminal offenses listed in s.943.0435(1)(a)1.a.(1), or a similar offense in another jurisdiction, against a victim who was under the age of 18 at the time of the offense: the following conditions are imposed in addition to all other conditions:

(a) A prohibition on visiting schools, child care facilities, parks, and playgrounds, without prior approval from the offender's supervising officer. The court may also designate additional locations to protect a victim. The prohibition ordered under this paragraph does not prohibit the offender from visiting a school, child care facility, park, or playground for the sole purpose of attending a religious service as defined in s. 775.0861 or picking up or dropping off the offender's children or grandchildren at a child care facility or school.

(b) A prohibition on distributing candy or other items to children on Halloween; wearing a Santa Claus costume, or other costume to appeal to children, on or preceding Christmas; wearing an Easter Bunny costume, or other costume to appeal to children, on or preceding Easter; entertaining at children's parties; or wearing a clown costume; without prior approval from the court.

(33) **Effective for offenders whose crime was committed on or after October 1, 2014,** and who is placed on probation or community control for a violation of chapter 794, s. 800.04, s. 827.071, s. 847.0135(5), or s. 847.0145, in addition to all other conditions imposed, is prohibited from viewing, accessing, owning, or possessing any obscene, pornographic, or sexually stimulating visual or auditory material unless otherwise indicated in the treatment plan provided by a qualified practitioner in the sexual offender treatment program. Visual or auditorty material includes, but is not limited to, telephone, electronic media, computer programs, and computer services.

YOU ARE HEREBY PLACED ON NOTICE that the court may at any time rescind or modify any of the conditions of your probation, or may extend the period of probation as authorized by law, or may discharge you from further supervision. If you violate any of the conditions of your probation, you may be arrested and the court may revoke your probation, adjudicate you guilty if adjudication of guilt was withheld, and impose any sentence that it might have imposed before placing you on probation or require you to serve the balance of the sentence.

IT IS FURTHER ORDERED that when you have been instructed as to the conditions of probation, you shall be released from custody if you are in custody, and if you are at liberty on bond, the sureties thereon shall stand discharged from liability. (This paragraph applies only if section 1 or section 2 is checked.)

IT IS FURTHER ORDERED that the clerk of this court file this order in the clerk's office and provide copies of same to the officer for use in compliance with the requirements of law.

DONE AND ORDERED, on June 9th 2019

Miguel A. Deraso, Circuit Judge

I acknowledge receipt of a copy of this order and that the conditions have been explained to me and I agree to abide by them.

Date: June 9th 2019

Defendant

Instructed by: Shara Henderson
Supervising Officer – (Sign & Print Name)

Instructed in Spanish By Interpreter

Distribution: White: Office Yellow - Probation Pink - Defendant

(Revised 9/04/15)

DIVISION CRIMINAL		CASE NUMBER
05/ Delgado	MEMORANDUM OF COSTS	F19006243
THE STATE OF FLORIDA	VS. Salas, Guillermo Enrique	
PLAINTIFF	DEFENDANT/RESPONDENT	

Court Costs/Fines/Fees	Amount	Statute	Discharge* Code
☐ Crime Prevention Fund (Ord.98-171)	**$50.00**	775.083(2)	
☐ County/State(LETTS))	**$5.00 (local)**	938.01(1)/938.15	
☐ Crimes Compensation Trust Fund(COCA))	**$50.00**	938.03(4)	
☐ Local Criminal Justice Trust Fund	**$225.00**	938.05(1)	
☐ Ad's Court Costs (Ord.04-116)	**$65.00**	939.185(1)(a)	
☐ Surcharge (Ord. 05-123)	**$85.00 (local)**	939.185(1)(b)	
☐ Cost of Prosecution ($100 minimum)	**$100.00**	938.27(8)	
Cost of Defense ($100 minimum)	☐ $100.00	938.29	
☐ Teen Court (Ord. 98-185)	☐ $3.00	938.19(2)	
☐ Public Defender Application Fee	☐ $50.00	27.52(1)(b)	
☐ Fine	☐ $_____	775.083(1)	
☐ Surcharge (5% of Fine	☐ $_____	938.04	
☐ Crime Stopper's Program	☐ $20.00	938.06	
☐ Prostitution Civil Penalty	☐ $500.00 (local)	796.07(6)	
☐ Domestic Violence Surcharge	☐ $201.00	938.08	
☐ Rape Crisis Trust Fund	☐ $151.00	938.085	
☐ Child Advocacy Trust	☐ $101.00	938.10(1)	
☐ FDLE Operating Trust Fund	☐ $100.00	938.25	
☐ Alcohol & Drug Abuse Programs	☐ $_____	938.21	
Training Trust Fund Surcharge	$ 2.00	948.09	
☐ _____			
TOTAL MANDATORY (ALL CASES)	**$583.00**		
Additional pursuant to specific requirements (fines/cost/fees as noted above)	$_____		
GRAND TOTAL	**$**	**DUE TODAY**	

Payment is to be made by **cash, credit card, (MC or VISA), money order, or cashier's check** made payable to the **Clerk of the Courts**
Credit card payments must be made in person. Note your name above case number, and write **"Fine/Costs"** on your payment.
Payment locations are: **Richard E. Gerstein Justice Building, 1351 NW 12th St., Suite 9000, Miami, FL 33125**
Miami-Dade Flagler Building, 140 W Flagler St., Room 1502, Miami, FL 33130

not a cond of probe

Distribution: White: Office Yellow – Probation Pink - Defendant

(Revised 9/4/15)

CIRCUIT COURT MIAMI-DADE COUNTY - CRIMINAL DIVISION

SECTION: F005
SALAS, GUILLERMO ENRIQUE
3701 N COUNTRY CLUB DR
AVENTURA, FL 33180-1732

F19006243
01/13/1967
W/M
3276734
ARRESTED: 03/28/2019

NEW ADDRESS

DATE	ADDRESS

DATE CERT. COPY INFO (del/mailed)

ADJ INSOLVENT - APPT.P.D./R.C./P.C.A.C.
MAR 2 9 2019 a.m. ONLY

DETERMINATION OF INDIGENCY
☐ INDIGENT
☐ NOT INDIGENT

CASE DISMISSED
NO ACTION
NOLLE PROS
TRANSFERRED JURISDICTION TO

STATE OF FLORIDA, COUNTY OF MIAMI DADE
I HEREBY CERTIFY that the foregoing is a true and correct copy of the original on file in this office
JUN 2 7 2019 AD 20
HARVEY RUVIN, Clerk of Circuit and County Courts
Deputy Clerk

BOND RELEASE
BOND ESTREATURE
TO BE ARRESTED ON

CIVIL JUDGMENT
POWER #
CIVIL CASE #

JUDGE/CLERK		DeLaOlma	Olma		
DATE	4-11-19	APR 2 6 2019	JUN 1 1 2019		
GUILTY			no Go		
NOT GUILTY	w/plea				
WAIVER OF JURY					
STATE		JBaez	y Baez		
DEFENSE	Ivan Abrams P.D	DNP	I Abrams		
		DNP	DP		
INTERPRETER					
CT. REPORTER		Cherrios	DO		
FIRM		Laws	DO		

CLERK'S MINUTES	DEFT - ACTION DATE	ORAL NOTICE	CONTINUED TO/FOR	S	D	C
4-11-19 Notice of appearance, written plea of not guilty, Notice of disavowal	APR 2 6 2019 MAY 0 8 2019	DNP DP	5/8/19 Plea 7/11/19 Sounding 7/22/19 Trial 6/11/19 plea			
APR 2 6 2019 disc files	JUN 1 1 2019	DP	closed			

CLK/CT 387 REV. 01/17

Exhibit 1
020

CLOSED CASE

JURY - NON-JURY TRIAL - PV HEARINGS

JUDGE/CLK						
DATE	JUN 1 1 2019					
STATE						
DEFENSE	See plea					
INTERPRETER						
CT. REPORTER						
FIRM						

CLERKS MINUTES JUN 1 1 2019

☑ DEFT. SWORN & VOIR DIRED RE PLEA.

☑ DEFT. WAIVES PSI

☑ SCORE SHEET SUBMITTED ☐ NOT SUBMITTED

DL REVOCATION ☐ IMPOSED ☐ NOT IMPOSED

☐ DNA NOT TAKEN ☑ DNA PREV. TAKEN

TOTAL COURT COST $ 598.00

SEE MEMO OF COST

STAY DUE DATE: 7/11/19

AS REDUCED ☐ LESSER INCLUDED OFFENSE ☐

ACQUITTED (COURT) (JURY)

FINDNG OF GUILT (COURT) Ct 1 ✓ JUN 1 1 2019 (JURY)

ADJ W/H Ct 1 JUN 1 1 2019 ✓

ADJ DELINQUENT

_____ CRT. ORD. D/L REVO.PURS. TO F.S. FOR _____ YRS.

_____ DNA TAKEN PURS. TO F.S.

-SENTENCE(S)-

TIME SERVED IN DCJ TO WIT: DAYS

(DA/MO) IN DCJ. SENT. TO BEGIN FROM DATE OF INCARCERATION ☐ NO CTS.

STAY OF EXECUTION UNTIL:

W/H & _____ (MO/YR) COMM.CTRL.

Ct 1 ✓ JUN 1 1 2019 W/H & 1 (MO/YR) PROB.

SP.COND.: OF ☐ COMM. CTRL ☐ PROB.

1. Anti theft Curfew Within 30 DAYS
2. 50 Hrs, At. S. Per Month Beginning in July
3. Stay from Nuisance in Pinellas Florida

SUC/UNSUC. TERM. OF COMM. CTRL./ PROB.

HARVEY RUVIN
CLERK
CIRCUIT AND COUNTY COURTS
CRIMINAL DIVISION
ROOM 9000
1351 N.W. 12TH STREET
MIAMI, FLORIDA 33125
CLK/CT 966 8/08 Printed on Recycled Paper

PRESORTED
FIRST CLASS

U.S. POSTAGE PITNEY BOWES
ZIP 33312 $ 001.05[5]
02 1W
0001404521 JUN 29 2019

Florida Department of Health
Aliza Hopkins, Government Analyst 1
4052 Bald Cypress Way Bin C-75
Tallahassee, FL 32399

Exhibit 1

July 10, 2019

CONFIDENTIAL
Guillermo E Salas
3701 N Country Club Dr Apt 1505
Aventura, FL 33180

Complaint #: 201910611

Dear Mr. Salas:

The Consumer Services Unit received the enclosed complaint. We have determined you may have violated the practice act regulating your profession. Therefore, we have opened an investigation. Please submit a written response within 20 days of receipt of this letter. Please include the complaint number 201910611 on any correspondence you provide to our office.

You may make a written request for a copy of the investigative file. This complaint and all investigative information will remain confidential until 10 days after the probable cause panel has determined a violation has occurred or you give up the right to confidentiality.

Sincerely,

Aliza Hopkins
Government Analyst I

Enclosure
DOH-Form300

STATE OF FLORIDA
BOARD OF PHARMACY

CASE NUMBER:	2017-15122
DATE OF COMPLAINT:	August 29, 2017
COMPLAINT MADE BY:	DOH/ISU
SUBJECT:	BriovaRx Infusion Services 203, Inc. f/k/a Ambient Healthcare of S. Florida, Inc. Permit No. PH27913 9984 Premier Parkway Miramar, Florida 33025
SUBJECT ATTORNEY:	Martin R. Dix, Esq. 201 E. Park Ave, Suite 300 Tallahassee, Florida 32301
REVIEWED BY:	Andrew Pietrylo Assistant General Counsel
RECOMMENDATION:	Dismiss (4097) Reconsideration

CLOSING ORDER

THE COMPLAINT: The Administrative Complaint alleges that Respondent violated section 465.023(1)(c), Florida Statutes (2017), through a violation of rule 64B16-27.797(1)(a), Florida Administrative Code, which governs the minimum practice standards for sterile compounding.

THE FACTS: On August 24, 2017, the Department conducted a sterile compounding inspection of Respondent's facilities located in Davie, Florida, which found numerous deficiencies. On March 22, 2018, the Department filed an Administrative Complaint alleging that Respondent violated multiple provisions of USP Chapter 797, as set forth therein. Respondent disputed the allegations and requested a formal administrative hearing.

Respondent subsequently relocated to a new facility in Miramar, Florida, and hired a new prescription department manager. On June 1, 2018, Respondent passed a change of location inspection by the Department and began operating at the new facility.

On May 7, 2019, the Respondent underwent a sterile compounding inspection which, despite finding several deficiencies, confirmed that Respondent had corrected most of the deficiencies from the August 2017 inspection. Responded promptly submitted a corrective action plan addressing each deficiency. On January 30, 2020, Respondent again underwent a sterile compounding inspection, which found that Respondent had corrected all deficiencies identified in the Administrative Complaint. Respondent passed this inspection with only four deficiencies found, which were promptly addressed through a corrective action plan.

Respondent has been permitted as a special sterile compounding pharmacy since March 2014, with no history of discipline. Additionally, Respondent only compounds low and medium-risk CSPs and there is no evidence of patient harm stemming from a deficiency.

THE LAW: Although there was sufficient evidence to support a finding of probable cause at the time of the filing of the Administrative Complaint in this case, in light of the circumstances set forth above, the Department recommends that the previous finding of probable cause be reconsidered and this case be dismissed without further prosecution.

Based on the foregoing facts and findings, and pursuant to section 456.073(4), Florida Statutes, the Probable Cause Panel dismisses this case with no further action to be taken.

It is, therefore, ORDERED that this matter should be and the same is hereby DISMISSED.

DONE and ORDERED this _____ day of _____, 2020.

_____

CHAIRPERSON, PROBABLE CAUSE PANEL
BOARD OF PHARMACY

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v. **CASE NO. 2017-15122**

BRIOVARX INFUSION SERVICES, 203, INC., F/K/A AMBIENT HEALTHCARE OF S. FLORIDA, INC.,

RESPONDENT.
_____/

ADMINISTRATIVE COMPLAINT

COMES NOW, Petitioner, Department of Health ("Department"), by and through its undersigned counsel, and files this Administrative Complaint before the Board of Pharmacy against Respondent, BriovaRx Infusion Services 2013, Inc., formerly known as Ambient Healthcare of S. Florida, Inc., and in support thereof alleges:

1. Petitioner is the state agency charged with regulating the practice of pharmacy pursuant to Section 20.43, Florida Statutes; Chapter 456, Florida Statutes; and Chapter 465, Florida Statutes.

2. At all times material to this Administrative Complaint, Respondent was a permitted special sterile compounding pharmacy within the state of Florida, having been issued permit number PH27913.

3. Respondent's address of record is 15951 S.W. 41st Street, Suite 500, Davie, Florida 33331.

4. At all times material to this Administrative Complaint, Respondent engaged in low-risk and medium-risk level sterile compounding.

5. On or about August 24, 2017, the Department conducted a sterile compounding inspection of Respondent.

6. During the inspection on or about August 24, 2017, one or more of the following deficiencies were found:

a. One or more single-dose containers sealed in ISO Class 5 or cleaner air were not assigned a beyond-use time not to exceed 6 hours after being punctured, and Respondent failed to indicate the time and date of initial entry of single dose containers;

b. From approximately July 14, 2017 through August 7, 2017, Respondent continued to engage in sterile compounding

using a primary engineering control which failed environmental certification without conducting an investigation into the source of contamination and eliminating the source of the problem;

c. Respondent's primary engineering controls were not placed in the buffer room in a manner to avoid conditions which could adversely affect their operation and in a manner to avoid room cross drafts; specifically, the primary engineering controls were exposed to dirty air entering from an unclassified space in the pharmacy into the buffer room due to Respondent's compounding personnel being observed leaving the ante room door open to unclassified air space while exiting and entering the buffer room;

d. Respondent failed to ensure that only furniture, equipment, supplies, and other material required for compounding activities were brought into the buffer room when a radio was found stored under the laminar flow hood in Respondent's buffer room;

e. Respondent's environmental sampling plan for airborne viable particles did not include the volume of air sampled;

f. Respondent's compounding personnel failed to wipe scissors with a suitable disinfecting agent prior to placing them inside the laminar flow hood;

g. No documentation to indicate that the shelving, walls, and ceilings in Respondent's ante and buffer rooms are cleaned on a consistent monthly basis;

h. One or more of Respondent's compounding personnel was observed to be in the buffer room wearing jewelry and/or cosmetics;

i. One or more of Respondent's compounding personnel failed to wear an appropriate beard cover while compounding sterile products;

j. Respondent failed to ensure that the annual media fill tests performed by one or more compounding personnel simulated the most challenging or stressful compounding conditions.

k. Respondent failed to ensure that one or more newly hired compounding personnel successfully completed gloved fingerprint testing no less than three times before being allowed to compound sterile preparations; and/or

l. Respondent failed to ensure that one or more compounding personnel performed annual observational assessments of hand hygiene, garbing, and cleaning techniques.

7. Section 465.023(1)(c), Florida Statutes (2017), provides that that the department or the board may revoke or suspend the permit of any pharmacy permittee, and may fine, place on probation, or otherwise discipline any pharmacy permittee if the permittee, or any affiliated person, partner, officer, director, or agent of the permittee violated any of the rules of the Board of Pharmacy.

8. Rule 64B16-27.797(1)(a), Florida Administrative Code, provides, in relevant part, that all sterile compounding shall be performed in accordance with the minimum practice and quality standards of the following chapters of the United States Pharmacopeia ("USP"), 36th revision, Second Supplement, incorporated and adopted by reference with

the effective chapter dates of December 1, 2013: Chapter 797, Pharmaceutical Compounding-Sterile Preparations.

9. USP Chapter 797 provides that opened or needle-punctured single-dose containers, such as bags, bottles, bottles, syringes, and vials of sterile products and compounded sterile preparations shall be used within 1 hour if opened in worse than ISO Class 5 air quality, and any remaining contents must be discarded. Single-dose vials exposed to ISO Class 5 or cleaner air may be used up to 6 hours after initial needle puncture.

10. USP Chapter 797 provides that an investigation into the source of the contamination shall be conducted. Sources could include HVAC systems, damaged HEPA filters, and changes in personnel garbing or work practices. The source of the problem shall be eliminated, the affected area cleaned, and resampling performed.

11. USP Chapter 797 provides that primary engineering controls shall be placed within a buffer area in such a manner as to avoid conditions that could adversely affect their operations.

12. USP Chapter 797 provides that only the furniture, equipment, supplies, and other material required for the compounding activities to be

performed shall be brought into the area, and they shall be nonpermeable, nonshedding, cleanable, and resistant to disinfectants.

13. USP Chapter 797 provides that an appropriate environmental sampling plan shall be developed for airborne viable particles based on a risk assessment of compounding activities performed. The plan shall include sample location, method of collection, frequency of sampling, volume of air sampled, and time of day as related to activity in the compounding area and action levels.

14. USP Chapter 797 provides that supplies and equipment removed from shipping cartons shall be wiped with a suitable disinfecting agent (e.g., sterile 70% IPA) delivered from a spray bottle or other suitable delivery method. After the disinfectant is sprayed or wiped on a surface to be disinfected, the disinfectant shall be allowed to dry, during which time the item shall not be used for compounding purposes.

15. USP Chapter 797 provides that the minimum frequency of cleaning and disinfecting walls, ceilings, and storage shelving in compounding areas in monthly.

16. USP Chapter 797 provides that before entering the buffer area or segregated compounding area compounding personnel shall remove

personal outer garments (e.g., bandannas, coats, hats, jackets, scarves, sweaters, vests); all cosmetics, because they shed flakes and particles; and all hand, wrist, and other visible jewelry or piercings (e.g., earrings, lip or eyebrow piercings) that can interfere with the effectiveness of personnel protective equipment (e.g., fit of gloves and cuffs of sleeves).

17. USP Chapter 797 provides that personnel shall don the following personnel protective equipment in an order that proceeds from those activities considered the dirtiest to those considered the cleanest. Garbing activities considered the dirtiest include donning of dedicated shoes or shoe covers, head and facial hair covers (e.g., beard covers in addition to face masks), and face masks/eye shields. Eye shields are optional unless working with irritants such as germicidal disinfecting agents or when preparing hazardous drugs.

18. USP Chapter 797 provides that media-fill tests shall represent the most challenging or stressful conditions actually encountered by the personnel being evaluated when they prepare low- and medium-risk level compounded sterile preparations and when sterilizing high-risk level compounded sterile preparations.

19. USP Chapter 797 provides that all compounding personnel shall successfully complete an initial competency evaluation and gloved fingertip/thumb sampling procedure (zero colony forming units) no less than three times before initially being allowed to compound CSPs for human use.

20. USP Chapter 797 provides that after completing the initial gowning and gloving competency evaluation, re-evaluation of all compounding personnel shall occur at least annually for low- and medium-risk level compounded sterile preparations and semiannually for high-risk level compounded sterile preparations before being allowed to continue compounding compounded sterile preparations.

21. As set forth above, Respondent violated one or more provisions of USP Chapter 797 through one or more of the deficiencies identified during the Department's inspection of Respondent on or about August 24, 2017.

22. Based on the foregoing, Respondent has violated Section 465.023(1)(c), Florida Statutes (2017), by and through a violation of Rule 64B16-27.797(1)(a), Florida Administrative Code.

WHEREFORE, the Petitioner respectfully requests that the Board of Pharmacy enter an order imposing one or more of the following penalties: permanent revocation or suspension of Respondent's license, restriction of practice, imposition of an administrative fine, issuance of a reprimand, placement of the Respondent on probation, corrective action, refund of fees billed or collected, remedial education and/or any other relief that the Board deems appropriate.

SIGNED this 22nd **day of** March **, 2018.**

Celeste Philip, M.D., M.P.H.
Surgeon General and Secretary

Christopher A. Jurich

CHRISTOPHER A. JURICH
Assistant General Counsel
Fla. Bar No. 0099014
Florida Department of Health
Office of the General Counsel
4052 Bald Cypress Way, Bin C-65
Tallahassee, FL 32399-3265
Telephone: (850) 558-9861
Facsimile: (850) 245-4662
Email: christopher.jurich@flhealth.gov

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK Amber Greene
DATE MAR 22 2018

PCP Meeting: March 22, 2018
PCP Members: Michele Weizer, Jeenu Philip

NOTICE OF RIGHTS

Respondent has the right to request a hearing to be conducted in accordance with Section 120.569 and 120.57, Florida Statutes, to be represented by counsel or other qualified representative, to present evidence and argument, to call and cross-examine witnesses and to have subpoena and subpoena duces tecum issued on his or her behalf if a hearing is requested.

A request or petition for an administrative hearing must be in writing and must be received by the Department within 21 days from the day Respondent received the Administrative Complaint, pursuant to Rule 28-106.111(2), Florida Administrative Code. If Respondent fails to request a hearing within 21 days of receipt of this Administrative Complaint, Respondent waives the right to request a hearing on the facts alleged in this Administrative Complaint pursuant to Rule 28-106.111(4), Florida Administrative Code. Any request for an administrative proceeding to challenge or contest the material facts or charges contained in the Administrative Complaint must conform to Rule 28-106.2015(5), Florida Administrative Code.

Please note that mediation under Section 120.573, Florida Statutes, is not available to resolve this Administrative Complaint.

NOTICE REGARDING ASSESSMENT OF COSTS

Respondent is placed on notice that Petitioner has incurred costs related to the investigation and prosecution of this matter. Pursuant to Section 456.072(4), Florida Statutes, the Board shall assess costs related to the investigation and prosecution of a disciplinary matter, which may include attorney hours and costs, on the Respondent in addition to any other discipline imposed.

ELECTION OF RIGHTS

Please sign and complete all of the information below:

The respondent received the Administrative Complaint on the following date: March 30, 2018.

PLEASE SELECT ONLY 1 OF THE 2 OPTIONS.

OPTION 1. ___ **I do not dispute the allegations** of material fact contained in the Administrative Complaint. I request a hearing be conducted pursuant to Section 120.57(2), Florida Statutes, where I will be permitted to appear, if I so choose, and submit oral and/or written evidence in mitigation of the complaint to the Board.

OPTION 2. __X__ **I do dispute the allegations** of material fact contained in the Administrative Complaint and I request this to be considered a petition for formal hearing, pursuant to Sections 120.569(2)(a) and 120.57(1), Florida Statutes, before an Administrative Law Judge appointed by the Division of Administrative Hearings. We hope to negotiate a settlement agreement with the Department and, if this matter can be resolved by a Board approved settlement agreement, we ask that this petition be dismissed. If the settlement agreement is not accepted by the Board of Pharmacy, we request that the Department forward this petition to DOAH after conclusion of the Board meeting at which the settlement agreement is presented to the Board. We waive the time period for forwarding this petition to DOAH until after the Board has acted as provided above. **Pursuant to the requirement of Uniform Rule 28-106.201(5), Florida Administrative Code, I specifically dispute the following material facts:**

Respondent disputes the allegations set forth in the Administrative Complaint and requires strict proof thereof and disputes whether the penalty proposed in the proposed settlement agreement is appropriate and considers all mitigating factors.

In the event that you fail to make an election in this matter within twenty-one (21) days from receipt of the Administrative Complaint, your failure to do so may be considered a waiver of your right to elect a hearing in this matter, pursuant to Rule 28-106.111(4), Florida Administrative Code, and the Board may proceed to hear your case.

PLEASE NOTE: Regardless of which option you choose, you may be able to reach a settlement agreement with the Department in your case. Please contact the prosecuting attorney if you wish to do so.

_____	_____
Respondent's Signature	Martin R. Dix, **Attorney/Qualified Representative***
Address: _____	Address: 106 E. College Ave., Suite 1200
_____	Tallahassee, FL 32301
Lic. No.: _____	Lic. No.: FL Bar #499080
Phone No.: _____	Phone No.: 850-224-9634
Fax No.: _____	Fax No.: 850-222-0103
Email: _____	Email: martin.dix@akerman.com

*** Qualified Representatives must file written requests to appear as such pursuant to Rule 28-06.106, Uniform Rules of Procedure.**

STATE OF FLORIDA
COUNTY OF _____

Before me, personally appeared _____, whose identity is known to me or who produced _____ (type of identification) and who acknowledges that his/her signature appears above.
Sworn to or affirmed by Affiant before me this ___day of _____ 20__.

_____ _____
Notary Public-State of Florida My Commission Expires

_____
Type or Print Name

PLEASE MAIL AND/OR FAX COMPLETED FORM TO: Christopher A. Jurich, Assistant General Counsel, DOH, Prosecution Services Unit, 4052 Bald Cypress Way, Bin C-65, Tallahassee, Florida 32399-3265. Telephone Number: (850) 245-4640; FAX (850) 245-4662; TDD 1-800-955-8771.

DOH v. BriovaRx Infusion Services, 203, Inc. f/k/a Ambient Healthcare of S. Florida, Inc. **Case No. 2017-15122**

Martin R. Dix

Akerman LLP
201 E. Park Avenue
Suite 300
Tallahassee, FL 32301

T: 850 224 9634
F: 850 222 0103

September 18, 2020

VIA E-MAIL

Andrew J. Pietrylo, Jr.
Assistant General Counsel
Office of the General Counsel
Prosecution Services Unit
Florida Department of Health
4052 Bald Cypress Way, Bin #C-65
Tallahassee, FL 32399-3265

Re: Additional Information for Reconsideration in DOH v. BriovaRX Infusion Services 203, Inc. f/k/a Ambient Healthcare of S. Florida, Inc. (2017 15122)

Dear Andrew:
As discussed in our e-mail exchange I am providing additional information on advancements/improvements by the pharmacy and the pharmacy staff for consideration by the Probable Cause Panel. In addition to the corrections made to address concerns raised in the August 24, 2017 Inspection, the following changes have occurred at Optum Infusion Services, Inc 203 - Briovarx Infusion Services, Inc 203, Inc F/K/A Ambient Healthcare of S. Florida, Inc.:

1. The Pharmacy manager who was there prior to the 2017 inspection was removed from his position and the company.
2. A new Pharmacy Manager, DOP, Mary Jo Giles, was hired.
3. The pharmacy moved to a new facility June 8th, 2018. The FL BOP completed an inspection and the pharmacy passed the inspection.
4. An inventory technician was hired, Anthony Montalvo.
5. A lead production Pharmacist, Leslie Nazaro, was hired.
    a. Leslie teaches Sterile Compounding to pharmacy students at Palm Beach College of Pharmacy.
    b. Leslie has the BPS (Board of Pharmacy Specialties) Compounded Sterile Preparation Certification.
6. Clinical Pharmacist – Shirley Adams completed and passed the BPS (Board of Pharmacy Specialties) Compounded Sterile Preparation Certification.

7. Clinical Pharmacist – Melodie Merzier-Michel is preparing to take the BPS (Board of Pharmacy Specialties) Compounded Sterile Preparation Certification.
8. Five new experienced compounding technicians were hired.
9. All staff members completed Critical Point Sterile Compounding and Hazardous Drug Compounding for 25 hours of continuing educations in 2020.
10. Director of Pharmacy, Mary Jo Giles, completed:
    a. Critical Point Sterile Compounding and Hazardous Drug Compounding - 25 hours of continuing education in 2020
    b. Certification of Hazardous Drugs and USP 800 by NPTA – 40 hours CE in 2019 Certification of Sterile Products and USP 797 by NPTA – 40 hours CE in 2019
    c. SCAT – (Sterile Compounding and Aseptic Technique) certification – 40 hours CE in 2017
    d. Preparing to take the BPS (Board of Pharmacy Specialties) Compounded Sterile Preparation Certification.
11. The pharmacy passed Inspections for 2019 and 2020.

Thank you for your consideration.

Sincerely,

Martin R. Dix

Martin R. Dix

Akerman LLP
Suite 1200
106 East College Avenue
Tallahassee, FL 32301

T: 850 224 9634
F: 850 222 0103

April 9, 2020

VIA E-MAIL AND U.S. MAIL

Andrew Pietrylo
Assistant General Counsel
Office of the General Counsel
Prosecution Services Unit,
Florida Department of Health
4052 Bald Cypress Way
Tallahassee, FL 32399-3265

Re: DOH vs. Briovarx Infusion Services 203 Inc., Case No. 2017-15122
Request for Reconsideration

Dear Andrew:
Sorry, for the delay on responding to you on this. My client, like most of the country, has been dealing with the Pandemic. You had asked whether I had submitted a response in this case. This case went to the probable cause panel prior to my involvement, so I had not submitted a response. I will provide my comments here. When I was first retained, the pharmacy had received an inspection of its special sterile compounding pharmacy permit and was in the process of drafting a corrective action plan ("CAP") to address the issues identified by the inspector. The CAP was completed and submitted to both the inspector and to Chris Jurich in the PSU and since you have a copy, I will not send another.

When I became involved, there was already an administrative complaint and a proposed settlement agreement. However, Chris Jurich said that he would wait until the pharmacy was re-inspected to see how the pharmacy did before deciding whether to go back to the probable cause panel for reconsideration or work on the proposed settlement. As you may know, the pharmacy moved to a new location in 2018 after the original 2017 inspection and CAP. The pharmacy had to be re-inspected as part of the change of location application process. Since the pharmacy was moving and was going to be re-inspected at that time, Chris said he would wait until the pharmacy was re-inspected to decide what to do.

The pharmacy moved to its new location in 2018. At the time, it does not appear that Mr. Jurich or I were made aware of the move or re-inspection by my client or by the DOH inspection team. Regardless, the pharmacy was re-inspected as part of the change in location application on June 1, 2018 and passed (see attached 2018 inspection form).

There was an inspection and CAP in 2019 and an inspection in 2020 for which the pharmacy has submitted a CAP to address the 4 issues raised (see attached CAP showing a total of only 4 issues raised). I would not think that these inspections are within the purview of the 2017 complaint.

We would also note that the prescription department manager ("PDM") is not the same manager that was at the pharmacy in 2017 when the issues which caused the inspector to file the complaint arose. Since the new PDM took over running the pharmacy, the comments from the inspector have been overall positive. I am also attaching the PDM's CE to show that she is working hard to stay on top of the sterile compounding issue.

Because the pharmacy addressed all of the issues raised in the 2017 inspection and the 2020 inspection only raised 4 issues that have since been addressed, we would respectfully request that the case be brought back to the probable cause panel for reconsideration.

Thank you for your consideration.

Sincerely,

Martin R. Dix

CC: Karen Peterson

CPE Monitor Standard Transcript

Participant Name: **Leslie Ann Nazario**
NABP e-Profile ID: **204158**
CPE Activity Date Range: **04/08/2018 - 04/08/2020**
Total CPE Hours Earned: **109.00**

Please allow 30 days for the CPE Provider to process your CPE and submit it through the CPE Monitor System. If it has been more than 35 days since you submitted the information necessary for CPE credit, contact the CPE Provider. Providers only have 60 days to submit or make changes.

ACPE Credits

Activity Date	Activity #	Credit Type	Source	Title	Topic	Provider	Live hours	Home hours
9/19/2019	0761-9999-19-070-H07-P	ACPE	ACPE	Sterility Testing Requirements of USP <71> and <797>	Compounding	Educational Review Systems	0.00	1.00
9/15/2019	0761-9999-19-072-H07-P	ACPE	ACPE	Moist and Dry-Heat Sterilization	Compounding	Educational Review Systems	0.00	1.00
9/15/2019	0761-9999-19-073-H07-P	ACPE	ACPE	Sterilization by Filtration	Compounding	Educational Review Systems	0.00	1.00
9/14/2019	0761-9999-18-262-H07-P	ACPE	ACPE	Use of Syringes, Needles, Vials, Ampules and Filters	Compounding	Educational Review Systems	0.00	1.00
9/13/2019	0761-9999-18-260-H07-P	ACPE	ACPE	Overview of Quality and Responsibilities of Compounding Personnel	Compounding	Educational Review Systems	0.00	1.00
9/13/2019	0761-9999-18-264-H07-P	ACPE	ACPE	Sterile Compounding on Patient Units	Compounding	Educational Review Systems	0.00	1.00
9/12/2019	0761-9999-18-261-H07-P	ACPE	ACPE	Proper Material Handling	Compounding	Educational Review Systems	0.00	1.00
9/12/2019	0761-9999-18-269-H07-P	ACPE	ACPE	Engineering Controls and Personal Protective Equipment	Compounding	Educational Review Systems	0.00	2.00
9/10/2019	0761-9999-18-270-H07-P	ACPE	ACPE	Hazardous Drug Work Practice Strategies	Compounding	Educational Review Systems	0.00	2.00
9/6/2019	0761-9999-18-268-H07-P	ACPE	ACPE	Hazardous Drug Health Effects, Occupational Risk and Safe Handling	Compounding	Educational Review Systems	0.00	1.00

9/4/2019	0761-9999-19-071-H07-P	ACPE	ACPE	Bacterial Endotoxin Testing	Compounding	Educational Review Systems	0.00	1.00
9/2/2019	0761-9999-18-263-H07-P	ACPE	ACPE	Aseptic Technique and Conduct in Controlled Environments	Compounding	Educational Review Systems	0.00	1.00
9/1/2019	0761-9999-18-257-H07-P	ACPE	ACPE	Overview of Cleaning and Disinfection of Pharmacy Controlled Environments	Compounding	Educational Review Systems	0.00	1.00
8/31/2019	0761-9999-18-259-H07-P	ACPE	ACPE	Cleaning and Disinfection of Secondary Engineering Controls and Segregated Compounding Areas	Compounding	Educational Review Systems	0.00	1.00
8/30/2019	0761-9999-18-258-H07-P	ACPE	ACPE	Cleaning an Disinfection of Primary Engineering Controls	Compounding	Educational Review Systems	0.00	1.00
8/28/2019	0761-9999-18-255-H07-P	ACPE	ACPE	Volumetric Air Sampling	Compounding	Educational Review Systems	0.00	1.00
8/27/2019	0761-9999-18-254-H07-P	ACPE	ACPE	Personnel Aseptic Media Fill and Competnecy Evaluation	Compounding	Educational Review Systems	0.00	1.00
8/27/2019	0761-9999-18-256-H07-P	ACPE	ACPE	Surface Sampling	Compounding	Educational Review Systems	0.00	1.00
8/26/2019	0761-9999-18-253-H07-P	ACPE	ACPE	Personnel Hand Hygiene, Garbing and Gloved Fingertip Sampling	Compounding	Educational Review Systems	0.00	2.00
8/21/2019	0761-9999-18-252-H07-P	ACPE	ACPE	Secondary Engineering Controls: Function, Use Testing and Certification	Compounding	Educational Review Systems	0.00	2.00
8/20/2019	0761-9999-18-250-H07-P	ACPE	ACPE	Use of Automated Compounding Devices (ACDs)	Compounding	Educational Review Systems	0.00	1.00
8/20/2019	0761-9999-18-251-H07-P	ACPE	ACPE	Primary Engineering Controls: Function, Testing and Certification	Compounding	Educational Review Systems	0.00	2.00
8/19/2019	0761-9999-18-243-H07-P	ACPE	ACPE	The History of Compounding and USP 797	Compounding	Educational Review Systems	0.00	1.00
8/19/2019	0761-9999-18-245-H07-P	ACPE	ACPE	Quality Releases an Final Check of CSPs	Compounding	Educational Review Systems	0.00	1.00
8/17/2019	0761-9999-18-246-H07-P	ACPE	ACPE	Labeling and Packaging	Compounding	Educational Review Systems	0.00	1.00
8/17/2019	0761-9999-18-248-H07-P	ACPE	ACPE	Purpose and Effective Use of Standard Operating Procedures	Compounding	Educational Review Systems	0.00	1.00
8/16/2019	0761-9999-18-244-H07-P	ACPE	ACPE	Determing Beyond Use Dating	Compounding	Educational Review Systems	0.00	1.00
8/16/2019	0761-9999-18-247-H07-P	ACPE	ACPE	Master Formulation and Compounding Records	Compounding	Educational Review Systems	0.00	1.00
8/16/2019	0761-9999-18-249-H07-P	ACPE	ACPE	General Elements of Documentation	Compounding	Educational Review Systems	0.00	1.00

8/12/2019	0761-9999-19-214-H07-P	ACPE	ACPE	Revised USP Sterile Compounding Standards: Implications for Home Infusion and Alternate Site Providers	Compounding	Educational Review Systems	0.00	1.00
7/10/2019	0384-0000-18-002-H07-P	ACPE	ACPE	Handling of Hazardous Drugs & USP <800> Certification	Compounding	National Pharmacy Technician Association (NPTA)	0.00	20.00
7/10/2019	0384-0000-18-002-L07-P	ACPE	ACPE	Handling of Hazardous Drugs & USP <800> Certification	Compounding	National Pharmacy Technician Association (NPTA)	20.00	0.00
12/16/2018	0012-0000-18-021-H01-P	ACPE	ACPE	Current Topics in Geriatric Patient Care	Disease State Mgmt/Drug Therapy	University of Florida College of Pharmacy	0.00	12.00
9/15/2018	0092-0000-18-027-L04-P	ACPE	ACPE	Consultant Law Review, Beers' Practice & Long Term Care	General Pharmacy Topics	Nova Southeastern University College of Pharmacy	4.00	0.00
9/15/2018	0092-0000-18-028-L04-P	ACPE	ACPE	MTM, Surgical Centers, Institutional Practice, and Preceptorship	General Pharmacy Topics	Nova Southeastern University College of Pharmacy	4.00	0.00
9/15/2018	0092-0000-18-029-L04-P	ACPE	ACPE	Assisted Living Facility, Behavioral Health, and Collaborative Agreements	General Pharmacy Topics	Nova Southeastern University College of Pharmacy	4.00	0.00
4/27/2018	0761-9999-16-167-H01-P	ACPE	ACPE	Hazardous Drug Work Practice Strategies	Disease State Mgmt/Drug Therapy	Educational Review Systems	0.00	2.00
4/26/2018	0761-9999-16-165-H01-P	ACPE	ACPE	Hazardous Drug Health Effects, Occupational Risk and Safe Handling	Disease State Mgmt/Drug Therapy	Educational Review Systems	0.00	1.00
4/20/2018	0761-9999-16-227-H01-P	ACPE	ACPE	Filtration and Sterility Testing	Disease State Mgmt/Drug Therapy	Educational Review Systems	0.00	1.00
4/20/2018	0761-9999-16-228-H01-P	ACPE	ACPE	Moist and Dry-Heat Sterilization	Disease State Mgmt/Drug Therapy	Educational Review Systems	0.00	1.00
4/18/2018	0761-9999-16-211-H01-P	ACPE	ACPE	General Elements of Documentation	Disease State Mgmt/Drug Therapy	Educational Review Systems	0.00	1.00
4/18/2018	0761-9999-16-214-H01-P	ACPE	ACPE	Secondary Engineering Controls: Function, Use Testing and Certification	Disease State Mgmt/Drug Therapy	Educational Review Systems	0.00	2.00
4/18/2018	0761-9999-16-217-H01-P	ACPE	ACPE	Volumetric Air Sampling	Disease State Mgmt/Drug Therapy	Educational Review Systems	0.00	1.00
4/18/2018	0761-9999-16-226-H01-P	ACPE	ACPE	Sterile Compounding on Patient Units	Disease State Mgmt/Drug Therapy	Educational Review Systems	0.00	1.00

Disclaimer:

The National Association of Boards of Pharmacy® (NABP®) generated this Activity Transcript (Transcript) or Compliance Report (Report) from NABP's systems. The Transcript or Report contains information provided to NABP from the Accreditation Council for Pharmacy Education (ACPE) and, if applicable, information from you, the non-ACPE course participant (Participant). The Transcript or Report can be used as proof of CPE credit for ACPE-accredited CPE. The ACPE provider is responsible for the accuracy of the ACPE course data and Participant is responsible for the accuracy of the non-ACPE course data on this Transcript or Report. Requests for changes to ACPE course data must be directed to the ACPE-accredited provider that offered the course. NABP affirms that it matches the ACPE-provided identifying data with corresponding identifying data in the NABP systems. Following the match, NABP adds the ACPE-submitted CPE data to NABP systems. If there is a discrepancy between this Transcript or Report and the data contained in the NABP systems, the data in the NABP systems is the correct data. Participant attested that any non-ACPE course data submitted to NABP is true and correct, that Participant complied with the NABP Terms of Use, and accepts full responsibility for all information submitted to NABP.

Corrective Action Preventative Action Plan (CAPA)

Branch location: **Miramar, FL**	Purpose of Correction: **FL BOP Inspection on 1/30/2020**	Date Initiated: **2/3/2020**
General Manager: **Mike Geraci**	DOP/PIC: **Mary Jo Giles**	DON: Not appplicable
Inspector/Auditor: **Monica Bower**	Date of Visit: **1/30/2020**	Date Due: **2/28/2020**

INSTRUCTIONS: Refer to Policy 6501 Performance Improvement Program

- Clinical Services team member (e.g. Regional Clinicial Pharmacist or Nurse) or branch management to initiate the CAPA with Findings indicated.
- Branch management to complete the remainder of the CAPA document ensuring that the plan is specific, measurable, achievable, relevant, documented, and within timeframe.
- All corrective actions will require evidence of completion to be submitted. If any follow up monitoring activities are assigned, Responsible Owner to submit evidence by date determined.
- The completed form and all applicable evidence of compliance must be emailed to your respective Regional and National leadership on the Clinical Services Team.

Finding	Corrective Action	Date of Correction	Responsible Owner	Preventative Action (to maintain compliance)	Comments (For internal use only)
52. Primary engineering controls provide unidirectional (i.e., laminar) HEPA filtered air. Air pattern analysis via smoke studies are conducted at the critical site to demonstrate unidirectional airflow and sweeping action over and away from the product under dynamic conditions.[ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls] *Smoke study videos done by certification company on 10/24/2019 indicate there were no employees simulating compounding; One of the VLFH's demonstrates smoke flow doesn't reach DCA; a video of HLFW demonstrates ebbs. There are three VLFH's that contain Pinnacle TPN machines used to compound TPNs; there are NO components attached to any of the Pinnacles, NO employees simulating compounding. There were NO LVP's, tubing, drugs attached to pinnacles during smoke studies.*	MTA was called to return and repeat the smoke studies on all three hoods containing PN compounders under dynamic conditions. All three VLFH's demonstrate smoke flowing to the DCA. Videos are available for review via the links below: https://fieldaware.s3.amazonaws.com/8dddfa37b2ba4d9aa11a928b81008411/VIDFeb%2004%202020%2010%3A20%3A31.MOV https://fieldaware.s3.amazonaws.com/935bce286b1c44c091b35f9b37d2f99a/VIDFeb%2004%202020%2010%3A26%3A40.MOV https://fieldaware.s3.amazonaws.com/bf5d7ffc945f4b9b93f0a0a793f9449e/VIDFeb%2004%202020%2010%3A28%3A53.MOV	2/4/2020	Mary Jo Giles, Director of Pharmacy (DOP)	Company staff member (delegated by DOP) will shadow/assist MTA technician during air dynamic/smoke studies at each certification visit. Smoke study videos will be reviewed prior to them exiting.	

Corrective Action Preventative Action Plan (CAPA)

Finding	Corrective Action	Date of Correction	Responsible Owner	Preventative Action (to maintain compliance)	Comments (For internal use only)
58. Facility has pressure gauges or velocity meters to monitor the pressure differential or airflow between the buffer area and ante-area, and the ante-area and the general environment outside the compounding area. The results are reviewed and documented on a log at least daily or by a continuous recording device. The pressures differentials meet or exceed 5 Pa (0.02 inch water column (w.c.)). Alternatively, in facilities where low- and medium-risk level CSPs are prepared, differential airflow is maintained at a minimum velocity of 0.2 meter/second (40 fpm) across a line of demarcation between buffer area and ante-area. [ENVIRONMENTAL QUALITY AND CONTROL : Pressure Differential Monitoring] *Differential pressure values are documented daily and electronically monitored through JLL . January 2020 records indicate anteroom and IV room pressures were at "0.01 or 0.00 on 11 days (Jan 1,3,6,7,8,10,13,16,21,22,24 and 27). Uknown if loss of pressure is due opening/closing door, duration of excursion. Per JLL representative, alerts are sent at an hour after initial excursion.*	JLL graphs printed for the 12 days of excursions for ante and clean rooms.USP 797 standard does not clearly define the duration time of an excursion. Upon review of the graphs, the excursions were due to opening and closing of the ante room door and/or clean room door during hours of operation. Staff will be re-educated on entering and exiting the sterile product complex to ensure that the doors are completely shut. Doors will not be opened for an extended time (i.e., longer than what one takes to enter or exit the room). An in-service sign-in sheet is attached for evidence of compliance. JLL-Jan.pdf Pharmacymeeting2.24.20.pdf	2/24/20	Mary Jo Giles, DOP	Upon review of daily JLL reports, any excursions will be noted and further print out of JLL graphs will be explored. The normal branch specific excursions will be compared and investigated if those times are exceeding.	

Corrective Action Preventative Action Plan (CAPA)

Finding	Corrective Action	Date of Correction	Responsible Owner	Preventative Action (to maintain compliance)	Comments (For internal use only)
67. When devices (e.g., computers and printers) and objects (e.g., carts and cabinets) are placed in buffer areas, air quality is verified by particle counts on certification. [ENVIRONMENTAL QUALITY AND CONTROL : ISO Class 5 Air Sources, Buffer Areas, and Ante-Areas] *Certifcation report does not indicate TPN Pinnacle machines (3) located in VLFH's were operational (drugs, LVP bags, sterile tubing not in hoods during certification).*	MTA was called to return and repeat the non-viable particle counts in the three hoods that contains PN compounders. The compounders were operating during the repeated tests. 3623 - Pharmacy - Labs - 2002 - Report	2/4/2020	Mary Jo Giles, DOP	Company staff member (delegated by DOP) will shadow/assist MTA technician during air dynamic/smoke studies at each certification visits. Smoke study videos will be reviewed prior to them exiting.	
106. Facility has written procedures for proper packaging, storage, and transportation conditions to maintain sterility, quality, purity, and strength of CSPs. [MAINTAINING STERILITY, PURITY, AND STABILITY OF DISPENSED AND DISTRIBUTED CSPs :] *Refrigerated CSP's are shipped same day or overnight via courier and are required to maintain temp of 2 to 8 celcius and shall not exceed 8 degrees C longer than 8 hours prior to patient receiving CSP. Policy does not indicate how temperature of CSP is known during transit or upon delivery.*	Company policy 9650 Medication and Supply, Packaging and Delivery Process is attached for review. The policy states the use of WarmMark® indicator as part of cold-chain process. Patients will recieve instruction sheet on the use of WarmMark® indicator as indicated at the bottom of the policy. 9650 Medication Supply Packaging D 9651A1 WarmMark Single Window Inst	2/4/2020	Mary Jo Giles, DOP	No further preventative action needed.	

STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES
INV797-Sterile Compounding

File # 21072
Insp # 158704

NAME	PERMIT NUMBER	DATE OF INSPECTION
BriovaRx Infusion Services 203, Inc.	27913	06/01/2018
DOING BUSINESS AS		
BRIOVARX INFUSION SERVICES 203, INC.		
STREET ADDRESS	**TELEPHONE #**	**EXT**
9984 PREMIER PARKWAY		
CITY	**COUNTY**	**STATE/ZIP**
MIRAMAR	BROWARD	FL/33025

Additional Information

Business Operation Hours

M-T-W-TH-F Y	Weekly Hours 8:30 am to 5:30
Monday N	Tuesday N
Wednesday N	Thursday N
Friday N	Saturday N
Sunday N	

Registered Pharmacist / Intern / Tech

License # PS49270	Licensee Name Shirley Elisbrun
License Type Registered Pharmacists	
License # PS36287	Licensee Name Vincent Ekebu
License Type Registered Pharmacists	
License # PS52096	Licensee Name Jacqueline Rodriguez
License Type Registered Pharmacists	
License # PS21110	Licensee Name Manuela Vega-Rivera
License Type Registered Pharmacists	
License # 29706	Licensee Name Katrina Phillip
License Type Pharmacy Tech	
License # PS46873	Licensee Name Mary Jo Giles
License Type Registered Pharmacists	

ACS Manager

Optional Information

Basic License Data - PSD

DEA Reg # BA7935490	

License Relations

Pharmacy Affiliate

ADLER, IAN	License #
BRONSON, DAVID	License #
DEBLASI, PAIGE	License #
FRENI, LAWRENCE	License #
KLEINMAN, IRA	License #
KRAMM, EDWARD P	License #
KRAMM, KATHEE M	License #
WILKINS, JOHN	License #

YORK, CHRISTOPHER	License #

RX DPT MGR/COR/POR

ELISBRUN, SHIRLEY	License # 49270

Special Sterile Compounding

BRIOVARX INFUSION SERVICES 203, INC.	License # 18740

INV797 - Sterile Compounding

LOW RISK

1. Low risk CSP's are properly identified: Aseptic manipulations within an ISO Class 5 environment using three or fewer sterile products and no more than two entries into any container. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Low-Risk Level CSPs]	
2. Low Risk CSP's, in absence of passing sterility test, stored not more than 48 hours at controlled room temperature, 14 days at cold temperature, or 45 days in solid frozen state at -25° to -10° or colder. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Low-Risk Level CSPs]	
3. Low Risk CSP's with 12 hour BUD are properly identified and comply with all four specific criteria. 1. PEC in Segregated Compounding area 2. Away from windows, doors , high traffic areas 3. Hygiene & garbing required, sinks not adjacent to PEC. 4. Cleaning & Disinfecting, Personnel training, Competency evaluation, Garbing, Aseptic work practices, Viable and non-viable environmental sampling apply. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Low-Risk Level CSPs]	

MEDIUM RISK

4. Medium Risk CSP's are properly identified: Aseptic manipulations within an ISO Class 5 environment using prolonged and complex mixing and transfer, more than three sterile products and entries into any container, and pooling ingredients from multiple sterile products to prepare multiple CSPs. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Medium-Risk Level CSPs]	
5. Medium Risk CSP's, In absence of passing sterility test, stored not more than 30 hours at controlled room temperature, 9 days at cold temperature, or 45 days in solid frozen state at -25° to -10° or colder. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Medium-Risk Level CSPs]	

HIGH RISK

6. Presterilization procedures for high-risk level CSPs, such as weighing and mixing, are completed in no worse than an ISO Class 8 environment. [ENVIRONMENTAL QUALITY AND CONTROL : Placement of Primary Engineering Controls Within ISO Class 7 Buffer Areas]	
7. High Risk CSP's are properly identified: Confirmed presence of nonsterile ingredients and devices, or confirmed or suspected exposure of sterile ingredients for more than one hour to air quality inferior to ISO Class 5 before final sterilization. [CSP MICROBIAL CONTAMINATION RISK LEVELS : High-Risk Level CSPs]	
8. High Risk CSP's, in absence of passing sterility test are not stored more than 24 hours at controlled room temperature, 3 days at cold temperature, or 45 days in solid frozen state at -25° to -10° or colder. [CSP MICROBIAL CONTAMINATION RISK LEVELS : High-Risk Level CSPs]	
9. A 0.2-µm certified sterilizing membrane filter is used that is chemically and physically compatible with the CSP. Filtration is completed rapidly without filter replacement. Sterilization method is verified to achieve sterility for the quantity and type of containers. [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Sterilization of High-Risk Level CSPs by Filtration]	
10. Sterilization method used has documentation that acceptable strength and purity of ingredients and integrity of containers is maintained. [CSP MICROBIAL CONTAMINATION RISK LEVELS : High-Risk Level CSPs]	
11. The manufacturer recommended filter integrity (e.g., bubble point) test is performed and documented for all sterilizing filters after filtering CSPs. [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Sterilization of High-Risk Level CSPs by Filtration]	
12. Autoclave cycle has been verified using appropriate biological indicators. Solutions are passed through a 1.2-µm or smaller filter into final containers to remove particulates before sterilization. [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Sterilization of High-Risk Level CSPs by Steam]	
13. Dry heat ovens used for sterilization have filtered forced air. Only those items that will be damaged by steam are sterilized by dry heat. [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Sterilization of High-Risk Level CSPs by Dry Heat]	
14. The description of dry heat sterilization conditions and duration for specific CSPs is included in written documentation in the compounding facility. The effectiveness of dry heat sterilization is verified using appropriate biological indicators and other confirmation. [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Sterilization of High-Risk Level CSPs by Dry Heat]	
15. Dry heat depyrogenation is used to render glassware or containers, such as vials free from pyrogens as well as viable microbes. The description of the dry heat depyrogenation cycle and duration for specific load items is included in written documentation in the compounding facility. The effectiveness of the dry heat depyrogenation cycle is verified using endotoxin challenge vials (ECVs). [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Depyrogenation by Dry Heat]	
16. Sterility testing is completed for all High-risk level CSPs prepared in batches of more than 25 identical containers, or exposed longer than 12 hours at 2° to 8°, and 6 hours at warmer than 8° before being sterilized. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Sterility Testing]	

USP <71> STERILITY TESTING (Outsourced)

17. Outsourced sterility testing results indicate that it is compliant with USP<71>. A method not described in the USP may be used if validation demonstrates that the alternative is at least as effective and reliable. [STERILITY TEST USP<71>]	
18. Outsourced: The number of articles tested are appropriate according to USP<71>. [STERILITY TEST USP<71> : Number of Articles to Be Tested]	
19. Outsourced: The volume/quantity tested is according to USP<71>. [STERILITY TEST USP<71> : Number of Articles to Be Tested]	
20. Outsourced: A USP<71> method suitability test has been done with appropriate inoculum, additives and rinses. [STERILITY TEST USP<71> : Method Suitability Test]	
21. Outsourced: Sterility testing reports are reviewed and appropriate actions taken and documented. [FINISHED PREPARATION RELEASE CHECKS AND TESTS]	

USP <71> STERILITY TESTING

22. On site: Membrane filtration is used if appropriate. (The technique of membrane filtration is used whenever the nature of the product permits; that is, for filterable aqueous preparations, for alcoholic or oily preparations, and for preparations miscible with, or soluble in, aqueous or oily solvents, provided these solvents do not have an antimicrobial effect in the conditions of the test.) Filters are rinsed according to USP<71>. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Sterility Testing]	
23. On site: Direct inoculation is done only when membrane filtration cannot be carried out. Volume to be inoculated does not exceed 10% of the culture media volume. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Sterility Testing]	
24. On site: The number of articles tested are appropriate according to USP<71>. [STERILITY TEST USP<71> : Number of Articles to Be Tested]	
25. On site: The volume/quantity tested is according to USP<71>. [STERILITY TEST USP<71> : Number of Articles to Be Tested]	
26. On site: A growth promotion test has been done on the media with the 5 specified organisms (not more than 100 CFU) according to USP<71>. [STERILITY TEST USP<71> : Growth Promotion Test of Aerobes, Anaerobes, and Fungi]	
27. On site: A USP<71> method suitability test has been done with appropriate inoculum, additives and rinses. [STERILITY TEST USP<71> : Method Suitability Test]	
28. On site: TSB or SCD is incubated at 20-25 C for 14 days (2 incubators present). [STERILITY TEST USP<71> : Culture Media and Incubation Temperatures]	
29. On site: FTM is incubated at 30-35 C for 14 days (2 incubators present). [STERILITY TEST USP<71> : Culture Media and Incubation Temperatures]	
30. On site: Sterility testing is documented including lot numbers and expiration dates of media. [FINISHED PREPARATION RELEASE CHECKS AND TESTS]	
31. On site: Sterility testing reports are reviewed and appropriate actions taken and documented. [FINISHED PREPARATION RELEASE CHECKS AND TESTS]	

ENDOTOXIN TESTING

32. Endotoxin testing is conducted for High-risk level CSP's that are prepared in batches of more than 25 identical containers, or exposed longer than 12 hours at 2° to 8°, and 6 hours at warmer than 8°, before being sterilized or in multidose containers for administration to multiple patients. (excluding those for inhalation and ophthalmic administration) [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Bacterial Endotoxin (Pyrogen) Testing]	
33. Endotoxin testing process indicates that it is compliant with USP<85>. [BACTERIAL ENDOTOXINS TEST USP<85>]	
34. High Risk CSP's are within allowable limits for bacterial endotoxins. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Bacterial Endotoxin (Pyrogen) Testing]	

IMMEDIATE USE COMPOUNDING

35. Immediate-use compounding complies with all six specified criteria. 1. Low-risk sterile nonhazardous products or diagnostic radiopharmaceutical products from the manufacturers' original containers. Anti-neoplastics shall not be prepared as immediate-use CSPs because they are hazardous drugs. 2. Unless required for the preparation, the compounding procedure is a continuous process not to exceed 1 hour. 3. During preparation, aseptic technique is followed and, if not immediately administered, the finished CSP is under continuous supervision to minimize the potential for contact with nonsterile surfaces, introduction of particulate matter or biological fluids, mix-ups with other CSPs, and direct contact of outside surfaces. 4. Administration begins not later than 1 hour following the start of the preparation of the CSP. 5. Unless immediately and completely administered by the person who prepared it or immediate and complete administration is witnessed by the preparer, the CSP shall bear a label listing patient identification information, the names and amounts of all ingredients, the name or initials of the person who prepared the CSP, and the exact 1-hour BUD and time. 6. If administration has not begun within 1 hour following the start of preparing the CSP, the CSP shall be promptly, properly, and safely discarded. [IMMEDIATE-USE CSPs]	N/A

SINGLE/MULTIPLE DOSE CONTAINER BUD

36. Beyond-use date does not exceed 28 days for multiple-dose containers after initial opening or entry, unless specified otherwise by the manufacturer. [SINGLE-DOSE AND MULTIPLE-DOSE CONTAINERS]	Yes
37. Beyond-use time does not exceed 6 hours for closure sealed single-dose containers in ISO Class 5 or cleaner air after initial opening or entry, unless specified otherwise by the manufacturer. [SINGLE-DOSE AND MULTIPLE-DOSE CONTAINERS] *Policy 7065 instructs SDV's and Pharmacy Bulk Packages to be discarded after six hours, but does not indicate if opened and remains in ISO 5 PEC*	No
38. Beyond-use time does not exceed 1 hour for closure sealed single-dose containers after being opened or entered in worse than ISO Class 5 air. [SINGLE-DOSE AND MULTIPLE-DOSE CONTAINERS]	N/A
39. Single-dose ampules are discarded immediately after use. [SINGLE-DOSE AND MULTIPLE-DOSE CONTAINERS]	Yes

HAZARDOUS DRUGS

40. A pressure indicator is installed and differential pressures are monitored and documented daily for hazardous buffer room. [HAZARDOUS DRUGS AS CSPs]	N/A
41. Hazardous drug buffer room is at least 0.01 inch water column negative pressure with 30 ACPH of HEPA filtered air. [HAZARDOUS DRUGS AS CSPs]	Yes
42. At least 0.01 inch water column negative pressure and 12 air changes per hour in non-cleanrooms in which CACIs are located. FAC: USP Chapter 797 requires that: "When closed-system vial-transfer devices (CSTDs) (i.e., vial-transfer systems that allow no venting or exposure of hazardous substance to the environment) are used, they shall be used within an ISO Class 5 environment of a BSC or CACI. The use of the CSTD is preferred because of their inherent closed system process. In facilities that prepare a low volume of hazardous drugs, the use of two tiers of containment (e.g., CSTD within a BSC or CACI that is located in a non-negative pressure room) is acceptable." For purpose of said provision, a "low volume of hazardous drugs" is defined as less than 40 doses per month. [HAZARDOUS DRUGS AS CSPs]	N/A
43. Personnel compounding hazardous drugs wear appropriate personal protective equipment. [HAZARDOUS DRUGS AS CSPs]	N/A
44. Hazardous drugs are handled with caution at all times using appropriate chemotherapy gloves during receiving, distribution, stocking, inventorying, preparing for administration, and disposal. Spill kits are available. [HAZARDOUS DRUGS AS CSPs]	Yes
45. Hazardous drugs are prepared in an ISO Class 5 environment (BSC or CACI) with protective engineering controls in place, following aseptic practices specified for the appropriate contamination risk levels. [HAZARDOUS DRUGS AS CSPs]	N/A
46. Hazardous drugs are stored separately from other inventory in a manner to prevent contamination and personnel exposure. [HAZARDOUS DRUGS AS CSPs] *Clean room suite contains a negative pressure storage room; -0.02"w.c. at time of inspection.*	Yes
47. Access to hazardous drug preparation areas is limited to authorized compounding personnel. [HAZARDOUS DRUGS AS CSPs]	N/A

48. Annual documentation of hazardous drug training of personnel regarding storage, handling, containment techniques and disposal of hazardous drugs is available. [HAZARDOUS DRUGS AS CSPs]	N/A
49. Compounding personnel of reproductive capability have confirmed in writing that they understand the risks of handling hazardous drugs. [HAZARDOUS DRUGS AS CSPs]	N/A
50. Facility maintains appropriate disposal containers for all hazardous waste. [HAZARDOUS DRUGS AS CSPs]	N/A

FACILITY DESIGN AND CERTIFICATION

51. Certification and testing of primary (LAFWs, BSCs, CAIs and CACIs) and secondary engineering controls (buffer and ante areas) have been performed by a qualified individual no less than every six months and whenever the device or room is relocated, altered, or major service to the facility is performed. Corrective action for deficiencies are documented. Certification procedures such as those outlined in the CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2006) are conducted under dynamic conditions. [ENVIRONMENTAL QUALITY AND CONTROL : Environmental Nonviable Particle Testing Program] *MTA certified ISO 7 ante, ISO 7 clean room, ISO 7 HD room and a negative pressure hazardous drug storage room. PEC's: 7 X LAFW and 1 BSC Class II A 2 all to ISO 5 under as built conditions.*	Yes
52. Primary engineering controls provide unidirectional (i.e., laminar) HEPA filtered air. Air pattern analysis via smoke studies are conducted at the critical site to demonstrate unidirectional airflow and sweeping action over and away from the product under dynamic conditions.[ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
53. The primary engineering controls are placed within a buffer area in such a manner as to avoid conditions that could adversely affect their operation. The PEC is placed out of the traffic flow and in a manner to avoid disruption from the HVAC system and room cross drafts. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
54. All HEPA filters are leak tested after installation and every six months thereafter. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes

ISOLATORS

55. CAIs are proven to maintain ISO Class 5 air when particle counts are sampled 6 to 12 inches upstream of critical site exposure areas during performance of normal inward and outward transfer of materials, and compounding manipulations when such CAIs are located in air quality worse than ISO Class 7. [ENVIRONMENTAL QUALITY AND CONTROL : Placement of Primary Engineering Controls Within ISO Class 7 Buffer Areas]	
56. Adequate recovery time for isolators to achieve ISO Class 5 air quality is allowed after material transfer before and during compounding operations. [ENVIRONMENTAL QUALITY AND CONTROL : Placement of Primary Engineering Controls Within ISO Class 7 Buffer Areas]	
57. Personnel garbing requirements are followed for CAIs unless manufacturer provides written documentation based on validated testing that any components of PPE are not required to maintain sterility of CSPs. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	

FACILITY DESIGN AND CERTIFICATION (Secondary Engineering Controls)

58. Facility has pressure gauges or velocity meters to monitor the pressure differential or airflow between the buffer area and ante-area, and the ante-area and the general environment outside the compounding area. The results are reviewed and documented on a log at least daily or by a continuous recording device. The pressures differentials meet or exceed 5 Pa (0.02 inch water column (w.c.)). Alternatively, in facilities where low- and medium-risk level CSPs are prepared, differential airflow is maintained at a minimum velocity of 0.2 meter/second (40 fpm) across a line of demarcation between buffer area and ante-area. [ENVIRONMENTAL QUALITY AND CONTROL : Pressure Differential Monitoring]	Yes
59. Clean rooms for nonhazardous and nonradioactive CSPs are supplied with HEPA filtered air that enters from ceilings with return vents low on walls, and that provides not less than 30 air changes per hour or qualifies for exception in 64B16-27.797(4)(c). [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
60. Activities and tasks carried out within the buffer area are limited to only those necessary when working within a controlled environment. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	N/A
61. Only the furniture, equipment, supplies, and other material required for the compounding activities to be performed are brought into the buffer room. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
62. Surfaces and essential furniture in buffer rooms or zones and clean rooms are nonporous, smooth, non-shedding, impermeable, cleanable, and resistant to disinfectants. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
63. The surfaces of ceilings, walls, floors, fixtures, shelving, counters, and cabinets in the buffer area are smooth, impervious, free from cracks and crevices, and non-shedding, thereby promoting cleanability, and minimizing spaces in which microorganisms and other contaminants may accumulate. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
64. Ceiling tiles are caulked around each perimeter and to walls to seal them to the support frame. The exterior lens surface of ceiling lighting fixtures is smooth, mounted flush, and sealed. All other penetrations through the ceiling or walls are sealed. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
65. The buffer area does not contain sources of water (sinks) or floor drains. Work surfaces are constructed of smooth, impervious materials, such as stainless steel or molded plastic, so that they are easily cleaned and disinfected. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
66. Storage shelving, counters, cabinets and carts/casters in the buffer area are smooth, impervious, free from cracks and crevices, non-shedding, non-porous, cleanable, and disinfectable. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
67. When devices (e.g., computers and printers) and objects (e.g., carts and cabinets) are placed in buffer areas, air quality is verified by particle counts on certification. [ENVIRONMENTAL QUALITY AND CONTROL : ISO Class 5 Air Sources, Buffer Areas, and Ante-Areas]	Yes

QUALITY AND CONTROL

68. An appropriate environmental sampling plan has been developed for airborne viable particles based on a risk assessment of compounding activities performed. Volumetric air sampling is conducted every six months and sites include locations within each ISO Class 5 environment and in the ISO Class 7 and 8 areas, and the areas at greatest risk of contamination (e.g., work areas near the ISO Class 5 environment, counters near doors, pass-through boxes). The plan includes sample locations, method of collection, frequency of sampling, volume of air sampled, and time of day as related to activity in the compounding area and action levels. [ENVIRONMENTAL QUALITY AND CONTROL : Environmental Viable Airborne Particle Testing Program—Sampling Plan] *Environmental policy 9701 does not include USP <797> required viable air sampling by impaction, amount of air to be sampled in each ISO class space and sampling locations. Advise to use viable air sampling locations to evaluate CFU trends.*	No
69. Evaluation of airborne microorganisms using volumetric collection methods in the controlled air environments is performed by properly trained individuals for all compounding risk levels. [ENVIRONMENTAL QUALITY AND CONTROL : Viable Air Sampling]	Yes
70. Volumetric air sampling using malt extract agar (MEA) or some other media that supports the growth of fungi is used in high-risk level compounding environments. [ENVIRONMENTAL QUALITY AND CONTROL : Growth Media]	N/A

71. For low-risk level CSPs with 12-hour or less BUD, air sampling is performed at locations inside the ISO Class 5 environment and other areas that are in close proximity to the ISO class 5 environment. [ENVIRONMENTAL QUALITY AND CONTROL : Viable Air Sampling]	N/A
72. The number of discrete colonies of microorganisms is counted and reported as colony-forming units (cfu) and documented on an environmental monitoring form. Counts from air monitoring are transformed into cfu/cubic meter of air and evaluated for adverse trends. [ENVIRONMENTAL QUALITY AND CONTROL : Incubation Period] *N/A*	Yes
73. Surface sampling is accomplished in all ISO classified areas on a periodic basis using TSA contact plates with lecithin and polysorbate 80 and/or swabs and is done at the conclusion of compounding. [ENVIRONMENTAL QUALITY AND CONTROL : Surface Cleaning and Disinfection Sampling and Assessment] *Facility does monthly surface sampling in house.*	Yes
74. Sampling data is collected and reviewed on a periodic basis as a means of evaluating the overall state of control of the compounding environment. [ENVIRONMENTAL QUALITY AND CONTROL : Action Levels, Documentation and Data Evaluation] *N/A*	Yes
75. Competent microbiology personnel are consulted if an environmental sampling consistently shows elevated levels of microbial growth. If any mold, yeast, coagulase positive staphylococcus, or gram negative rods are detected immediate remediation and investigation into the cause and source was conducted. [ENVIRONMENTAL QUALITY AND CONTROL : Action Levels, Documentation and Data Evaluation] *Hazardous drug clean room viable air sampling resulted in fungal growth; investigation and terminal cleaning was completed. Retesting was completed on May 21st, results pending.*	Yes
76. Surfaces in the LAFWs, BSCs, CAIs, and CACIs are cleaned and disinfected frequently, including at the beginning of each work shift, before each batch preparation is started, every 30 minutes during continuous compounding periods of individual CSPs, when there are spills, and when surface contamination is known or suspected from procedural breaches. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas] *N/A*	Yes
77. Cleaning and disinfecting occurs before compounding is performed. Items are removed from all areas to be cleaned, and surfaces are cleaned by removing loose material and residue from spills, e.g., water-soluble solid residues are removed with Sterile Water and low-shedding wipes. This shall be followed by wiping with a residue-free disinfecting agent, such as sterile 70% IPA, which is allowed to dry before compounding begins. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas] *N/A*	Yes
78. Cleaning and disinfecting agents and methods of application are in accordance with written SOPs and followed by custodial and/or compounding personnel. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
79. Cleaning materials, such as wipes, sponges, and mops, are non-shedding, preferably composed of synthetic micro fibers, and dedicated to use in the buffer area, ante-area, and segregated compounding areas and are not removed from these areas except for disposal. If cleaning materials are reused (e.g., mops), there are procedures based on manufacturer recommendations that ensure that the effectiveness of the cleaning device is maintained and repeated use does not add to the bioburden of the area being cleaned. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
80. Supplies and equipment removed from shipping cartons are wiped with a suitable disinfecting agent (e.g., sterile 70% IPA). [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
81. Disinfectant sprayed or wiped on a surface to be disinfected is allowed to dry, and during this time the item is not be used for compounding purposes. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
82. Sterile 70% IPA pads are used to disinfect the sterile entry points of packages and devices. Wetted gauze pads or other particle-generating material are not appropriate. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes

QUALITY AND CONTROL (Secondary Engineering Controls)

83. Work surfaces in ISO Class 7 and 8 areas and segregated compounding areas are cleaned at least daily. IPA (70% isopropyl alcohol) remains on surfaces to be disinfected for at least 30 seconds before such surfaces are used to prepare CSPs. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	N/A
84. Floors in ISO Class 7 and 8 areas are mopped daily by trained personnel at a time when no aseptic operations are in progress using approved agents and procedures described in written SOP's. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	N/A
85. Shelving, walls, and ceilings in ante-areas and buffer areas are cleaned and disinfected at least monthly. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	N/A

PERSONNEL CLEANSING, GARBING & COMPETENCY EVALUATION

86. Personnel preparing CSP's are free from rashes, sunburn, weeping sores, conjunctivitis, and active respiratory infections. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	Yes
87. Compounding personnel remove personal outer garments; cosmetics; artificial nails; hand, wrist, and body jewelry that can interfere with the fit of gowns and gloves; and visible body piercing above the neck. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	Yes
88. Facility has adequate supplies to meet PPE requirements of USP<797>. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	Yes
89. Garbing and hand hygiene are accomplished in the ante-area in order of dirtiest to cleanest: shoes or shoe covers, head and facial hair covers, face mask, fingernail cleansing, hand and forearm washing and drying; non-shedding gown. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	Yes
90. Sterile gloves are donned in the buffer room/isolator after hand cleansing with an alcohol-based product with persistent activity and hands are allowed to dry. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	Yes
91. Gloves are routinely disinfected with sterile 70% IPA after contacting nonsterile objects. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	Yes
92. Personnel repeat garbing and hand hygiene after they are exposed to direct contact contamination or worse than ISO Class 8 air. Gowns may be hung in the anteroom and reused during the same workshift. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	Yes
93. Low/Medium Risk media-fill tests that closely simulate the most challenging or stressful conditions encountered during compounding are completed at least annually by compounding personnel. Media-filled vials are appropriately incubated for 14 days. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Medium-Risk Level CSPs]	Yes
94. High Risk Media-fill tests that closely simulate the most challenging or stressful conditions encountered during compounding have been completed at least semiannually by compounding personnel. Media-filled vials are appropriately incubated for 14 days. [CSP MICROBIAL CONTAMINATION RISK LEVELS : High-Risk Level CSPs]	N/A

95. Documentation indicates compounding personnel have successfully completed didactic training, passed written competency assessments, undergone skill assessment using observational audit tools (hand hygiene, garbing, aseptic technique) and media-fill testing annually or semiannually (high risk) and before any compounding personnel begin to prepare CSPs . [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures]	Yes
96. Compounding personnel who fail written tests, observational audits, or whose media-fill test vials have one or more units showing visible microbial contamination, are reinstructed and re-evaluated by expert compounding personnel to ensure correction of all aseptic work practice deficiencies. Corrective action is documented. Compounding personnel pass all evaluations prior to resuming compounding of sterile preparations. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures]	N/A
97. Other cleaning personnel performing cleaning and disinfecting procedures (e.g. environmental) are thoroughly trained in proper hand hygiene, and garbing, cleaning, and disinfection procedures by a qualified aseptic compounding expert. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures]	N/A
98. Compounding personnel and other personnel responsible for cleaning routinely undergo performance evaluation of proper hand hygiene, garbing, and all applicable cleaning and disinfecting procedures conducted by a qualified aseptic compounding expert. Visual observation of hand hygiene, garbing and cleaning is documented and maintained to provide a permanent record and long-term assessment of personnel competency. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures]	Yes
99. Immediately after the compounder completes the hand hygiene and garbing procedure, the evaluator collects a gloved fingertip and thumb sample from both hands of the compounder onto appropriate agar plates. The plates are incubated at 30-35° for 2–3 days. All compounding personnel have successfully completed an initial competency evaluation and gloved fingertip/thumb sampling procedure (0 cfu) no less than three times before initially being allowed to compound CSPs for human use. [ENVIRONMENTAL QUALITY AND CONTROL : Gloved Fingertip Sampling] *Policy 9705 indicates new employees shall complete hand hygiene three times, but not regarb three times.*	No
100. Re-evaluation of glove fingertip testing onto appropriate agar plates (Trypticase soy agar (TSA) with lecithin and polysorbate 80) for all compounding personnel occurs at least annually for low- and medium-risk level CSPs and semiannually for high-risk level CSPs before being allowed to continue compounding CSPs. Gloves shall not be disinfected with sterile 70% IPA prior to testing. The cfu action level is based on the total number of cfu on both gloves and not per hand. [ENVIRONMENTAL QUALITY AND CONTROL : Gloved Fingertip Sampling]	Yes

VERIFICATION

101. Labels of CSPs contain name and address of pharmacy, correct names and amounts or concentrations of ingredients, total volumes, beyond-use dates, storage conditions, and route(s) of administration. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Identity and Strength Verification of Ingredients] *N/A*	Yes
102. Facility has documentation that procedures have been followed to ensure sterility, purity, correct identities and amounts of ingredients, and stability. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Inspection of Solution Dosage Forms and Review of Compounding Procedures]	Yes
103. CSP's are visually inspected for abnormal particulate matter and color, and intact containers and seals. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Inspection of Solution Dosage Forms and Review of Compounding Procedures]	Yes
104. Beyond Use Dates are assigned using direct stability-indicating assays or authoritative literature that supports the assigned BUD. [STORAGE AND BEYOND-USE DATING : Determining Beyond-Use Dates] *N/A*	Yes
105. Storage time of assembled bag and vial systems are according to the manufacturer recommendations. (eg Minibag plus, Addvantage, Add-ease) [STORAGE AND BEYOND-USE DATING : Proprietary Bag and Vial Systems]	N/A

DISPENSING/DISTRIBUTION

106. Facility has written procedures for proper packaging, storage, and transportation conditions to maintain sterility, quality, purity, and strength of CSPs. [MAINTAINING STERILITY, PURITY, AND STABILITY OF DISPENSED AND DISTRIBUTED CSPs :]	N/A
107. Modes of transport are used that maintain appropriate temperatures and prevent damage to CSPs. [MAINTAINING STERILITY, PURITY, AND STABILITY OF DISPENSED AND DISTRIBUTED CSPs : Packaging and Transporting CSPs]	N/A
108. Facility provides a multiple component formal training program to ensure patients and caregivers understand the proper storage, handling, use, and disposal of CSPs. [PATIENT OR CAREGIVER TRAINING]	N/A

POLICY/PROCEDURE

109. Written procedures detail cleaning and disinfecting the sterile compounding areas including cleansers, disinfectants, and non-shedding wipe and mop materials. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
110. A written procedure is in place for cleaning and disinfecting the Direct Compounding Areas. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
111. Facility has written procedures to verify correct identity, quality, amounts, and purities of ingredients used in CSPs. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Identity and Strength Verification of Ingredients]	Yes
112. Policies address packaging to maintain physical integrity, sterility, stability, and purity of CSPs. [MAINTAINING STERILITY, PURITY, AND STABILITY OF DISPENSED AND DISTRIBUTED CSPs : Packaging and Transporting CSPs]	Yes
113. Written standard procedures describe means for patients to ask questions and report concerns and adverse events with CSPs, and for compounding pharmacists to correct and prevent future problems. [PATIENT MONITORING AND ADVERSE EVENTS REPORTING]	Yes

RADIOPHARMACEUTICALS

114. Facility has appropriate primary engineering controls and radioactivity containment and shielding. Location of primary engineering controls permitted in ISO Class 8 controlled environment. [RADIOPHARMACEUTICALS AS CSPs]	
115. Radiopharmaceuticals prepared as low-risk level CSPs with 12-hour or less BUD are prepared in a segregated compounding area. Segregated compounding area is designated with a line of demarcation. [RADIOPHARMACEUTICALS AS CSPs]	
116. Technetium-99m/Molybdenum-99 generators are eluted in ISO Class 8 conditions. [RADIOPHARMACEUTICALS AS CSPs]	

MISCELLANEOUS

117. Facility engaged in office use sterile compounding for human use is registered with FDA as an outsourcing facility. [FAC 64B16-27.700 (3)(g]	N/A
118. Compounding records are properly maintained. [FAC 64B16-28.140(4)]	N/A

119. When compounding activities require the manipulation of a patient's blood-derived or other biological material, the manipulations are clearly separated from routine material-handling procedures and equipment used in CSP preparation activities, and they are controlled by specific standard operating procedures in order to avoid any cross-contamination. [ENVIRONMENTAL QUALITY AND CONTROL : Placement of Primary Engineering Controls Within ISO Class 7 Buffer Areas]	N/A

SPECIAL PARENTERAL ENTERAL & EXTENDED SCOPE

120. Pharmacy technicians properly identified and supervised. [64B16-27.420, F.A.C.]	
121. Medication properly labeled. [465.0255, F.S.] [64B16-28.108, F.A.C.]	
122. Expired medications removed from the shelves. [64B16-28.110, F.A.C.]	
123. CQI Policy and Procedures and quarterly meetings. [766.101, F.S.] [64B16-27.300, F.A.C.]	
124. Prescriptions have the date dispensed and dispensing pharmacists. [893.04(1)(c) 6, F.S.] [64B16-28.140(3)(b), F.A.C.]	
125. Pharmacy maintains patient profile records. [64B16-27.800, F.A.C.]	
126. All controlled substance prescriptions contain information required. [893.04, F.S.]	
127. Prescriptions for controlled substances are on counterfeit-proof prescription pads or blanks purchased from a Department-approved vendor and the quantity and date meet the requirements of [456.42(2), F.S.].	
128. Controlled substance inventory taken on a biennial basis and available for inspection. [893.07(1)(a), F.S.]	
129. DEA 222 order forms properly completed. [893.07, F.S.]	
130. Controlled substance records and Rx information in computer system is retrievable. [21CFR 1306.22] [64B16-28.140, F.A.C.]	
131. Controlled substance records maintained for 4 years. [465.022(12)(b), F.S.]	
132. Certified daily log OR printout maintained. [21CFR 1306.22(b)(3)] [64B16-28.140(3)(b), F.A.C.]	
133. Pharmacy is reporting to the PDMP within 7 days of dispensing controlled substance. [893.055(4), F.S.]	
134. Pharmacy maintains invoices documenting that medicinal drugs were obtained from a Florida licensed distributor. 499.005 (14)	

Remarks:

This is a change of location inspection; Previously located at 15951 SW 41 St; Davie under the name of Ambient Healthcare of So. Florida, Inc. Many answers are N/A; Firm will not be compounding hazardous CSP's at this time, but has a negative pressure chemical room and a negative pressure clean room. Inspection conducted with Shirley Elisbrun Rph PIC and Mary Jo Giles RXM; Please send inspector a corrective action plan for all deficiencies on or before July 2, 2018.

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge. I have received a copy of the Licensee Bill of Rights.

Inspector Signature:

Date:6/1/2018

Representative:

Shirley Elisbrun

Date:6/1/2018

Corrective Action Preventative Action Plan (CAPA)

Branch location: **Miramar, FL**	Purpose of Correction: **FL Board of Pharmacy Inspection Findings**	Date Initiated: **05/07/2019**
General Manager: **Mike Geraci**	DOP/PIC: **Mary Jo Giles**	DON: **N/A**
Inspector/Auditor: **Monica Bower, FL BOP Inspector**	Date of Visit: **5/7/2019**	Date Due: **6/7/2019**

NSTR CT NS:

- Clinical Services team member (e.g. Regional Clinical Pharmacist) or branch management to initiate the CAPA with Findings indicated.
- Branch management to complete the remainder of the CAPA document ensuring that the plan is specific, measurable, achievable, relevant, documented, and within timeframe.
- All corrective actions will require evidence of completion to be submitted. If any follow up monitoring activities are assigned, Responsible Owner to submit evidence by date determined.
- The completed form and all applicable evidence of compliance must be emailed to your respective Regional and National leadership on the Clinical Services Team.

Finding	Corrective Action	Date of Correction	Responsible Owner	Preventative Action (to maintain compliance)	Comments (For internal use only)
37. Beyond-use time does not exceed 6 hours for closure sealed single-dose containers in ISO Class 5 or cleaner air after initial opening or entry, unless specified otherwise by the manufacturer. [SINGLE-DOSE AND MULTIPLE-DOSE CONTAINERS] *Preservative free Vancomycin 1g/vial stored in refrigerator without discard/entry time; D5W and NaCl preservative free IV bags hanging in PEC's without discard/entry time.*	There will be no punctured preservative free vials stored in the refrigerator. There will be no preservative free IV bags hanging in the PECs without a time and date of entry label on the IV bags. **ACT N:** Director of Pharmacy (DOP) reviewed Policy #7065 with compounding technicians and pharmacists for thorough understanding. Stressed to the staff that it is absolutely prohibited for any punctured preservative free single dose vials be placed into the refrigerator and outside of the ISO 5 areas. In addition, DOP also stressed to the staff that all punctured IV bags or vials hanging in the PECs must have time and date of entry label and discarded after 6 hours. A copy of meeting log signatures and Policy #7065 are included as evidence of compliance.	5/10/2019	DOP	DOP or trained designee to ensure Policy #7065 is thoroughly understood and signed by all compounding staff. DOP or trained designee to ensure that the Sterile Compounding Weekly PIP Audit Tool-Indicator #2 is done and signed off weekly: Appropriately labeled IV solutions used in hood with date/exp. time. Perform surprise weekly audit using PIP tool to prevent and improve nonconformities. DOP or trained designee to conduct a daily check to make sure there are no punctured vials in the refrigerator and outside of the ISO 5 areas.	

Corrective Action Preventative Action Plan (CAPA)

Finding	Corrective Action	Date of Correction	Responsible Owner	Preventative Action (to maintain compliance)	Comments (For internal use only)
51. Certification and testing of primary (LAFWs, BSCs, CAIs and CACIs) and secondary engineering controls (buffer and ante areas) have been performed by a qualified individual no less than every six months and whenever the device or room is relocated, altered, or major service to the facility is performed. Corrective actions for deficiencies are documented. Certification procedures such as those outlined in the CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2006) are conducted under dynamic conditions. [ENVIRONMENTAL QUALITY AND CONTROL : Environmental Nonviable Particle Testing Program] *On 4/25/2019, MTA certified ISO 7 anteroom, ISO 7 IV room, ISO 7 HD room, ISO 7 negative pressure storage room. Equipment used in compounding inside PEC's include 3 TPN Pinnacle machines, 4 X repeater pumps, 2 X Tube rollers; all electronic. PEC's: 6 X VLF's (3 of which used for compounding* *TPN's with Pinnacle machines), 1 X HLF and 1 X BSC all to ISO 5, with only the Pinnacle machines operational.*	During MTA certification, all equipment (i.e., tube rollers, repeater pumps, and PN compounders) will be running to create dynamic conditions while the smoke study test is being conducted. **ACT N:** DOP or trained designee will instruct MTA certification company that all equipment (i.e., tube rollers, repeater pumps, and PN compounders) must be running to create dynamic conditions when conducting the smoke study test. Reviewed with compounding technicians that they must be present and ensure that all equipment is running during the smoke study test. Additionally, DOP or trained designee will be present during MTA certification testing to ensure compliance. A copy of meeting log signatures is included as evidence of compliance.	5/10/2019	DOP	DOP or trained designee will be present during MTA certification testing to ensure compliance of the new process. DOP will review and sign each MTA certification reports to ensure proper documentation that the smoke test is completed under dynamic conditions. Next certification scheduled for 11/2019.	
67. When devices (e.g., computers and printers) and objects (e.g., carts and cabinets) are placed in buffer areas, air quality is verified by particle counts on certification. [ENVIRONMENTAL QUALITY AND CONTROL : ISO Class 5 Air Sources, Buffer Areas, and Ante-Areas] *There are 4 X repeater pumps, 3 X Pinnacle machines and 2 Tube rollers that are located in PEC's. Per Rph, only the Pinnacle TPN machines are* *operational during particle counts.*	During MTA certification, all equipment (i.e., tube rollers, repeater pumps, and PN compounders) will be running to create dynamic conditions while the particle counts test is being conducted. **ACT N:** DOP or trained designee will instruct MTA certification company that all equipment (i.e., tube rollers, repeater pumps, and PN compounders) must be running to create dynamic conditions when conducting the particle counts test. Reviewed with compounding technicians	5/10/2019	DOP	DOP or trained designee will be present during MTA certification testing to ensure compliance of the new process. DOP will review and sign each MTA certification reports to ensure proper documentation that the particle counts test is completed under dynamic conditions. Next certification scheduled for 11/2019.	

Corrective Action Preventative Action Plan (CAPA)

Finding	Corrective Action	Date of Correction	Responsible Owner	Preventative Action (to maintain compliance)	Comments (For internal use only)
	that they must be present and ensure all equipment must be running during the particle counts test. DOP or trained designee will be present during MTA certification testing to ensure compliance. A copy of meeting log signatures is included as evidence of compliance.				
72. The number of discrete colonies of microorganisms is counted and reported as colony-forming units (cfu) and documented on an environmental monitoring form. Counts from air monitoring are transformed into cfu/cubic meter of air and evaluated for adverse trends. [ENVIRONMENTAL QUALITY AND CONTROL : Incubation Period] *Trending data is in the process of being implemented by corporate.*	Trending SPC sampling data has been implemented and will be maintained by DOP or trained designee on a monthly basis. **ACT N:** In-service on new SPC Map and trending of sampling data tool was completed on 5/16/19 on the Southeast Region Director of Pharmacy call. Monthly surface and Quarterly air sampling data were transferred to the new trending tool to date. Monthly update of the tool will be done when new sampling data is available. A copy of the sampling data trends from January to May of 2019 is included as evidence of compliance.	5/16/19	DOP	DOP or trained designee will ensure that all monthly surface and quarterly air logs are completed thoroughly and uploaded to the shared drive as per USP 797 and Florida Board of Pharmacy regulations and Policy #9701.	
73. Surface sampling is accomplished in all ISO classified areas on a periodic basis using TSA contact plates with lecithin and polysorbate 80 and/or swabs and is done at the conclusion of compounding. [ENVIRONMENTAL QUALITY AND CONTROL : Surface Cleaning and Disinfection Sampling and Assessment] *This is done in house monthly, per policy. EM policy 9701 (implemented March 2019) requires two incubation temperatures, 30-35 degrees C X 2 days, then 20-25 degrees C X 5 days. Facility*	Monthly surface sampling will be incubated under two sets of temperature: 30-35 degrees C for 2 days, then 20-25 degrees C for 5 days. **ACT N:** DOP reviewed updated policy 9701 and form 9701.F3 that detailed the monthly surface testing dual incubation under 30-35 degrees C for 2 days, then 20-25 degrees C for 5 days. The new form and process were implemented immediately.	5/10/19	DOP	DOP or trained designee will ensure that monthly surface samples are incubated under two different sets of temperatures and that form 9701.F3 is thoroughly completed and signed.	

Corrective Action Preventative Action Plan (CAPA)

Finding	Corrective Action	Date of Correction	Responsible Owner	Preventative Action (to maintain compliance)	Comments (For internal use only)
practice is incubation at 30-35 C X 72 hours.	A copy of May 2019 Monthly Surface Sampling Testing Log form 9701.F3 is included as evidence of compliance.				
80. Supplies and equipment removed from shipping cartons are wiped with a suitable disinfecting agent (e.g., sterile 70% IPA). [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas] *Inspector observed RPT remove sterile drug component from ISO 5 air into ISO 7 air, remove cap and return item to ISO 5 without disinfecting.*	Compounding staff must never remove sterile drug component from ISO 5 air into a dirtier quality of air and return back to ISO 5 area without properly disinfecting with sterile alcohol. **ACT N**: DOP reviewed policy #9611 with all compounding technicians and pharmacists during a staff meeting. Technician GT was retrained and reassessed for aseptic technique and related practices and signed off. A copy of Assessment of aseptic and related practices form 9710.F2 is included as evidence of compliance.	5/28/19	DOP	Weekly in-house meeting will be conducted to review and emphasize the importance of aseptic techniques. DOP or trained designee will perform surprised weekly audit using the PIP tool to prevent and improve nonconformities. The Sterile Compounding Weekly Audit tool will include but not limited to: Indicator #4: Observed using appropriate aseptic technique during compounding ISO 5 area. Indicator #5: Observation of appropriate glove disinfection when moving in and out of ISO 5 environment.	
82. Sterile 70% IPA pads are used to disinfect the sterile entry points of packages and devices. Wetted gauze pads or other particle-generating material are not appropriate. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas] *Inspector observed RPT spray septum with sIPA without wiping.*	Compounding staff must not spray sterile IPA inside of hood. All drug entry septum must be wiped down with sterile alcohol prior to compounding. **ACT N:** DOP reviewed policy #9612 with all compounding technicians and pharmacists during a staff meeting. Technician GT was retrained and reassessed for aseptic technique and related practices and signed off. A copy of meeting log with signatures is included as evidence of compliance.	5/28/19	DOP	Weekly in-house meeting will be conducted to review and emphasize the importance of aseptic techniques. DOP or trained designee will perform surprised weekly audit using the PIP tool to prevent and improve nonconformities. The Sterile Compounding Weekly Audit tool will include but not limited to Indicator #4: Observed using appropriate aseptic technique during compounding ISO 5 area	

Corrective Action Preventative Action Plan (CAPA)

Finding	Corrective Action	Date of Correction	Responsible Owner	Preventative Action (to maintain compliance)	Comments (For internal use only)
96. Compounding personnel who fail written tests, observational audits, or whose media-fill test vials have one or more units showing visible microbial contamination, are reinstructed and re-evaluated by expert compounding personnel to ensure correction of all aseptic work practice deficiencies. Corrective action is documented. Compounding personnel pass all evaluations prior to resuming compounding of sterile preparations. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures] *Media fill tests for three compounding RPT's (RS, WG, GT) indicate particles found in media; Employees were not re-validated.*	All compounding staff must be revalidated if any particulate matter is found in the media fill tests. **ACT N:** Employees (RS, WG, GT) aseptic techniques were revalidated, completed and passed the media fill test. . A copy of media fill log form 9710.F5 is included for each of the above mentioned employee as evidence of compliance.	5/13/19	DOP	DOP or trained designee will thoroughly review Policy #9710 with each technician and pharmacist prior to testing to ensure understanding. DOP will review and sign off on media fill results to ensure compliance.	
98. Compounding personnel and other personnel responsible for cleaning routinely undergo performance evaluation of proper hand hygiene, garbing, and all applicable cleaning and disinfecting procedures conducted by a qualified aseptic compounding expert. Visual observation of hand hygiene, garbing and cleaning is documented and maintained to provide a permanent record and long-term assessment of personnel competency. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures] *GT RPT performs monthly cleaning, but has not demonstrated proficiency for this task.*	All compounding staff who performs cleaning activities in the SPC must demonstrate proficiency for the task; this includes daily and monthly clean of the SPC. **ACT N:** Technician GT has been retrained and re-assessed for cleaning and disinfection practices. A copy of form 9710.F4 is included as evidence of compliance.	5/9/19	DOP	DOP or trained designee will ensure that the most updated forms are used for employee assessments.	

Corrective Action Preventative Action Plan (CAPA)

Finding	Corrective Action	Date of Correction	Responsible Owner	Preventative Action (to maintain compliance)	Comments (For internal use only)
99. Immediately after the compounder completes the hand hygiene and garbing procedure, the evaluator collects a gloved fingertip and thumb sample from both hands of the compounder onto appropriate agar plates. The plates are incubated at 30-35° for 2–3 days. All compounding personnel have successfully completed an initial competency evaluation and gloved fingertip/thumb sampling procedure (0 cfu) no less than three times before initially being allowed to compound CSPs for human use. [ENVIRONMENTAL QUALITY AND CONTROL : Gloved Fingertip Sampling] *Employee DB RPH failed one set of GFT on initial test, redone only once. Policy 9705 (1)(j) indicates to repeat for the number of failed GFT's observed, NOT three times.*	All compounding staff will repeat all three initial gloved fingertip tests if a growth occurs on any of the gloved fingertip samples. **ACT N:** Pharmacist DB repeated all three initial gloved fingertip tests and passed. An addendum was added to policy 9705 to be compliant to Florida State Board of Pharmacy. A copy of DB's repeated gloved fingertip tests and policy addendum are included as evidence of compliance.	5/20/19	DOP	DOP or trained designee will ensure that all new compounding staff repeats all 3 initial gloved fingertip tests if there is growth on any of the test samples.	

Date: 5/10/19

Pharmacy Staff Meeting- BOP inspection review

Attendees:

Cynthia Lewis

Anthony Montalvo

Leslie Nazario

Tony Ottley

Jennifer Palmer

Rangelo Soriano

Gsa-Gsa Talamas

Mary Jo Giles

Natalia Holguin

Iris Henry

BOP Inspection Minutes-May 10th 2019 staff meeting.

1. #37 No BUD- Vancomycin found in fridge diluted with no information. There will be no punctured preservative free vials in refrigerator.

2. #37 Several bags of NACL and Dextrose 5% found in ABX hood without time and date of entry. All hanging bags in the PEC must have time date of entry and discarded after 6 hours.

3. #51 MTA **smoke study** should be conducted under dynamic conditions with tube roller and repeater pump running. DOP or designee will be present during MTA certification testing to ensure compliance.

4. #67 During MTA certification, all equipment (i.e., tube rollers, repeater pumps, and PN compounders) will be running to create dynamic conditions while the **particle counts** test is being conducted.

5. #72 Trending of air sampling on MTA reports. DOP or trained designee will ensure that all monthly surface and quarterly air logs are completed and uploaded into the O: drive.

6. #73 Monthly surface sampling incubation- policy states dual incubation period for plates. DOP or trained designee will ensure that monthly surface samples are incubated under two different sets of temperature and that log form 9701.F3 is thoroughly completed.

7. #80 Review of Aseptic Technique. Compounding staff must never remove sterile drug component from ISO 5 air into a dirtier quality of air and return back to ISO 5 area without properly disinfecting with sterile alcohol.

A. When entering and reentering PEC- compounding staff must wipe down supplies and IPA hands.

B. Vial septum(s) must be wiped with sIPA inside of hood.

C. #82 Compounding staff must not spray sterile IPA inside of hood. All drug entry septum must be wiped down with sterile alcohol prior to compounding.

D. Keep excess material in hood to minimum: syringes, locks

7. Monthly cleaning- put in specific date 5/1/19 when documenting monthly cleaning on monthly sanitation and maintenance log.

8. #96 Re- do media fill due to particle in bag- employees GT,WG,RS. All compounding staff must be revalidated if any particulate matter is found in the media fill tests.

9. #98 Cleaning assessment- redo employee GT. All compounding staff who perform cleaning activities in the SPC must demonstrate proficiency for the task, this includes daily and monthly clean of the SPC.

10. #99 Glove assessment. Re-do employee DB. New employee must repeat all three fingertips if failure occurs. Reference policy #9705. All compounding staff will repeat all three initial gloved fingertip tests if a growth occurs on any of the gloved fingertip samples.

12. Employees are not to sit on carpet during breaks. Explained importance to keeping scrubs clean at all times.

Policies and Procedures

SUBJECT:	Single Dose / Multiple Dose Drug Vials or Ampules, Overwrapped Containers	REFERENCE #:	7065
DEPARTMENT	Clinical Operations	EFFECTIVE DATE:	05/01/2015
APPROVED BY:	VP Pharmacy Operations		
ANNUAL REVIEW DATE:	10/01/2019	APPROVAL DATE:	05/01/2019

SCOPE

This policy and procedure applies to pharmacies or other entities under the ownership or control of BriovaRx Infusion Services, Inc. (the Company).

PURPOSE

To establish a uniform policy on shelf life and handling of all multiple dose vials, single dose medications or unit dose ampules, and overwrapped solution containers used for patient care.

DEFINITIONS/REFERENCES/REQUIREMENTS

Single dose drug products contain no preservatives. Single dose drug products may contain more than one dose.

Multiple dose drug products are preserved to help retard the growth of bacteria that may be inadvertently introduced with the penetration of the stopper by the needle. Multiple dose vials contain more than one dose.

Overwrapped solutions are those solutions or premixed medications that are packaged in plastic or foil to prevent loss of solution as part of the evaporation process. Examples include overwrapped packages of 24, 100ml 0.9% NaCl manufactured by Baxter, 1000ml containers of hydration, milrinone, Cipro, etc.

POLICY

Single dose containers are preferred over multiple dose containers. If this is not possible, the smallest multiple dose container available should be used.

PROCEDURE

1. Single Dose Drug Vials or Ampules

    a. Single dose (i.e. unit dose) glass ampules/syringes are specifically designed for single dose only. Any unused portions of medications must be discarded immediately.

b. Opened single dose drug vials used in the preparation of parenteral nutrition (i.e. vials of electrolytes, trace elements) will remain in the ISO class 5 area, be labeled with the time and date of initial entry and disposed after six (6) hours of the initial entry or sooner per manufacturer guidelines.

c. Bulk containers used in the preparation of parenteral nutrition or reconstitution of medication (i.e. those solutions that are set up on an automated compounding device (ACD)) will remain in the ISO class 5 area, be labeled with the time and date or initial entry and be disposed of after six (6) hours of the initial entry or per manufacturer guidelines if more stringent.

d. Single dose drug vials used in the preparation of antibiotics, if not completely used, will be discarded.

   1) To avoid wastage, vials should be selected which meet the total amount required. For example, if compounding a 14 gram total dose of vancomycin, 2 x 5gm and 4 x 1gm should be selected.

e. A sterile syringe and needle or needleless device must be used to withdraw the required amount of medication from single dose vials.

f. For withdrawing medication from single dose glass ampule, use a 5 micron filter needle. The filter needle will prevent minute particles of glass from entering the syringe. Prior to administering the medication to the patient, the filter needle must be replaced with a regular sterile needle for parenteral injection or a needleless adapter.

2. Multiple Dose Drug Vials

a. Ideally, BULK antibiotic vials should only be used on one patient; they cannot be shared across multiple patients due to potential billing or reimbursement issues. Picking exact doses is important as shown below:

   1) To avoid wastage, vials should be selected which meet the total amount required. For example, if compounding a 14 gram total dose of ceftriaxone, 1 x 10gm and 4 x 1gm or 2 x 2gm should be selected.

b. Aseptic technique is always used. Wipe the top of the vial access port with sterile 70% isopropyl alcohol and allow it to dry for at least 10 seconds prior to withdrawing the fluid.

c. Visual inspection of the vial should be accomplished each time medication is withdrawn to determine that the stopper is intact and that no unusual particulate matter is in the vial. Check the vial for turbidity, discoloration, and integrity of rubber stopper seal.

d. A sterile unused vial adapter may be used for each bottle.

e. Avoid opening more than one multiple dose vial of the same medication at the same time.

f. Refrigeration of opened multiple dose vials is product specific (i.e., insulin, heparin, etc., will be refrigerated). Routine refrigeration of opened multiple dose vials is not recommended. Read the label.

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g. Multiple dose vials will be discarded when they are empty or when the manufacturer's expiration date is reached, whichever comes first.

   1) If the manufacturer does not provide guidelines as to when to discard a partially used multiple dose vial, the date used will be 28 days in the future from which the vial is first entered.

h. Multiple doses vials will have the date at which it should be discarded on the label with indelible ink.

3. Overwrapped solutions

   a. Overwrapped solutions that have had the overwrap opened will be discarded based on the manufacturer's recommendations. For example Baxter recommends that their 50ml overwrapped minibags be not used past 15 days once the overwrap is opened.

   b. Any remaining solutions in an open overwrap will be labeled or marked with a "Do not use beyond_____(write in date)".

   c. Beyond use dating on the overwrapped solution is to be taken into consideration when preparing a CSP utilizing the solution.

      Example: A 100ml Baxter Minibag Plus (MB+) overwrap is opened on 05/01/18. It is good for 30 days, so the "Do not use beyond" date would be 05/31/18.

      1) If the MB+ bags are used immediately for compounding, the BUD for the finished CSP is 05/31/18.

      2) If the opened MB+ bags are utilized at a later date for compounding, they will still expire 05/31/18, i.e. used to prepare a CSP on the 15th, the BUD on the finished CSP is still 05/31/18.

CURRENT REVISION DATE	05/01/2019

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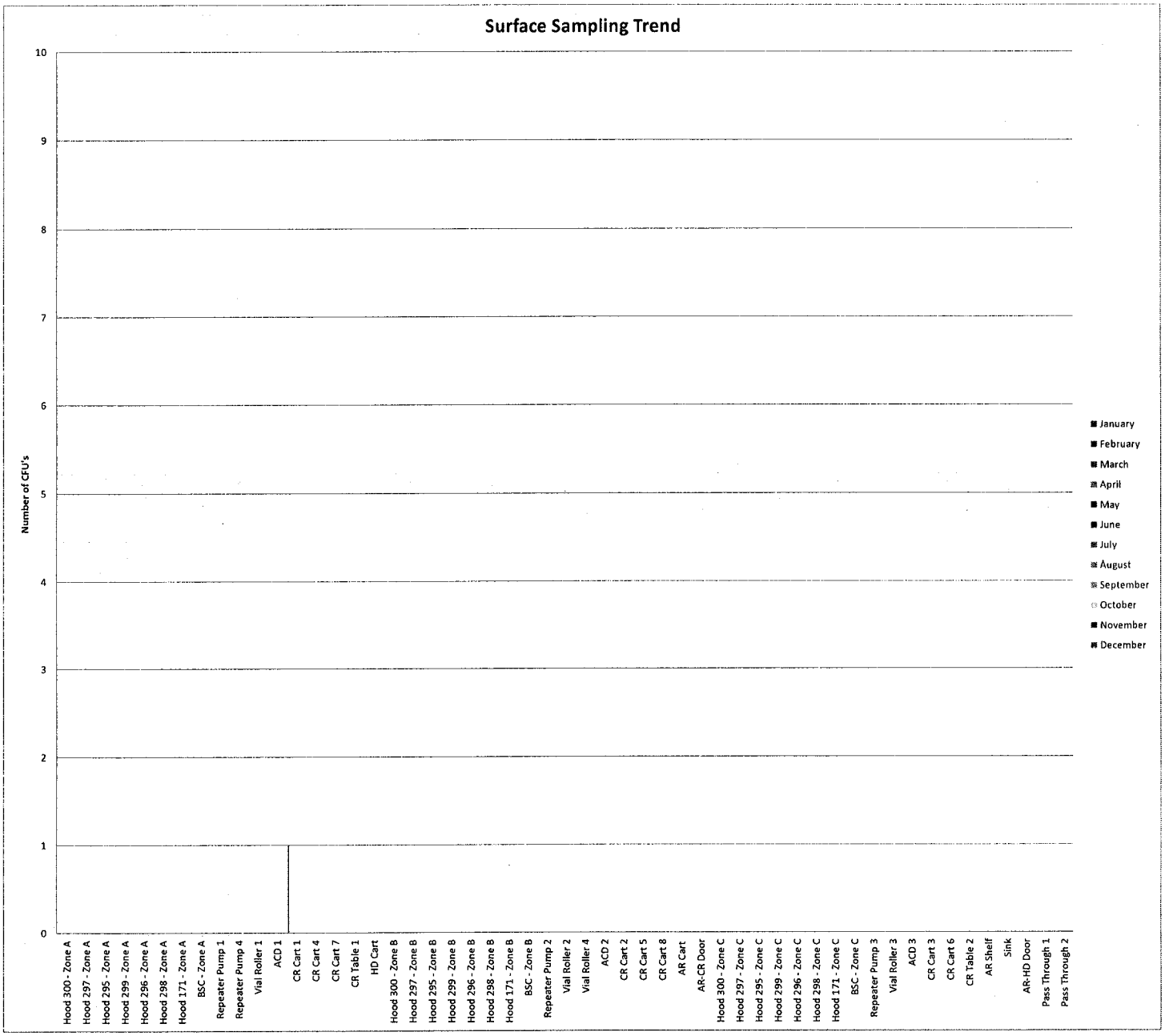
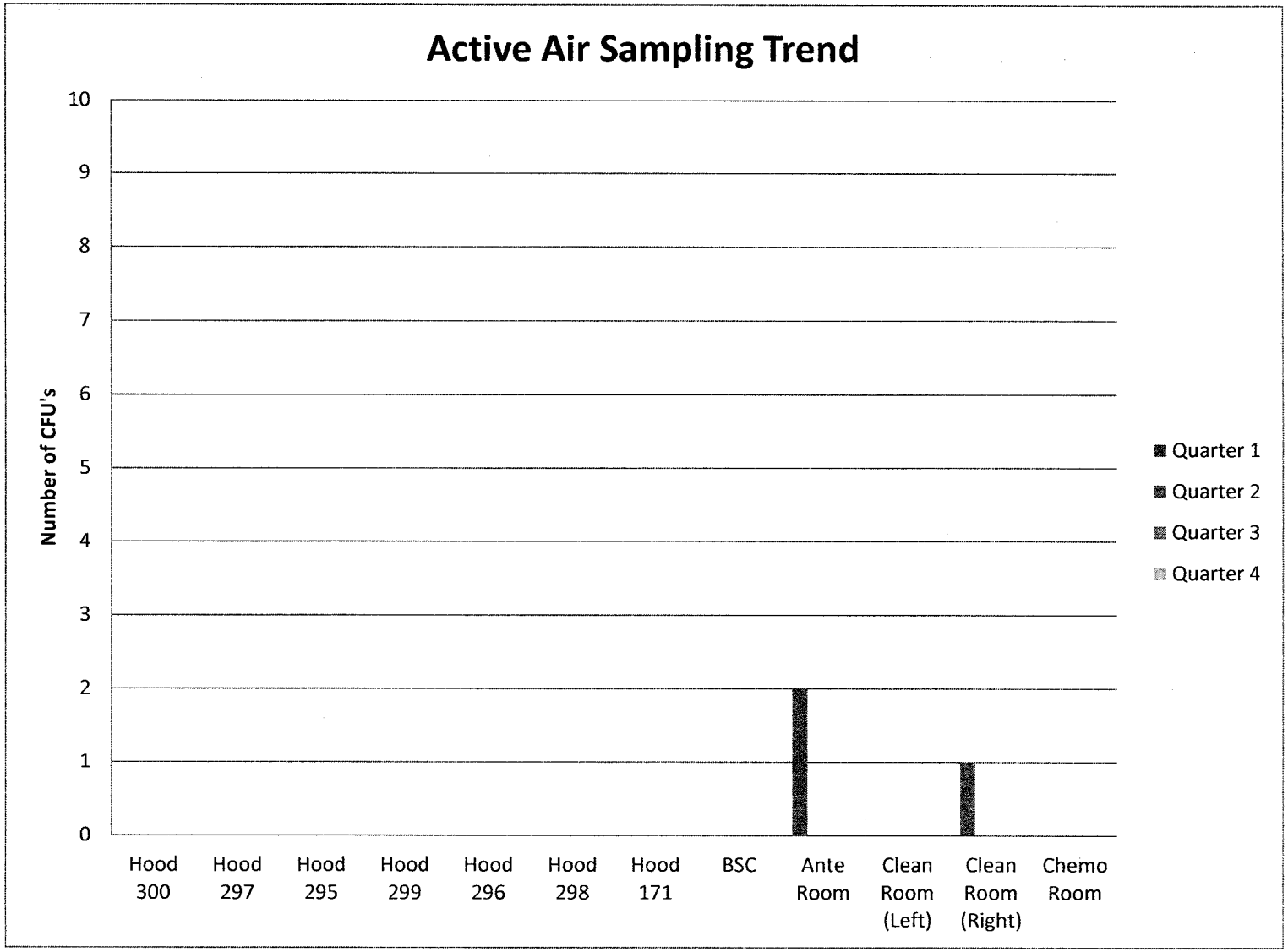
Branch: Miramar Year: 2019

Surface Sampling Data

	Quarter 1			Quarter 2			Quarter 3			Quarter 4		
	January	February	March	April	May	June	July	August	September	October	November	December
Hood 300 - Zone A	0			0								
Hood 297 - Zone A	0			0								
Hood 295 - Zone A	0			0								
Hood 299 - Zone A	0			0								
Hood 296 - Zone A	0			0								
Hood 298 - Zone A	0			0								
Hood 171 - Zone A	0			0								
BSC - Zone A	0			0								
Repeater Pump 1	0			0								
Repeater Pump 4	0			0								
Vial Roller 1	0			0								
ACD 1	0			0								
CR Cart 1	1			0								
CR Cart 4	0			0								
CR Cart 7	0			0								
CR Table 1	0			0								
HD Cart	0			0								
Hood 300 - Zone B		0			0							
Hood 297 - Zone B		0			0							
Hood 295 - Zone B		0			0							
Hood 299 - Zone B		0			0							
Hood 296 - Zone B		0			0							
Hood 298 - Zone B		0			0							
Hood 171 - Zone B		0			0							
BSC - Zone B		0			0							
Repeater Pump 2		0			0							
Vial Roller 2		0			0							
Vial Roller 4		0			0							
ACD 2		0			0							
CR Cart 2		0			0							
CR Cart 5		0			0							
CR Cart 8		0			0							
AR Cart		0			0							
AR-CR Door		0			0							
Hood 300 - Zone C			0									
Hood 297 - Zone C			0									
Hood 295 - Zone C			0									
Hood 299 - Zone C			0									
Hood 296 - Zone C			0									
Hood 298 - Zone C			0									
Hood 171 - Zone C			0									
BSC - Zone C			0									
Repeater Pump 3			0									
Vial Roller 3			0									
ACD 3			0									
CR Cart 3			0									
CR Cart 6			0									
CR Table 2			0									
AR Shelf			0									
Sink			0									
AR-HD Door			0									
Pass Through 1	0	0	0									
Pass Through 2	0	0	0									
Positive Growth	non pathogenic Staphlococcus hominis novobiosepticus 1/23-CR-cart1 retested- 0 cfu											

Instruction: Fill in the grid with the total # CFU's from sampling results (i.e., 0, 1, 2, etc.)
Sampling rotation is color coded by month. The areas in black are to be sampled MONTHLY.
Enter positive growth description on the last row, if applicable


Surface Sampling Trend
Number of CFU's
0
1
2
3
4
5
6
7
8
9
10
Hood 300 - Zone A
Hood 297 - Zone A
Hood 295 - Zone A
Hood 299 - Zone A
Hood 296 - Zone A
Hood 298 - Zone A
Hood 171 - Zone A
BSC - Zone A
Repeater Pump 1
Repeater Pump 4
Vial Roller 1
ACD 1
CR Cart 1
CR Cart 4
CR Cart 7
CR Table 1
HD Cart
Hood 300 - Zone B
Hood 297 - Zone B
Hood 295 - Zone B
Hood 299 - Zone B
Hood 296 - Zone B
Hood 298 - Zone B
Hood 171 - Zone B
BSC - Zone B
Repeater Pump 2
Vial Roller 2
Vial Roller 4
ACD 2
CR Cart 2
CR Cart 5
CR Cart 8
AR Cart
AR-CR Door
Hood 300 - Zone C
Hood 297 - Zone C
Hood 295 - Zone C
Hood 299 - Zone C
Hood 296 - Zone C
Hood 298 - Zone C
Hood 171 - Zone C
BSC - Zone C
Repeater Pump 3
Vial Roller 3
ACD 3
CR Cart 3
CR Cart 6
CR Table 2
AR Shelf
Sink
AR-HD Door
Pass Through 1
Pass Through 2
January
February
March
April
May
June
July
August
September
October
November
December


Active Air Sampling Trend
Number of CFU's
10
9
8
7
6
5
4
3
2
1
0
Hood 300
Hood 297
Hood 295
Hood 299
Hood 296
Hood 298
Hood 171
BSC
Ante Room
Clean Room (Left)
Clean Room (Right)
Chemo Room
Quarter 1
Quarter 2
Quarter 3
Quarter 4

Branch: **Miramar** Year: **2019**

Active Air Sampling Data

	Quarter 1	Quarter 2	Quarter 3	Quarter 4
Hood 300	0	0		
Hood 297	0	0		
Hood 295	0	0		
Hood 299	0	0		
Hood 296	0	0		
Hood 298	0	0		
Hood 171	0	0		
BSC	0	0		
Ante Room	2	0		
Clean Room (Left)	0	0		
Clean Room (Right)	1	0		
Chemo Room	0	0		
Positive Growth	Anteroom- 2 micrococcus,CRright-1staphlococcus Coagulase			

Instruction: Fill in the grid with the total # CFU's from sampling results (i.e., 0, 1, 2, etc.)
All ISO classified areas are to be sampled QUARTERLY.
Enter positive growth description on the last row, if applicable

(1)

Monthly Surface Sample testing log

Month May Year 2019

Sampling Tester Name: Leslie Nazario

Branch: Miramar

Nutrient Agar: TSA Plate

Incubator serial #: 0817253 Incubator 1 (days 1-2)
1217427 Incubator 2 (days 3-7)

Zone B

Media		Zone B Surface Sample locations (*i.e., Hood 1 Zone A*)					
	Date:	5/22/19					
	Lot	190220/190501D	1 Hood 300	2 Hood 297	3 Hood 295		
	Exp	6/12/19 / 11/1/19	4 Hood 299	5 Hood 296	6 Hood 298		
	Lot (opt)	See above	7 Hood 171	8 BSC	9 RP-2		
	Exp	See above	10 VR-2	11 VR-4	12 ACD2		
	Time:	10:35 Am.	13 CR-Cart 2	14 CR-Cart 5	15 CR-Cart 8		

0= no growth, 1 = 1 CFU, 2 = 2 CFU etc.; ND = no data - office closed

	Day	Range °C	Temp	Sample 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	Control
5/23	1	**30-35**	34°C	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
5/24	2	**30-35**	30°C	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
5/25	3	20-25	22°C	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
5/26	4	20-25	22°C	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
5/27	5	20-25	22°C	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
5/28	6	20-25	22°C	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
5/29	7	20-25	21°C	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	Total # CFUs:			0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Incubate each test under two temperature ranges for both bacterial and fungal growth. See PP 9701 for details

Results acceptable (YES) [NO] CIRCLE ONE If NO, remediation plan required. See PP 9701F6

Signature of Sampling tester: Leslie Nazario

(RPh) [Technician] Circle One

Signature of reviewer (PM/PIC or designee): [signature]

Date Reviewed: 5/29/19

Title of reviewer: Pharmacist

Complete all appropriate lines and if not applicable, write "N/A"

(2)

Monthly Surface Sample testing log

Month May Year 2019

Sampling Tester Name: Leslie Nazario

Branch: Miramar.

Nutrient Agar: TSA Plate

Incubator serial #: 081 71253 / Incubator 1
121 71427 / Incubator 2
(days 3-7)

Zone B Surface Sample locations (*i.e., Hood 1 Zone A*)

Media								
Date:	5/22/19							
Lot	1902120/1905018	1	AR-Cart	2	AR-CR Door	3	Pass-thru 1	
Exp	6/12/19 / 11/1/19	4	Pass-Thru 2	5		6		
Lot (opt)	See above	7		8		9		
Exp	See above	10		11		12		
Time:	10:40 Am	13		14		15		

0= no growth, 1 = 1 CFU, 2 = 2 CFU etc.; ND = no data - office closed

Day	Range °C	Temp	Sample 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	Control
1	**30-35**	34°C	Ø	Ø	Ø	Ø												
2	**30-35**	30°C	Ø	Ø	Ø	Ø												
3	20-25	22°C	Ø	Ø	Ø	Ø												
4	20-25	22°C	Ø	Ø	Ø	Ø												
5	20-25	22°C	Ø	Ø	Ø	Ø												
6	20-25	22°C	Ø	Ø	Ø	Ø												
7	20-25	21°C	Ø	Ø	Ø	Ø												
Total # CFUs:			Ø	Ø	Ø	Ø												

Incubate each test under two temperature ranges for both bacterial and fungal growth. See PP 9701 for details

Results acceptable [YES] [NO] CIRCLE ONE If NO, remediation plan required. See PP 9701F6

Signature of Sampling tester: Leslie Nazario

[RPh] [Technician] Circle One

Signature of reviewer (PM/PIC or designee): [illegible]

Date Reviewed: 5/29/19

Title of reviewer: Pharmacist

Complete all appropriate lines and if not applicable, write "N/A"

Assessment of Aseptic Technique and Related Practices

Miramar
Branch

Gsa-Gsa Talamas
Employee Name

5/28/19
Date

PROCEDURE	SCORE YES	SCORE NO	COMMENTS AND RECOMMENDATIONS
Performs proper hand hygiene, garbing and gowning according to PP	✓		
Disinfects ISO Class 5 PEC surfaces with an appropriate agent	✓		
Disinfects components/vials with an appropriate agent prior to placing into ISO Class 5 work area	✓		
Introduces only essential materials in a proper arrangement in the ISO Class 5 work area	✓		
Does not interrupt, impede or divert flow of first-air to critical sites	✓		
Performs manipulations only in the appropriate direct compounding area of the ISO Class 5 work area	✓		
Does not expose critical sites to contact contamination or worse than ISO Class 5 air	✓		
Disinfects stoppers, injection ports and ampule necks by wiping with sterile 70% IPA and allows sufficient time to dry	✓		
Affixes needles to syringe without contact contamination	✓		
Punctures vial stoppers and spikes infusion ports without contact contamination	✓		
Disinfects sterile gloves routinely by wiping with sterile 70% IPA during prolonged compounding manipulations or after touching items or surfaces that may contaminate gloves	✓		
Disinfects sterile gloves with sterile 70% IPA when leaving the ISO 5 area and prior to re-entering the ISO 5 area	✓		
Cleans, sets up and calibrates automated compounding devices (e.g. TPN compounder, syringe filling pump) according to manufacturer's instructions	✓		
Filters used per policy and when appropriate (e.g. glass ampules)	✓		
Every completed admixture inspected for thorough mix of contents, presence of particulate matter, evidence of incompatibility, container closure integrity	✓		
Compounding accuracy checks performed per policy when technicians compounding, including use of compounding device(s)	✓		
Completion of compounding sheets per policy by pharmacists and technicians (lot numbers {verified}, signatures, dates, times, drug wastage)	✓		
Disposes of sharps and waste according to policy or recognized guidelines	✓		

100% compliance required

Signature of Compounder — RPh/(Tech) — 5/28/19 Date

Signature of Reviewer (PIC or designee) — (RPh)/Tech — 5/28/19 Date

briovaRx

Process Simulation Testing (PST) Log

Branch: Miramar

Employee name: Rangelo Soriano

Date test initiated: 5/8/19

Commercial kit used: Valiteq RC-2

LOT/EXP: 010918103 Aug 2020

Device used for simulation: Pinnacle

Incubator SN: 1217-1427

DAY	DATE	Incubator temperature	Daily Observation Growth = (+) No Growth = (-)	Initials	Comments
1	5/9/19	22°C	(-)	[illegible]	
2	5/10/19	22°C	(-)	[illegible]	
3	5/11/19	24°C	(-)	[illegible]	Sat
4	5/12/19	25°C	(-)	[illegible]	Sun
5	5/13/19	25°C	(-)	[illegible]	
6	5/14/19	25°C	(-)	[illegible]	
7	5/15/19	22°C	(-)	[illegible]	
8	5/16/19	22°C	(-)	[illegible]	
9	5/17/19	22°C	(-)	[illegible]	
10	5/18/19				Sat
11	5/19/19				Sun
12	5/20/19	22°C	(-)	[illegible]	
13	5/21/19	22°C	(-)	[illegible]	
14	5/22/19	22°C	(-)	[illegible]	

Note: 1 PST required for initial, annual / semi-annual competency. PSTs observed for 14 days at manufacturer's recommended temperature.
See policy 9710

PASS

FAIL

If fail - repeat test; 2nd fail - Retrain & Document; 2nd fail must pass prior to resuming compounding.

Initial PST process must pass prior to compounding

Signature of Compounder

RPh/Tech

5/22/19
Date

Signature of Reviewer (PIC or designee)

RPh/Tech

5/22/19
Date

briovaRx

Process Simulation Testing (PST) Log

Branch: Miramar

Employee name: Waldi Guillaume

Date test initiated: 5/13/19

Commercial kit used: Valiteq RL-2

LOT/EXP: D109151802 Aug 2020

Device used for simulation: Pinnacle

Incubator SN: #12171427

DAY	DATE	Incubator temperature	Daily Observation Growth = (+) No Growth = (-)	Initials	Comments
1	5/14/19	22°c	(-)		
2	5/15/19	22°c	(-)		
3	5/16/19	22°c	(-)		
4	5/17/19	22°c	(-)		
5	5/18/19				Sat
6	5/19/19				Sun
7	5/20/19	22°c	(-)		
8	5/21/19	22°c	(-)		
9	5/22/19	22°c	(-)		
10	5/23/19	22°c	(-)		
11	5/24/19	22°c	(-)		
12	5/25/19	22°C	(-)		Sat
13	5/26/19	22°C	(-)		Sun.
14	5/27/19	22°C	(-)		

Note: 1 PST required for initial, annual / semi-annual competency. PSTs observed for 14 days at manufacturer's recommended temperature.

See policy 9710

PASS

FAIL

If fail - repeat test; 2nd fail - Retrain & Document; 2nd fail must pass prior to resuming compounding.

Initial PST process must pass prior to compounding

Signature of Compounder

RPh/Tech

5/28/19
Date

Signature of Reviewer (PIC or designee)

RPh/Tech

5/28/19
Date

briovaRx

Process Simulation Testing (PST) Log

Branch: Miramar

Employee name: Gsa-Gsa Talamas

Date test initiated: 5/8/19

Commercial kit used: Valiteq RL-2

LOT/EXP: 010918103 Aug 2020

Device used for simulation: Pinnacle

Incubator SN: 12171427

DAY	DATE	Incubator temperature	Daily Observation Growth = (+) No Growth = (-)	Initials	Comments
1	5/9/19	22°c	(-)	[illegible]	
2	5/10/19	22°C	(-)	[illegible]	
3	5/11/19	24°C	(-)	[illegible]	Sat
4	5/12/19	25°C	(-)	[illegible]	Sun.
5	5/13/19	25°c	(-)	[illegible]	
6	5/14/19	25°c	(-)	[illegible]	
7	5/15/19	22°c	(-)	[illegible]	
8	5/16/19	22°c	(-)	[illegible]	
9	5/17/19	22°c	(-)	[illegible]	
10	5/18/19				Sat
11	5/19/19				Sun.
12	5/20/19	22°c	(-)	[illegible]	
13	5/21/19	22°c	(-)	[illegible]	
14	5/22/19	22°c	(-)	[illegible]	

Note: 1 PST required for initial, annual / semi-annual competency. PSTs observed for 14 days at manufacturer's recommended temperature.
See policy 9710

PASS [illegible]

FAIL

If fail - repeat test; 2nd fail - Retrain & Document; 2nd fail must pass prior to resuming compounding.

Initial PST process must pass prior to compounding

Signature of Compounder [illegible] RPh/Tech

Date 5-22-19

Signature of Reviewer (PIC or designee) [illegible] RPh/Tech

Date 5/22/19

Assessment of Cleaning and Disinfection Practices

Gsa- Gsa Talamas
Employee Name

Miramar
Branch

PROCEDURE	SCORE YES	SCORE NO	COMMENTS AND RECOMMENDATIONS
Daily Tasks:			
Prepares correct concentration of disinfectant solution according to manufacturer's instructions – Use RTU solution when available	✓		
Uses appropriately labeled container for the type of surface to be cleaned (floor, wall, production bins, etc.)	✓		
Documents disinfectant solution	✓		
Follows proper garbing procedure when performing any cleaning activities	✓		
At the beginning of the day, cleans all ISO Class 5 PEC's prior to compounding in the following order: side surfaces, IV bar, automated compounder, work surfaces	✓		
Uses a lint free wipe soaked in sterile 70% IPA or other approved disinfectant solution and allows to dry completely	✓		
Removes compounder components that may have been left from the previous day	✓		
Discards all partially used vials and containers that may have been left from the previous day	✓		
Cleans all counters and easily cleanable work surfaces	✓		
Mops floors, using the dedicated clean room mop, starting at the wall opposite the room entry door; mops floor surface in even strokes toward the operator. Moves carts as needed to clean entire floor surface. Use of a microfiber cleaning system is an acceptable alternative to mops	✓		
In the ante area, cleans sink and all contact surfaces; cleans floor with a disinfection solution and clean room dedicated mop or microfiber cleaning system	✓		
Monthly Tasks:			
Performs monthly (weekly) cleaning on designated day. Prepares disinfectant solution as stated in daily tasks that is appropriate for the surfaces to be cleaned	✓		
Cleans buffer area ceiling, walls and storage shelving with a disinfectant solution and a mop or uses a microfiber cleaning system then repeats process in ante area	✓		
Once ISO Class 5 area is clean, cleans compounding room ceiling, followed by walls and ending with the floor. Uses appropriate labeled mops or microfiber cleaning system	✓		
Cleans all buffer area totes and storage shelves by; removing contents, use of germicidal detergent on lint free wipe. Cleans inside surfaces and then entire exterior surface of tote. Allows to air dry. Prior to replacing contents, wipes tote with sterile 70% IPA to remove disinfectant residue. Uses new wipes as needed.	✓		
Cleans buffer area chairs, the interior and exterior of trash bins, and storage bins using disinfectant solution soaked lint free wipe	✓		
Documents all cleaning activities as to who performed such activities with date and time noted	✓		
Totals	100%		Score =

(total # of yes responses ÷ 17)

A score of 100% indicates the employee is in compliance and competent to perform above listed duties.
Employees scoring less than 100% are to be retrained and retested/observed for compliance.

Signature of Compounder — RPh/Tech — Date: 5-09-19

Signature of Reviewer (PIC or designee) — RPh/Tech — Date: 5/9/19

Form 9710F4

REV: 12/2018

Gloved Fingertip Sampling (GFS) Competency Log

Employee Name: Debra Botta
Nutrient Agar: TSA Plate (recommended)

Branch: Miramar
Incubator serial #: 12171399
Incubator #3

GFS Type: Initial (New Employee)

Re-test

	GFS 1	GFS 2	GFS 3	GFS 4
	Post-gloving	After media fill	Post-gloving	Post-gloving
Date:	5/20/19		5/20/19	5/20/19
Lot(s)	1902120		1902120	1902120
Exp	6/12/19		6/12/19	6/12/19
Time:	10:21 Am		10:26 Am	10:31 Am

0= no growth, 1 = 1 CFU, 2 = 2 CFU etc.

Day	Range F	Range C	LH	RH	Date	Temp	LH	RH	Date	Temp	LH	RH	Date	Temp	LH	RH	Date	Temp
1	86-95	30-35	0	0	5/21	32°C			5/21	32°C	0	0	5/21	32°C	0	0	5/21	32°C
2	86-95	30-35	0	0	5/22	32°C			5/22	32°C	0	0	5/22	32°C	0	0	5/22	32°C
3	86-95	30-35	0	0	5/23	32°C			5/23	32°C	0	0	5/23	32°C	0	0	5/23	32°C
4																		
5																		
6																		
7																		
		# CFUs:	0	0		# CFUs:	0			# CFUs:	0	0		# CFUs:	0	0		

NOTE: The initial competency requires 4 GFS: 3 after garbing and gloving and 1 immediately after media-fill test. Indicate date and time of each. Incubate each test per manufacturer's guidelines. See PP 9705

[PASS] [FAIL] CIRCLE ONE

Total CFUs: 0 Post hand washing, gowning and garbing must have 0 CFU. Post media fill must have ≤ 3 CFU combined for both hands.
Fail: re-educate and re-test

Signature of Compounder: Debra A. Botta

[RPh] [Technician] Circle One

Signature of reviewer (PM/PIC or designee): Mazari

Date Reviewed: 5/23/19

Title of reviewer: Pharmacist

Complete all appropriate lines and if not applicable, write "N/A"

Policies and Procedures

SUBJECT:	Certification of Aseptic Technique - Gloved Fingertip Sampling	REFERENCE #:	9705
DEPARTMENT	Pharmacy Operations	EFFECTIVE DATE:	10/01/2014
APPROVED BY:	VP of Pharmacy		
ANNUAL REVIEW DATE:	05/30/2020	APPROVAL DATE:	05/20/2019

SCOPE

This policy and procedure applies to pharmacies or other entities under the ownership or control of BriovaRx Infusion Services, Inc. (the Company).

PURPOSE

To reduce the risk of touch contamination during sterile compounding by periodically testing and validating compounding personnel competency in the proper technique for hand hygiene and sterile gloving.

POLICY

1. Gloved fingertip sampling shall be used to evaluate the competency of personnel in performing hand hygiene and garbing procedures in addition to educating sterile compounding personnel on proper work practices.

2. New employees will be required to successfully complete three separate hand hygiene, gowning and sterile gloving competency evaluations and three (3) separate gloved fingertip tests before being allowed to compound sterile products.

3. Employees that compound low and medium risk level sterile preparations shall also perform a gloved fingertip test as part of a series with one media fill test at time of hire and annually as outlined in Company policy.

4. Employees that compound high risk level sterile preparations shall perform gloved fingertip testing as a series with media fill test, at time of hire and every 6 months as outlined in Company policy.

PROCEDURE

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Supplies:

a. Trypticase soy agar (TSA) with lecithin and polysorbate 80 agar plates

b. For High Risk compounding facilities, Malt extract agar plates should be used (supports growth of fungi.)

1. New Employee Gloved Fingertip Sampling

After appropriate hand hygiene and gowning process, the employee will enter the cleanroom, apply alcohol based hand wash with persistent activity and don sterile gloves.

a. Gloved hands are NOT to be sprayed with sterile 70% IPA.

b. Open agar plates using aseptic technique in the ISO 5 environment, one for each hand.

c. Gently roll each fingertip/thumb of one hand on the plate testing surface.

d. Repeat the same process for the opposite hand on a different agar plate.

e. Aseptically cover the agar plates and invert. Write the date (day of test) indicate if right or left hand and the testing employees initials using a permanent marker..

f. Tape the agar plate lid to the plate and place inverted (lid facing down) in the incubator. The TSA with lecithin and polysorbate 80 plates are to be incubated at 30-35^{0}C for 48-72 hours.

g. Discard all gloves, gowns, garb and repeat the complete series of hand hygiene, gowning and gloving prior to next tests.

h. An employee must complete and successfully pass three (3) GFT samplings of both hands during initial testing and prior to being allowed to perform any sterile compounding.

i. Sterile compounding employees must successfully complete one (1) GFT test of both hands annually to continue sterile compounding.

j. The colony forming unit (CFU) count for all GFT tests must be zero in order to pass.

- Should growth occur on any of the gloved fingertip samples the test will need to be repeated for the number of failed GFT test(s) observed. Employees will not be allowed to sterile compound until they successfully pass (zero CFU count)all required GFT tests for appropriate testing period, i.e., three (3) for initial testing or one (1) for annual testing.

2. Initial and Annual Gloved Fingertip sampling as part of the aseptic media fill testing series. This GFT test is to sample both hands **immediately** after completing the media fill test.

a. Complete aseptic media fill test per policy 9710. DO NOT spray gloves with sterile 70% IPA.

b. Open agar plates using aseptic technique in the ISO 5 environment, one for each hand.

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c. Gently roll each fingertip of one hand including the placement of the thumb on the plate testing surface.

d. Repeat the same process for opposite hand on a different agar plate.

e. Aseptically cover the agar plates. Invert the plate, write the testing date (day of test), right or left hand and testing employee's initials using a permanent marker.

f. Tape the agar plate lid to the plate and place inverted (lid facing down) in the incubator.

g. Discard sampled gloves, remove garb, and complete proper hand hygiene.

h. TSA with lecithin and polysorbate 80 are to be incubated at 30-35°C for 48-72 hours.

i. The GFT after media fill CFUcount must be less than or equal to three to pass.

3. The Pharmacy Director/PIC or designee will observe the agar plates daily for 3 days and record all appropriate information (date, incubator temperature, observations for growth) on the GFT testing log (9710F6).

   a. Positive results (visible CFUs) and exceeding the allowable number of units (3) must be reported to the Pharmacy Director/PIC immediately.

   b. The employee with a failing score is to be re-trained and re-tested immediately.

   c. If this is an initial post media fill GFT test, the employee will not be allowed to compound until they successfully pass.

   d. If this is an annual test, the employee may continue to compound but must complete the GFT re-test immediately. A subsequent failing score will require the employee to review appropriate aseptic polices, be re-validated on donning of sterile gloves and aseptic process. They will not be allowed to compound sterile products until they have successfully been observed for and complete appropriate hand hygiene, gowning/gloving procedures aseptic technique media fill tests with successful post media fill GFT testing.

4. Revalidation testing will occur annually as outlined above or more often as determined by the Pharmacy Director/PIC.

RECORDS

Employee competency records

FORMS

9710F6 Gloved Fingertip Log

CURRENT REVISION DATE	05/20/2019

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All compounding personnel will successfully complete an initial competency evaluation and glove finger tip sampling procedure no less than three times with 0 CFU before being allowed to compound sterile products (CSPs.)

If any of the initial 3 fingertip tests result in >0 CFU, the employee is to repeat all 3 fingertip tests. The employee will not compound CSPs until all 3 repeated tests are successfully passed with 0 CFU.

STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES
INV797-Sterile Compounding

File # 21072
Insp # 159892

NAME	PERMIT NUMBER	DATE OF INSPECTION
BriovaRx Infusion Services 203, Inc.	27913	05/07/2019
DOING BUSINESS AS BRIOVARX INFUSION SERVICES 203, INC.		
STREET ADDRESS 9984 PREMIER PARKWAY	**TELEPHONE #**	**EXT**
CITY MIRAMAR	**COUNTY** BROWARD	**STATE/ZIP** FL/33025

Additional Information

Business Operation Hours

M-T-W-TH-F Y	Weekly Hours 8:30 am to 5:30
Monday N	Tuesday N
Wednesday N	Thursday N
Friday N	Saturday N
Sunday N	

Registered Pharmacist / Intern / Tech

License # PS49270	Licensee Name Shirley Elisbrun Adams
License Type Registered Pharmacists	
License # PS36287	Licensee Name Vincent Ekebu
License Type Registered Pharmacists	
License # PS52096	Licensee Name Jacqueline Rodriguez
License Type Registered Pharmacists	
License # PS21110	Licensee Name Manuela Vega-Rivera
License Type Registered Pharmacists	
License # PS46873	Licensee Name Mary Jo Giles
License Type Registered Pharmacists	
License # PS38581	Licensee Name Leslie Nazario
License Type Registered Pharmacists	
License # RPT35999	Licensee Name Anthony Quinton Ottley
License Type Pharmacy Tech	
License # RPT38111	Licensee Name Gsa Gsa Alexandria Talamas
License Type Registered Pharmacists	

ACS Manager

Optional Information

Basic License Data - PSD

DEA Reg # BA7935490	

License Relations

Pharmacy Affiliate

ADLER, IAN	License #
BRONSON, DAVID	License #
DEBLASI, PAIGE	License #
FRENI, LAWRENCE	License #

KLEINMAN, IRA	License #
KRAMM, EDWARD P	License #
KRAMM, KATHEE M	License #
WILKINS, JOHN	License #
YORK, CHRISTOPHER	License #

RX DPT MGR/COR/POR

GILES, MARY JO B	License # 46873

Special Sterile Compounding

BRIOVARX INFUSION SERVICES 203, INC.	License # 18740

INV797 - Sterile Compounding

LOW RISK

1. Low risk CSP's are properly identified: Aseptic manipulations within an ISO Class 5 environment using three or fewer sterile products and no more than two entries into any container. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Low-Risk Level CSPs]	Yes
2. Low Risk CSP's, in absence of passing sterility test, stored not more than 48 hours at controlled room temperature, 14 days at cold temperature, or 45 days in solid frozen state at -25° to -10° or colder. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Low-Risk Level CSPs]	Yes
3. Low Risk CSP's with 12 hour BUD are properly identified and comply with all four specific criteria. 1. PEC in Segregated Compounding area 2. Away from windows, doors , high traffic areas 3. Hygiene & garbing required, sinks not adjacent to PEC. 4. Cleaning & Disinfecting, Personnel training, Competency evaluation, Garbing, Aseptic work practices, Viable and non-viable environmental sampling apply. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Low-Risk Level CSPs]	N/A

MEDIUM RISK

4. Medium Risk CSP's are properly identified: Aseptic manipulations within an ISO Class 5 environment using prolonged and complex mixing and transfer, more than three sterile products and entries into any container, and pooling ingredients from multiple sterile products to prepare multiple CSPs. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Medium-Risk Level CSPs]	Yes
5. Medium Risk CSP's, In absence of passing sterility test, stored not more than 30 hours at controlled room temperature, 9 days at cold temperature, or 45 days in solid frozen state at -25° to -10° or colder. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Medium-Risk Level CSPs]	Yes

HIGH RISK

6. Presterilization procedures for high-risk level CSPs, such as weighing and mixing, are completed in no worse than an ISO Class 8 environment. [ENVIRONMENTAL QUALITY AND CONTROL : Placement of Primary Engineering Controls Within ISO Class 7 Buffer Areas]	
7. High Risk CSP's are properly identified: Confirmed presence of nonsterile ingredients and devices, or confirmed or suspected exposure of sterile ingredients for more than one hour to air quality inferior to ISO Class 5 before final sterilization. [CSP MICROBIAL CONTAMINATION RISK LEVELS : High-Risk Level CSPs]	
8. High Risk CSP's, in absence of passing sterility test are not stored more than 24 hours at controlled room temperature, 3 days at cold temperature, or 45 days in solid frozen state at -25° to -10° or colder. [CSP MICROBIAL CONTAMINATION RISK LEVELS : High-Risk Level CSPs]	
9. A 0.2-µm certified sterilizing membrane filter is used that is chemically and physically compatible with the CSP. Filtration is completed rapidly without filter replacement. Sterilization method is verified to achieve sterility for the quantity and type of containers. [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Sterilization of High-Risk Level CSPs by Filtration]	
10. Sterilization method used has documentation that acceptable strength and purity of ingredients and integrity of containers is maintained. [CSP MICROBIAL CONTAMINATION RISK LEVELS : High-Risk Level CSPs]	
11. The manufacturer recommended filter integrity (e.g., bubble point) test is performed and documented for all sterilizing filters after filtering CSPs. [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Sterilization of High-Risk Level CSPs by Filtration]	
12. Autoclave cycle has been verified using appropriate biological indicators. Solutions are passed through a 1.2-µm or smaller filter into final containers to remove particulates before sterilization. [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Sterilization of High-Risk Level CSPs by Steam]	
13. Dry heat ovens used for sterilization have filtered forced air. Only those items that will be damaged by steam are sterilized by dry heat. [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Sterilization of High-Risk Level CSPs by Dry Heat]	
14. The description of dry heat sterilization conditions and duration for specific CSPs is included in written documentation in the compounding facility. The effectiveness of dry heat sterilization is verified using appropriate biological indicators and other confirmation. [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Sterilization of High-Risk Level CSPs by Dry Heat]	
15. Dry heat depyrogenation is used to render glassware or containers, such as vials free from pyrogens as well as viable microbes. The description of the dry heat depyrogenation cycle and duration for specific load items is included in written documentation in the compounding facility. The effectiveness of the dry heat depyrogenation cycle is verified using endotoxin challenge vials (ECVs). [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Depyrogenation by Dry Heat]	
16. Sterility testing is completed for all High-risk level CSPs prepared in batches of more than 25 identical containers, or exposed longer than 12 hours at 2° to 8°, and 6 hours at warmer than 8° before being sterilized. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Sterility Testing]	

USP <71> STERILITY TESTING (Outsourced)

17. Outsourced sterility testing results indicate that it is compliant with USP<71>. A method not described in the USP may be used if validation demonstrates that the alternative is at least as effective and reliable. [STERILITY TEST USP<71>]	
18. Outsourced: The number of articles tested are appropriate according to USP<71>. [STERILITY TEST USP<71> : Number of Articles to Be Tested]	
19. Outsourced: The volume/quantity tested is according to USP<71>. [STERILITY TEST USP<71> : Number of Articles to Be Tested]	
20. Outsourced: A USP<71> method suitability test has been done with appropriate inoculum, additives and rinses. [STERILITY TEST USP<71> : Method Suitability Test]	

21. Outsourced: Sterility testing reports are reviewed and appropriate actions taken and documented. [FINISHED PREPARATION RELEASE CHECKS AND TESTS]	

USP <71> STERILITY TESTING

22. On site: Membrane filtration is used if appropriate. (The technique of membrane filtration is used whenever the nature of the product permits; that is, for filterable aqueous preparations, for alcoholic or oily preparations, and for preparations miscible with, or soluble in, aqueous or oily solvents, provided these solvents do not have an antimicrobial effect in the conditions of the test.) Filters are rinsed according to USP<71>. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Sterility Testing]	
23. On site: Direct inoculation is done only when membrane filtration cannot be carried out. Volume to be inoculated does not exceed 10% of the culture media volume. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Sterility Testing]	
24. On site: The number of articles tested are appropriate according to USP<71>. [STERILITY TEST USP<71> : Number of Articles to Be Tested]	
25. On site: The volume/quantity tested is according to USP<71>. [STERILITY TEST USP<71> : Number of Articles to Be Tested]	
26. On site: A growth promotion test has been done on the media with the 5 specified organisms (not more than 100 CFU) according to USP<71>. [STERILITY TEST USP<71> : Growth Promotion Test of Aerobes, Anaerobes, and Fungi]	
27. On site: A USP<71> method suitability test has been done with appropriate inoculum, additives and rinses. [STERILITY TEST USP<71> : Method Suitability Test]	
28. On site: TSB or SCD is incubated at 20-25 C for 14 days (2 incubators present). [STERILITY TEST USP<71> : Culture Media and Incubation Temperatures]	
29. On site: FTM is incubated at 30-35 C for 14 days (2 incubators present). [STERILITY TEST USP<71> : Culture Media and Incubation Temperatures]	
30. On site: Sterility testing is documented including lot numbers and expiration dates of media. [FINISHED PREPARATION RELEASE CHECKS AND TESTS]	
31. On site: Sterility testing reports are reviewed and appropriate actions taken and documented. [FINISHED PREPARATION RELEASE CHECKS AND TESTS]	

ENDOTOXIN TESTING

32. Endotoxin testing is conducted for High-risk level CSP's that are prepared in batches of more than 25 identical containers, or exposed longer than 12 hours at 2° to 8°, and 6 hours at warmer than 8°, before being sterilized or in multidose containers for administration to multiple patients. (excluding those for inhalation and ophthalmic administration) [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Bacterial Endotoxin (Pyrogen) Testing]	
33. Endotoxin testing process indicates that it is compliant with USP<85>. [BACTERIAL ENDOTOXINS TEST USP<85>]	
34. High Risk CSP's are within allowable limits for bacterial endotoxins. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Bacterial Endotoxin (Pyrogen) Testing]	

IMMEDIATE USE COMPOUNDING

35. Immediate-use compounding complies with all six specified criteria. 1. Low-risk sterile nonhazardous products or diagnostic radiopharmaceutical products from the manufacturers' original containers. Anti-neoplastics shall not be prepared as immediate-use CSPs because they are hazardous drugs. 2. Unless required for the preparation, the compounding procedure is a continuous process not to exceed 1 hour. 3. During preparation, aseptic technique is followed and, if not immediately administered, the finished CSP is under continuous supervision to minimize the potential for contact with nonsterile surfaces, introduction of particulate matter or biological fluids, mix-ups with other CSPs, and direct contact of outside surfaces. 4. Administration begins not later than 1 hour following the start of the preparation of the CSP. 5. Unless immediately and completely administered by the person who prepared it or immediate and complete administration is witnessed by the preparer, the CSP shall bear a label listing patient identification information, the names and amounts of all ingredients, the name or initials of the person who prepared the CSP, and the exact 1-hour BUD and time. 6. If administration has not begun within 1 hour following the start of preparing the CSP, the CSP shall be promptly, properly, and safely discarded. [IMMEDIATE-USE CSPs]	N/A

SINGLE/MULTIPLE DOSE CONTAINER BUD

36. Beyond-use date does not exceed 28 days for multiple-dose containers after initial opening or entry, unless specified otherwise by the manufacturer. [SINGLE-DOSE AND MULTIPLE-DOSE CONTAINERS]	Yes
37. Beyond-use time does not exceed 6 hours for closure sealed single-dose containers in ISO Class 5 or cleaner air after initial opening or entry, unless specified otherwise by the manufacturer. [SINGLE-DOSE AND MULTIPLE-DOSE CONTAINERS] *Preservative free Vancomycin 1g/vial stored in refrigerator without discard/entry time; D5W and NaCl preservative free IV bags hanging in PEC's without discard/entry time.*	No
38. Beyond-use time does not exceed 1 hour for closure sealed single-dose containers after being opened or entered in worse than ISO Class 5 air. [SINGLE-DOSE AND MULTIPLE-DOSE CONTAINERS]	N/A
39. Single-dose ampules are discarded immediately after use. [SINGLE-DOSE AND MULTIPLE-DOSE CONTAINERS]	Yes

HAZARDOUS DRUGS

40. A pressure indicator is installed and differential pressures are monitored and documented daily for hazardous buffer room. [HAZARDOUS DRUGS AS CSPs]	Yes
41. Hazardous drug buffer room is at least 0.01 inch water column negative pressure with 30 ACPH of HEPA filtered air. [HAZARDOUS DRUGS AS CSPs]	Yes
42. At least 0.01 inch water column negative pressure and 12 air changes per hour in non-cleanrooms in which CACIs are located. FAC: USP Chapter 797 requires that: "When closed-system vial-transfer devices (CSTDs) (i.e., vial-transfer systems that allow no venting or exposure of hazardous substance to the environment) are used, they shall be used within an ISO Class 5 environment of a BSC or CACI. The use of the CSTD is preferred because of their inherent closed system process. In facilities that prepare a low volume of hazardous drugs, the use of two tiers of containment (e.g., CSTD within a BSC or CACI that is located in a non-negative pressure room) is acceptable." For purpose of said provision, a "low volume of hazardous drugs" is defined as less than 40 doses per month. [HAZARDOUS DRUGS AS CSPs]	N/A
43. Personnel compounding hazardous drugs wear appropriate personal protective equipment. [HAZARDOUS DRUGS AS CSPs]	N/A
44. Hazardous drugs are handled with caution at all times using appropriate chemotherapy gloves during receiving, distribution, stocking, inventorying, preparing for administration, and disposal. Spill kits are available. [HAZARDOUS DRUGS AS CSPs]	N/A
45. Hazardous drugs are prepared in an ISO Class 5 environment (BSC or CACI) with protective engineering controls in place, following aseptic practices specified for the appropriate contamination risk levels. [HAZARDOUS DRUGS AS CSPs]	N/A

46. Hazardous drugs are stored separately from other inventory in a manner to prevent contamination and personnel exposure. [HAZARDOUS DRUGS AS CSPs]	Yes
47. Access to hazardous drug preparation areas is limited to authorized compounding personnel. [HAZARDOUS DRUGS AS CSPs]	Yes
48. Annual documentation of hazardous drug training of personnel regarding storage, handling, containment techniques and disposal of hazardous drugs is available. [HAZARDOUS DRUGS AS CSPs] *HD compounding has not been implented.*	N/A
49. Compounding personnel of reproductive capability have confirmed in writing that they understand the risks of handling hazardous drugs. [HAZARDOUS DRUGS AS CSPs] *HD compounding has not been implented.*	N/A
50. Facility maintains appropriate disposal containers for all hazardous waste. [HAZARDOUS DRUGS AS CSPs]	Yes

FACILITY DESIGN AND CERTIFICATION

51. Certification and testing of primary (LAFWs, BSCs, CAIs and CACIs) and secondary engineering controls (buffer and ante areas) have been performed by a qualified individual no less than every six months and whenever the device or room is relocated, altered, or major service to the facility is performed. Corrective action for deficiencies are documented. Certification procedures such as those outlined in the CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2006) are conducted under dynamic conditions. [ENVIRONMENTAL QUALITY AND CONTROL : Environmental Nonviable Particle Testing Program] *On 4/25/2019, MTA certified ISO 7 anteroom, ISO 7 IV room, ISO 7 HD room, ISO 7 negative pressure storage room. Equipment used in compounding inside PEC's include 3 TPN Pinnacle machines, 4 X repeater pumps, 2 X Tube rollers; all electronic. PEC's: 6 X VLF's (3 of which used for compounding TPN's with Pinnacle machines), 1 X HLF and 1 X BSC all to ISO 5, with only the Pinnacle machines operational.*	No
52. Primary engineering controls provide unidirectional (i.e., laminar) HEPA filtered air. Air pattern analysis via smoke studies are conducted at the critical site to demonstrate unidirectional airflow and sweeping action over and away from the product under dynamic conditions.[ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
53. The primary engineering controls are placed within a buffer area in such a manner as to avoid conditions that could adversely affect their operation. The PEC is placed out of the traffic flow and in a manner to avoid disruption from the HVAC system and room cross drafts. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
54. All HEPA filters are leak tested after installation and every six months thereafter. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes

ISOLATORS

55. CAIs are proven to maintain ISO Class 5 air when particle counts are sampled 6 to 12 inches upstream of critical site exposure areas during performance of normal inward and outward transfer of materials, and compounding manipulations when such CAIs are located in air quality worse than ISO Class 7. [ENVIRONMENTAL QUALITY AND CONTROL : Placement of Primary Engineering Controls Within ISO Class 7 Buffer Areas]	
56. Adequate recovery time for isolators to achieve ISO Class 5 air quality is allowed after material transfer before and during compounding operations. [ENVIRONMENTAL QUALITY AND CONTROL : Placement of Primary Engineering Controls Within ISO Class 7 Buffer Areas]	
57. Personnel garbing requirements are followed for CAIs unless manufacturer provides written documentation based on validated testing that any components of PPE are not required to maintain sterility of CSPs. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	

FACILITY DESIGN AND CERTIFICATION (Secondary Engineering Controls)

58. Facility has pressure gauges or velocity meters to monitor the pressure differential or airflow between the buffer area and ante-area, and the ante-area and the general environment outside the compounding area. The results are reviewed and documented on a log at least daily or by a continuous recording device. The pressures differentials meet or exceed 5 Pa (0.02 inch water column (w.c.)). Alternatively, in facilities where low- and medium-risk level CSPs are prepared, differential airflow is maintained at a minimum velocity of 0.2 meter/second (40 fpm) across a line of demarcation between buffer area and ante-area. [ENVIRONMENTAL QUALITY AND CONTROL : Pressure Differential Monitoring]	Yes
59. Clean rooms for nonhazardous and nonradioactive CSPs are supplied with HEPA filtered air that enters from ceilings with return vents low on walls, and that provides not less than 30 air changes per hour or qualifies for exception in 64B16-27.797(4)(c). [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
60. Activities and tasks carried out within the buffer area are limited to only those necessary when working within a controlled environment. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
61. Only the furniture, equipment, supplies, and other material required for the compounding activities to be performed are brought into the buffer room. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
62. Surfaces and essential furniture in buffer rooms or zones and clean rooms are nonporous, smooth, non-shedding, impermeable, cleanable, and resistant to disinfectants. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
63. The surfaces of ceilings, walls, floors, fixtures, shelving, counters, and cabinets in the buffer area are smooth, impervious, free from cracks and crevices, and non-shedding, thereby promoting cleanability, and minimizing spaces in which microorganisms and other contaminants may accumulate. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
64. Ceiling tiles are caulked around each perimeter and to walls to seal them to the support frame. The exterior lens surface of ceiling lighting fixtures is smooth, mounted flush, and sealed. All other penetrations through the ceiling or walls are sealed. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
65. The buffer area does not contain sources of water (sinks) or floor drains. Work surfaces are constructed of smooth, impervious materials, such as stainless steel or molded plastic, so that they are easily cleaned and disinfected. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
66. Storage shelving, counters, cabinets and carts/casters in the buffer area are smooth, impervious, free from cracks and crevices, non-shedding, non-porous, cleanable, and disinfectable. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
67. When devices (e.g., computers and printers) and objects (e.g., carts and cabinets) are placed in buffer areas, air quality is verified by particle counts on certification. [ENVIRONMENTAL QUALITY AND CONTROL : ISO Class 5 Air Sources, Buffer Areas, and Ante-Areas] *There are 4 X repeater pumps, 3 X Pinnacle machines and 2 Tube rollers that are located in PEC's. Per Rph, only the Pinnacle TPN machines are operational during particle counts.*	No

QUALITY AND CONTROL

68. An appropriate environmental sampling plan has been developed for airborne viable particles based on a risk assessment of compounding activities performed. Volumetric air sampling is conducted every six months and sites include locations within each ISO Class 5 environment and in the ISO Class 7 and 8 areas, and the areas at greatest risk of contamination (e.g., work areas near the ISO Class 5 environment, counters near doors, pass-through boxes). The plan includes sample locations, method of collection, frequency of sampling, volume of air sampled, and time of day as related to activity in the compounding area and action levels. [ENVIRONMENTAL QUALITY AND CONTROL : Environmental Viable Airborne Particle Testing Program—Sampling Plan]	Yes
69. Evaluation of airborne microorganisms using volumetric collection methods in the controlled air environments is performed by properly trained individuals for all compounding risk levels. [ENVIRONMENTAL QUALITY AND CONTROL : Viable Air Sampling] *Per policy 9701 quarterly VAS (using CLIMET impactor) is collected in all ISO classified air.*	Yes
70. Volumetric air sampling using malt extract agar (MEA) or some other media that supports the growth of fungi is used in high-risk level compounding environments. [ENVIRONMENTAL QUALITY AND CONTROL : Growth Media]	N/A
71. For low-risk level CSPs with 12-hour or less BUD, air sampling is performed at locations inside the ISO Class 5 environment and other areas that are in close proximity to the ISO class 5 environment. [ENVIRONMENTAL QUALITY AND CONTROL : Viable Air Sampling]	N/A
72. The number of discrete colonies of microorganisms is counted and reported as colony-forming units (cfu) and documented on an environmental monitoring form. Counts from air monitoring are transformed into cfu/cubic meter of air and evaluated for adverse trends. [ENVIRONMENTAL QUALITY AND CONTROL : Incubation Period] *Trending data is in the process of being implemented by corporate.*	No
73. Surface sampling is accomplished in all ISO classified areas on a periodic basis using TSA contact plates with lecithin and polysorbate 80 and/or swabs and is done at the conclusion of compounding. [ENVIRONMENTAL QUALITY AND CONTROL : Surface Cleaning and Disinfection Sampling and Assessment] *This is done in house monthly, per policy. EM policy 9701 (implemented March 2019) requires two incubation temperatures, 30-35 degrees C X 2 days, then 20-25 degrees C X 5 days. Facility practice is incubation at 30-35 C X 72 hours.*	No
74. Sampling data is collected and reviewed on a periodic basis as a means of evaluating the overall state of control of the compounding environment. [ENVIRONMENTAL QUALITY AND CONTROL : Action Levels, Documentation and Data Evaluation]	Yes
75. Competent microbiology personnel are consulted if an environmental sampling consistently shows elevated levels of microbial growth. If any mold, yeast, coagulase positive staphylococcus, or gram negative rods are detected immediate remediation and investigation into the cause and source was conducted. [ENVIRONMENTAL QUALITY AND CONTROL : Action Levels, Documentation and Data Evaluation]	Yes
76. Surfaces in the LAFWs, BSCs, CAIs, and CACIs are cleaned and disinfected frequently, including at the beginning of each work shift, before each batch preparation is started, every 30 minutes during continuous compounding periods of individual CSPs, when there are spills, and when surface contamination is known or suspected from procedural breaches. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
77. Cleaning and disinfecting occurs before compounding is performed. Items are removed from all areas to be cleaned, and surfaces are cleaned by removing loose material and residue from spills, e.g., water-soluble solid residues are removed with Sterile Water and low-shedding wipes. This shall be followed by wiping with a residue-free disinfecting agent, such as sterile 70% IPA, which is allowed to dry before compounding begins. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
78. Cleaning and disinfecting agents and methods of application are in accordance with written SOPs and followed by custodial and/or compounding personnel. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
79. Cleaning materials, such as wipes, sponges, and mops, are non-shedding, preferably composed of synthetic micro fibers, and dedicated to use in the buffer area, ante-area, and segregated compounding areas and are not removed from these areas except for disposal. If cleaning materials are reused (e.g., mops), there are procedures based on manufacturer recommendations that ensure that the effectiveness of the cleaning device is maintained and repeated use does not add to the bioburden of the area being cleaned. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
80. Supplies and equipment removed from shipping cartons are wiped with a suitable disinfecting agent (e.g., sterile 70% IPA). [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas] *Inspector observed RPT remove sterile drug component from ISO 5 air into ISO 7 air, remove cap and return item to ISO 5 without disinfecting.*	No
81. Disinfectant sprayed or wiped on a surface to be disinfected is allowed to dry, and during this time the item is not be used for compounding purposes. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
82. Sterile 70% IPA pads are used to disinfect the sterile entry points of packages and devices. Wetted gauze pads or other particle-generating material are not appropriate. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas] *Inspector observed RPT spray septum with sIPA without wiping.*	No

QUALITY AND CONTROL (Secondary Engineering Controls)

83. Work surfaces in ISO Class 7 and 8 areas and segregated compounding areas are cleaned at least daily. IPA (70% isopropyl alcohol) remains on surfaces to be disinfected for at least 30 seconds before such surfaces are used to prepare CSPs. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
84. Floors in ISO Class 7 and 8 areas are mopped daily by trained personnel at a time when no aseptic operations are in progress using approved agents and procedures described in written SOP's. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
85. Shelving, walls, and ceilings in ante-areas and buffer areas are cleaned and disinfected at least monthly. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas] *Yes, BUT advise to document day of monthly cleaning to ensure consistency.*	Yes

PERSONNEL CLEANSING, GARBING & COMPETENCY EVALUATION

86. Personnel preparing CSP's are free from rashes, sunburn, weeping sores, conjunctivitis, and active respiratory infections. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	Yes
87. Compounding personnel remove personal outer garments; cosmetics; artificial nails; hand, wrist, and body jewelry that can interfere with the fit of gowns and gloves; and visible body piercing above the neck. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	Yes
88. Facility has adequate supplies to meet PPE requirements of USP<797>. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	Yes
89. Garbing and hand hygiene are accomplished in the ante-area in order of dirtiest to cleanest: shoes or shoe covers, head and facial hair covers, face mask, fingernail cleansing, hand and forearm washing and drying; non-shedding gown. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	Yes
90. Sterile gloves are donned in the buffer room/isolator after hand cleansing with an alcohol-based product with persistent activity and hands are allowed to dry. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	Yes
91. Gloves are routinely disinfected with sterile 70% IPA after contacting nonsterile objects. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	Yes

92. Personnel repeat garbing and hand hygiene after they are exposed to direct contact contamination or worse than ISO Class 8 air. Gowns may be hung in the anteroom and reused during the same workshift. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	Yes
93. Low/Medium Risk media-fill tests that closely simulate the most challenging or stressful conditions encountered during compounding are completed at least annually by compounding personnel. Media-filled vials are appropriately incubated for 14 days. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Medium-Risk Level CSPs]	Yes
94. High Risk Media-fill tests that closely simulate the most challenging or stressful conditions encountered during compounding have been completed at least semiannually by compounding personnel. Media-filled vials are appropriately incubated for 14 days. [CSP MICROBIAL CONTAMINATION RISK LEVELS : High-Risk Level CSPs]	N/A
95. Documentation indicates compounding personnel have successfully completed didactic training, passed written competency assessments, undergone skill assessment using observational audit tools (hand hygiene, garbing, aseptic technique) and media-fill testing annually or semiannually (high risk) and before any compounding personnel begin to prepare CSPs . [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures]	Yes
96. Compounding personnel who fail written tests, observational audits, or whose media-fill test vials have one or more units showing visible microbial contamination, are reinstructed and re-evaluated by expert compounding personnel to ensure correction of all aseptic work practice deficiencies. Corrective action is documented. Compounding personnel pass all evaluations prior to resuming compounding of sterile preparations. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures] *Media fill tests for three compounding RPT's (RS, WG, GT) indicate particles found in media; Employees were not re-validated.*	No
97. Other cleaning personnel performing cleaning and disinfecting procedures (e.g. environmental) are thoroughly trained in proper hand hygiene, and garbing, cleaning, and disinfection procedures by a qualified aseptic compounding expert. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures]	N/A
98. Compounding personnel and other personnel responsible for cleaning routinely undergo performance evaluation of proper hand hygiene, garbing, and all applicable cleaning and disinfecting procedures conducted by a qualified aseptic compounding expert. Visual observation of hand hygiene, garbing and cleaning is documented and maintained to provide a permanent record and long-term assessment of personnel competency. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures] *GT RPT performs monthly cleaning, but has not demonstrated proficency for this task.*	No
99. Immediately after the compounder completes the hand hygiene and garbing procedure, the evaluator collects a gloved fingertip and thumb sample from both hands of the compounder onto appropriate agar plates. The plates are incubated at 30-35° for 2–3 days. All compounding personnel have successfully completed an initial competency evaluation and gloved fingertip/thumb sampling procedure (0 cfu) no less than three times before initially being allowed to compound CSPs for human use. [ENVIRONMENTAL QUALITY AND CONTROL : Gloved Fingertip Sampling] *Employee DB RPH failed one set of GFT on initial test, redone only once. Policy 9705 (1)(j) indicates to repeat for the number of failed GFT's observed, NOT three times.*	No
100. Re-evaluation of glove fingertip testing onto appropriate agar plates (Trypticase soy agar (TSA) with lecithin and polysorbate 80) for all compounding personnel occurs at least annually for low- and medium-risk level CSPs and semiannually for high-risk level CSPs before being allowed to continue compounding CSPs. Gloves shall not be disinfected with sterile 70% IPA prior to testing. The cfu action level is based on the total number of cfu on both gloves and not per hand. [ENVIRONMENTAL QUALITY AND CONTROL : Gloved Fingertip Sampling]	Yes

VERIFICATION

101. Labels of CSPs contain name and address of pharmacy, correct names and amounts or concentrations of ingredients, total volumes, beyond-use dates, storage conditions, and route(s) of administration. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Identity and Strength Verification of Ingredients]	Yes
102. Facility has documentation that procedures have been followed to ensure sterility, purity, correct identities and amounts of ingredients, and stability. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Inspection of Solution Dosage Forms and Review of Compounding Procedures]	Yes
103. CSP's are visually inspected for abnormal particulate matter and color, and intact containers and seals. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Inspection of Solution Dosage Forms and Review of Compounding Procedures] *Yes, BUT company policy 9620 requires use of black/white light box to inspect CSP's for particulates but this isn't being done.*	Yes
104. Beyond Use Dates are assigned using direct stability-indicating assays or authoritative literature that supports the assigned BUD. [STORAGE AND BEYOND-USE DATING : Determining Beyond-Use Dates]	Yes
105. Storage time of assembled bag and vial systems are according to the manufacturer recommendations. (eg Minibag plus, Addvantage, Add-ease) [STORAGE AND BEYOND-USE DATING : Proprietary Bag and Vial Systems]	Yes

DISPENSING/DISTRIBUTION

106. Facility has written procedures for proper packaging, storage, and transportation conditions to maintain sterility, quality, purity, and strength of CSPs. [MAINTAINING STERILITY, PURITY, AND STABILITY OF DISPENSED AND DISTRIBUTED CSPs :]	Yes
107. Modes of transport are used that maintain appropriate temperatures and prevent damage to CSPs. [MAINTAINING STERILITY, PURITY, AND STABILITY OF DISPENSED AND DISTRIBUTED CSPs : Packaging and Transporting CSPs]	Yes
108. Facility provides a multiple component formal training program to ensure patients and caregivers understand the proper storage, handling, use, and disposal of CSPs. [PATIENT OR CAREGIVER TRAINING]	Yes

POLICY/PROCEDURE

109. Written procedures detail cleaning and disinfecting the sterile compounding areas including cleansers, disinfectants, and non-shedding wipe and mop materials. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
110. A written procedure is in place for cleaning and disinfecting the Direct Compounding Areas. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
111. Facility has written procedures to verify correct identity, quality, amounts, and purities of ingredients used in CSPs. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Identity and Strength Verification of Ingredients]	Yes
112. Policies address packaging to maintain physical integrity, sterility, stability, and purity of CSPs. [MAINTAINING STERILITY, PURITY, AND STABILITY OF DISPENSED AND DISTRIBUTED CSPs : Packaging and Transporting CSPs]	Yes
113. Written standard procedures describe means for patients to ask questions and report concerns and adverse events with CSPs, and for compounding pharmacists to correct and prevent future problems. [PATIENT MONITORING AND ADVERSE EVENTS REPORTING]	N/A

RADIOPHARMACEUTICALS

114. Facility has appropriate primary engineering controls and radioactivity containment and shielding. Location of primary engineering controls permitted in ISO Class 8 controlled environment. [RADIOPHARMACEUTICALS AS CSPs]	

115. Radiopharmaceuticals prepared as low-risk level CSPs with 12-hour or less BUD are prepared in a segregated compounding area. Segregated compounding area is designated with a line of demarcation. [RADIOPHARMACEUTICALS AS CSPs]	
116. Technetium-99m/Molybdenum-99 generators are eluted in ISO Class 8 conditions. [RADIOPHARMACEUTICALS AS CSPs]	

MISCELLANEOUS

117. Facility engaged in office use sterile compounding for human use is registered with FDA as an outsourcing facility. [FAC 64B16-27.700 (3)(g]	N/A
118. Compounding records are properly maintained. [FAC 64B16-28.140(4)]	Yes
119. When compounding activities require the manipulation of a patient's blood-derived or other biological material, the manipulations are clearly separated from routine material-handling procedures and equipment used in CSP preparation activities, and they are controlled by specific standard operating procedures in order to avoid any cross-contamination. [ENVIRONMENTAL QUALITY AND CONTROL : Placement of Primary Engineering Controls Within ISO Class 7 Buffer Areas]	N/A

SPECIAL PARENTERAL ENTERAL & EXTENDED SCOPE

120. Pharmacy technicians properly identified and supervised. [64B16-27.420, F.A.C.]	
121. Medication properly labeled. [465.0255, F.S.] [64B16-28.108, F.A.C.]	
122. Expired medications removed from the shelves. [64B16-28.110, F.A.C.]	
123. CQI Policy and Procedures and quarterly meetings. [766.101, F.S.] [64B16-27.300, F.A.C.]	
124. Prescriptions have the date dispensed and dispensing pharmacists. [893.04(1)(c) 6, F.S.] [64B16-28.140(3)(b), F.A.C.]	
125. Pharmacy maintains patient profile records. [64B16-27.800, F.A.C.]	
126. All controlled substance prescriptions contain information required. [893.04, F.S.]	
127. Prescriptions for controlled substances are on counterfeit-proof prescription pads or blanks purchased from a Department-approved vendor and the quantity and date meet the requirements of [456.42(2), F.S.].	
128. Controlled substance inventory taken on a biennial basis and available for inspection. [893.07(1)(a), F.S.]	
129. DEA 222 order forms properly completed. [893.07, F.S.]	
130. Controlled substance records and Rx information in computer system is retrievable. [21CFR 1306.22] [64B16-28.140, F.A.C.]	
131. Controlled substance records maintained for 4 years. [465.022(12)(b), F.S.]	
132. Certified daily log OR printout maintained. [21CFR 1306.22(b)(3)] [64B16-28.140(3)(b), F.A.C.]	
133. Pharmacy is reporting to the PDMP within 7 days of dispensing controlled substance. [893.055(4), F.S.]	
134. Pharmacy maintains invoices documenting that medicinal drugs were obtained from a Florida licensed distributor. 499.005 (14)	

Remarks:

Facility has certified an ISO 7 negtive pressure hazardous cleanroom and negative pressure HD storage room. Hazardous comopounding has not been implemented at this facility at this time.
Routine inspection conducted with Shirley Adams RPH, Leslie Nazario, and Mary Jo Giles (PIC) .
Corrective action requested for all items marked "no" on or before June 7, 2019.

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge. I have received a copy of the Licensee Bill of Rights.

Inspector Signature:

Date:5/7/2019

Representative:

Mary Jo Giles

Date:5/7/2019

Corrective Action Plan for

BriovaRx Infusion Services, 203, Inc. f/k/a Ambient Healthcare of S. Florida, Inc.
9984 Premier Parkway
Miramar, Florida 33025

Pharmacy Permit No. 27913

DOH Case No. 2017-15122

The references below are to the items noted on the inspection sheet dated 6/1/2018, the inspector's comments to the inspection sheet, and BriovaRx Infusion Services 203, Inc.'s ("BriovaRx") response.

37. Beyond-use time does not exceed 6 hours for closure sealed single-dose containers in ISO Class 5 or cleaner air after initial opening or entry, unless specified otherwise by the manufacturer. [SINGLE-DOSE AND MULTIPLE-DOSE CONTAINERS]

Inspector's Comments: Policy 7065 instructs SDVs and Pharmacy Bulk Packages to be discarded after six hours, but does not indicate if opened and remains in ISO 5 PEC.

RESPONSE: Policy 7065 (attached) has been revised to state that single dose containers and pharmacy bulk containers will remain in the ISO 5 PEC.

68. An appropriate environmental sampling plan has been developed for airborne viable particles based on a risk assessment of compounding activities performed. Volumetric air sampling is conducted every six months and sites include locations within each ISO Class 5 environment and in the ISO Class 7 and 8 areas, and the areas at greatest risk of contamination (e.g., work areas near the ISO Class 5 environment, counters near doors, pass-through boxes). The plan includes sample locations, method of collection, frequency of sampling, volume of air sampled, and time of day as related to activity in the compounding area and action levels. [ENVIRONMENTAL QUALITY AND CONTROL : Environmental Viable Airborne Particle Testing Program—Sampling Plan]

Inspector's Comments: Environmental policy 9701 does not include USP <797> required viable air sampling by impaction, amount of air to be sampled in each ISO class space and sampling locations. Advise to use viable air sampling locations to evaluate CFU trends.

RESPONSE: Policies 9701, 9702, 9702.A1, and 9702.E1, (copies attached) have been revised to address USP <797> required viable air sampling by impaction, the amount of air to be sampled in each ISO class space and the attached Miramar SPC Map show sampling locations as well as the use of viable air sampling locations to evaluate CFU trends.

99. Immediately after the compounder completes the hand hygiene and garbing procedure, the evaluator collects a gloved fingertip and thumb sample from both hands of the

compounder onto appropriate agar plates. The plates are incubated at 30-35° for 2–3 days. All compounding personnel have successfully completed an initial competency evaluation and gloved fingertip/thumb sampling procedure (0 cfu) no less than three times before initially being allowed to compound CSPs for human use. [ENVIRONMENTAL QUALITY AND CONTROL : Gloved Fingertip Sampling]

Inspector's comments: Policy 9705 indicates new employees shall complete hand hygiene three times, but not regarb three times.

RESPONSE: Policy 9705 (copy attached) has been revised to address regarbing (addressed as gowning).

CI-95A
MICROBIAL SAMPLER
OPERATOR'S MANUAL

Revision 3.04 – May 18, 2017 **Manual P/N 03009509**

CLIMET INSTRUMENTS
1320 West Colton Avenue, Redlands, CA 92374
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Section 1: Introduction

1.1 Caution

Service by qualified personnel only.

1.2 Notes

1.2.1 Notice

The CI-95A should never be operated with the transit lid installed. This may result in damage to the blower or other internal components.

1.2.2 Battery life

Batteries offer portability, but all batteries have limited life. The choice of Nickel Metal Hydride batteries offers greater power density than comparable Nickel-Cadmium batteries, and the elimination of cadmium from the battery chemistry reduces environmental concerns associated with NI-Cad batteries. In other respects, including long-term life, the batteries are similar. Manufacturers of NI-MH batteries recommend that they be stored *open circuit* (i.e., disconnected) if stored for extended periods.

1.2.3 Calibration interval

The CI-95A is based on technology proven in a variety of reliable, stable instruments, and can be expected to maintain its calibration within specified tolerances for several years. However, it is recommended that the instrument be calibrated annually to insure the accuracy of the volume of air sampled.

1.3 Unpacking and installation

1.3.1 Unpacking

The CI-95A is packed in a specially designed shipping container, which has been tested to withstand normal amounts of shock and vibration in accordance with the National Safe Transit Association (NSTA). Save the shipping box to minimize the chance of shipping damage when the instrument needs to be returned for calibration or repair.

After unpacking the CI-95A, inspect the instrument for any signs of damage. If there is any damage, you should file a claim with the shipping company and contact CLiMET Instruments.

1.3.2 Power requirements

The CI-95A is powered by an external power supply (15V 4.0A) equipped with a universal input AC power supply that supports inputs from 100–240 VAC, 47–63 Hz.

1.3.3 Safety

The operator or maintenance person should not remove any of the covers on the CLiMET microbial sampler, except in accordance with the procedures provided by the manufacturer.

The CI-95A contains a 9.6 volt, maintenance-free, rechargeable nickel metal hydride battery, which can be replaced by the user.

The CI-95A external power supply comes with a three prong, grounded AC power cord. Do not use a two-to-three prong adapter unless its ground connection has been properly connected to a good ground on the wall socket.

1.3.4 Cleaning

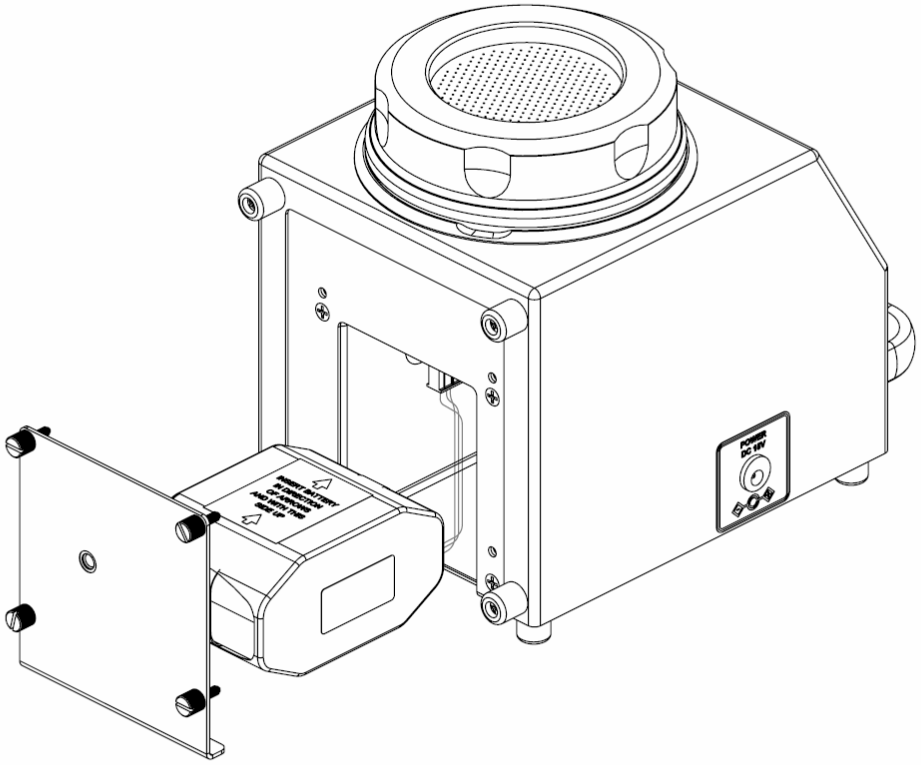
The CI-95A's enclosure, sample lid, and polyester overlay are resistant to most cleaning chemicals. When cleaning the unit, follow these precautions:

- Turn the unit off and remove the power cord.
- Install the transit lid to prevent fluid from entering the blower assembly.
- Wipe the surface of the unit with a cloth or wipe, dampened with cleaning solutions.
- When cleaning agents are sprayed near the instrument, be sure that the instrument is off, and that the transit lid is installed.

1.3.5 Storage

If the CI-95A is to be stored for three months or longer without use, the battery should be disconnected to prevent damage to the battery from a deep discharge. To gain access to the battery, unscrew the four thumbscrews on the battery cover on the rear of the unit. The battery has a single connector that is easier to unplug if you slide the battery out fisrt then unplug the connector then slide the battery back in for storage (see figure on page 3). Reconnect the battery again before use. Make sure that no wires or cable assemblies are pinched when reassembling the enclosure.

BATTERY INSTALLATION,
CI-95A 100 LPM



1.3.6 Packing for shipment

The packing container used for shipping the CI-95A has been tested according to the standards of the National Safe Transit Association. For this reason, it is recommended that the original packing container be saved for reuse if it has no obvious damage. The packing container consists of an outer double-walled cardboard box, two foam inserts, and an internal cardboard box used to hold accessories. This internal box also serves the important function of tightening the foam inserts against the CI-95A.

If the original shipping carton was discarded, select a cardboard box large enough that at least 3 inches of heavy bubble wrap can be placed on ***all*** sides of the instrument. Any extensions (handle, feet) should be especially well protected, because the impact is amplified if the carton is dropped on a part that extends out from the rest of the chassis. Avoid the use of loose packing materials such as *peanuts*, because they shift and leave one side of the instrument unprotected. Shipping companies do not accept responsibility for damage when the instrument is poorly packed.

NOTE: *When returning the CI-95A for servicing, keep the accessories in a safe place at your facility. No accessories are needed during calibration or repair.*

1.4 Overview of CI-95A features

The CI-95A (CLiMET Instruments 95A) is a microbial air sampler that can capture biologically active particles (bacteria, fungi, etc.) onto a petri dish loaded with nutrient agar. This sample can then be incubated so that the captured microbes can grow into colonies. The colonies formed after incubation are counted to determine the concentration of CFU's (colony forming units) present in the sampled air.

The CI-95A is a fully self-contained unit, operating on battery power or AC power for sampling convenience (AC operation will simultaneously charge the battery). It has a stainless steel enclosure that makes it suitable for applications requiring a sterile wipe down. The standard flow rate is 100 liters per minute (100 LPM), requiring only 10 minutes to take a full 1 cubic meter sample. The built-in battery can provide approximately 8 hours of continuous sampling (pump running) on a single charge. The CI-95A interfaces with the user through a 4x20 character LCD display and a keypad overlay. The unit also has a blower with automatic flow control to ensure accurate sample volumes. The sample air is filtered before being exhausted through the bottom panel to ensure the sampled environment is not contaminated.

The CI-95A has menu options that allow the user to set up a UNIT ID name to identify the CI-95A used, a USER ID name to identify the user who took the sample, and a SITE (LOCATION) ID to identify where the sample was taken. The sample volume and other parameters related to extended-time sampling are also stored within Site IDs. In addition, the user can specify the initial time delay to allow the user to exit the area, the flow out of tolerance alarm, the beep on completion of sample, the security options, and the date/time.

The main screen provides the operator with all pertinent information. The top line always displays the site, while the second line either displays the delay time countdown

(before a sample begins) or the volume of air moved thus far (during a sample). By pressing the DSPL key, the operator can alternately select one of the following items to be displayed on the third line: flow rate, battery life, user ID, date + time, unit ID, and the time remaining to complete the sample. The fourth line lists the functions of the 4 keys below the LCD screen.

Three LED's below the LCD screen also supply the user with additional information. The green SAMPLE LED is continuously lit while a sample is in progress, but not during the delay countdown before the sample. It will continually flash once the sample has completed. The green CHARGER LED will be continuously lit if the battery is charging, and will continually flash once it is fully charged (whether or not the unit is powered on). The red ALARM LED will continually flash if a flow alarm occurs or the battery life indication reaches < 0.5 HR.

When the battery life reaches < 0.5 HR, the unit will force the main screen third line to display battery life (in addition to the ALARM LED flashing). This serves as an extra reminder the battery is getting low. The user can, however, override this by then pressing the DSPL key to display a different item on the third line.

1.5 Interpreting the Results

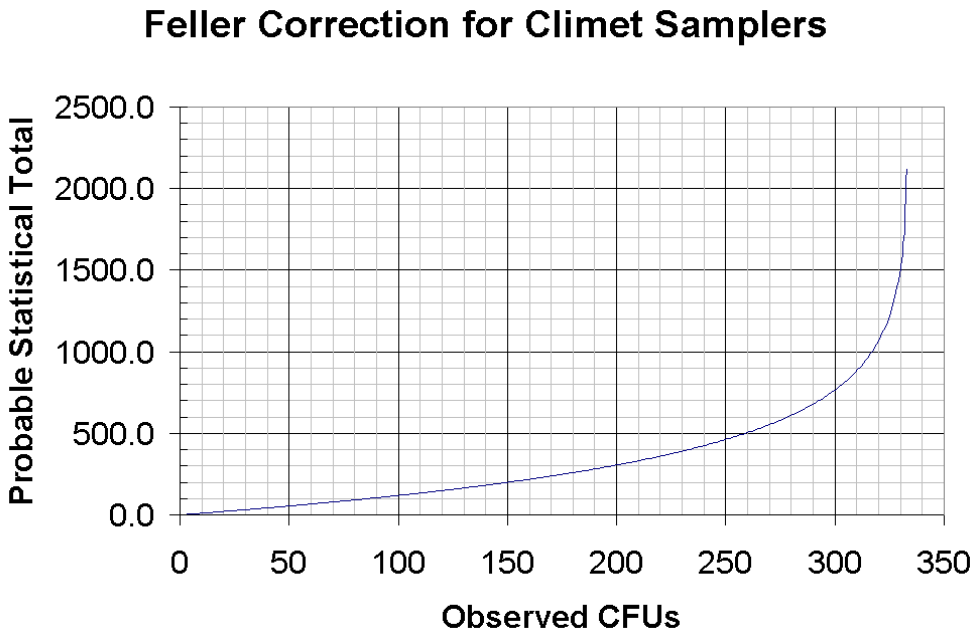
The Petri dishes are incubated for a period of time to allow the entrapped microbes to grow into colonies large enough to observe macroscopically. By counting the number of colonies, one can get an idea of the concentration of microorganisms in the sample volume. Unfortunately, a simple count doesn't translate directly into concentration.

A statistical analysis of the system considers a variety of things such as the following:

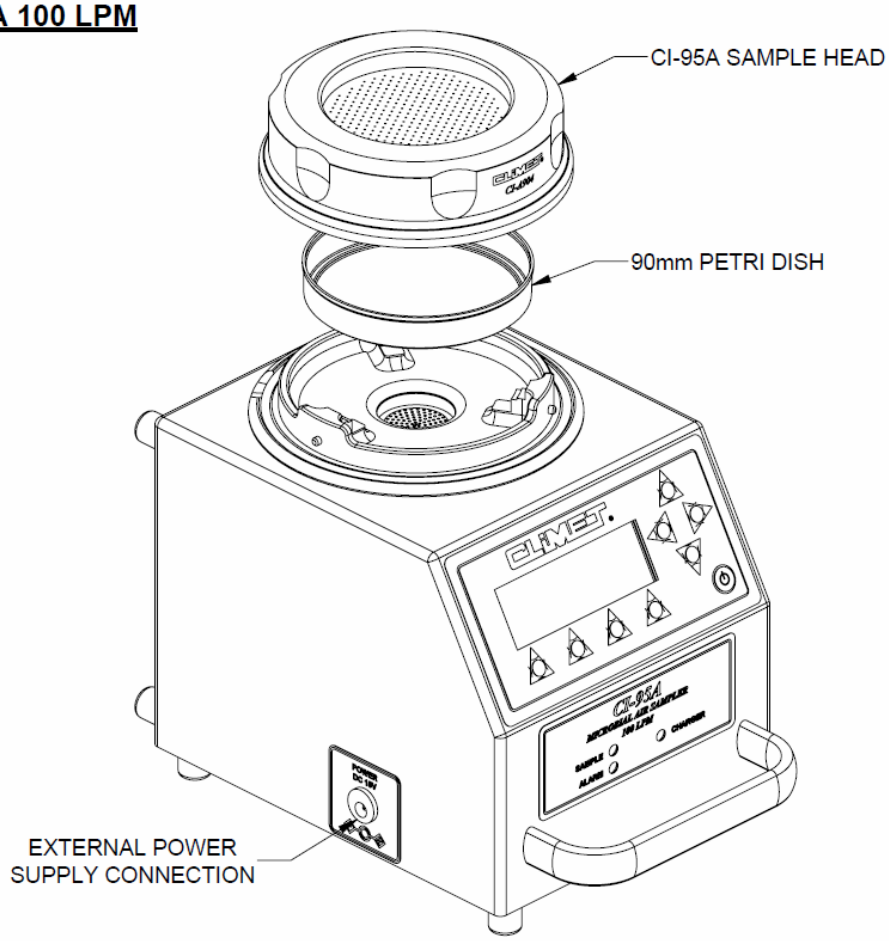
- There is no way to tell if a colony had one or more Colony-Forming Units (CFUs) prior to incubation
- Each perforation is uniform and equally likely to pass a CFU to the media
- The more colonies that are observed, the more likely it is that more than one CFU was present before incubation in any given colony

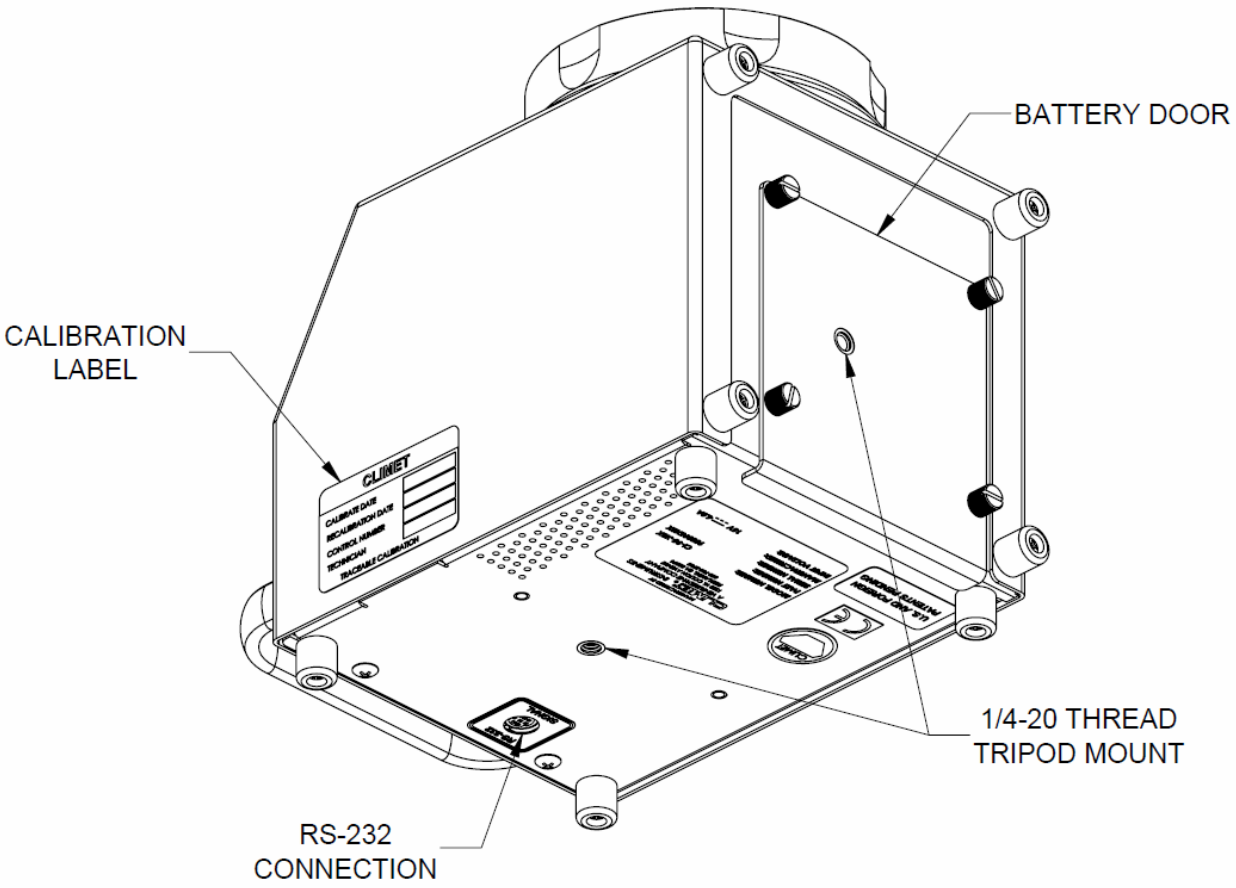
The Feller Correction in the Appendix provides the accepted method to compensate for the undercounting that results. The graph below shows that as the number of colonies observed approaches the number of perforations, the greater the undercount. The easiest way to correct the observed values into Probable Statistical Totals is to use the table in the appendix. Look up the observed value in column A, and find the Probable Total in the adjacent column B to the right. For example, given these two values:

Colonies counted	Probable Total
10	10.1
87	100.7


Feller Correction for Climet Samplers
Probable Statistical Total
2500.0
2000.0
1500.0
1000.0
500.0
0.0
0
50
100
150
200
250
300
350
Observed CFUs

HEAD AND DISH INSTALLATION,
CI-95A 100 LPM




BATTERY DOOR
CALIBRATION
LABEL
1/4-20 THREAD
TRIPOD MOUNT
RS-232
CONNECTION

1.6 Specifications

Sample Lid:	Clear Anodized Aluminum with 333 .028" holes. Autoclavable @ 134C for 20 minutes
Enclosure:	304L Stainless Steel
Sample flow rate:	100 liters per minute (0.10 cubic meter or 3.53 cubic feet per minute)
Flow rate control:	Electronic, automatic closed loop
Battery:	Replaceable 9.6 Volts, 7.6 Amp hour Nickel Metal Hydride Battery operation time: 7.5 to 9 hours of continuous operation Time to charge battery: 2.0 to 2.5 hours
Display:	4x20 character LCD with backlight
Unit ID:	User selectable; 6 characters long.
User ID:	Up to 10 users; 9 characters long.
Security:	Security to prevent settings changes, or aborting a sample in progress
Location ID:	Up to 70, 15 characters long.
Input/Output:	RS-232 9600 bps, 8-bit, 1 stop, no parity, no handshaking
Audible alarm:	Built-in
Alarm limits:	± 10% deviation from 100 LPM flow rate.
Dimensions:	H-W-D: 7.5 X 5.75 X 9.25 inches (19.0 X 14.6 X 23.5 cm)
Weight:	8.0 lb (3.6 Kg) with battery
Power:	Auto switching: 100–240 VAC, 47/63 Hz
Operating range:	0–36º C, 10–95% RH, non-condensing
Calibration:	Factory Prime Calibration of flow system accuracy.
Calibration frequency:	Recommended every 12 months.

Section 2: Operation

2.1 Basic operation of the CI-95A

2.1.1 How to take a sample

Before taking a sample, first make sure the yellow transit cover is removed. This will prevent possible damage to the internal blower or other electronics.

If not already set up, the sample volume can be set from the main screen by pressing [MORE] [SETUP] and using the left/right keys to set the desired sample volume. From the same menu the sample delay can be set. The unit can also be set to beep on completion of the sample, and the flow alarm can be enabled, which will cause an alarm condition if the flow deviates beyond ±10% from nominal.

The sampling process can be initiated from the main screen by pressing [START]. After the sample delay has expired, the bright green sample LED will light to provide a high visibility indicator of sampling in progress. Sampling can be stopped at any time by pressing [STOP] (unless the secure sample option has been enabled). Following completion of the specified sample volume, the pump will shut off and the bright green sample LED will flash (until a button is pressed) to provide a high visibility indication. Then the screen will display a message giving the date/time that the sample ended. Also, the beeper will sound six times at sample completion if that option had been enabled in the setup menu.

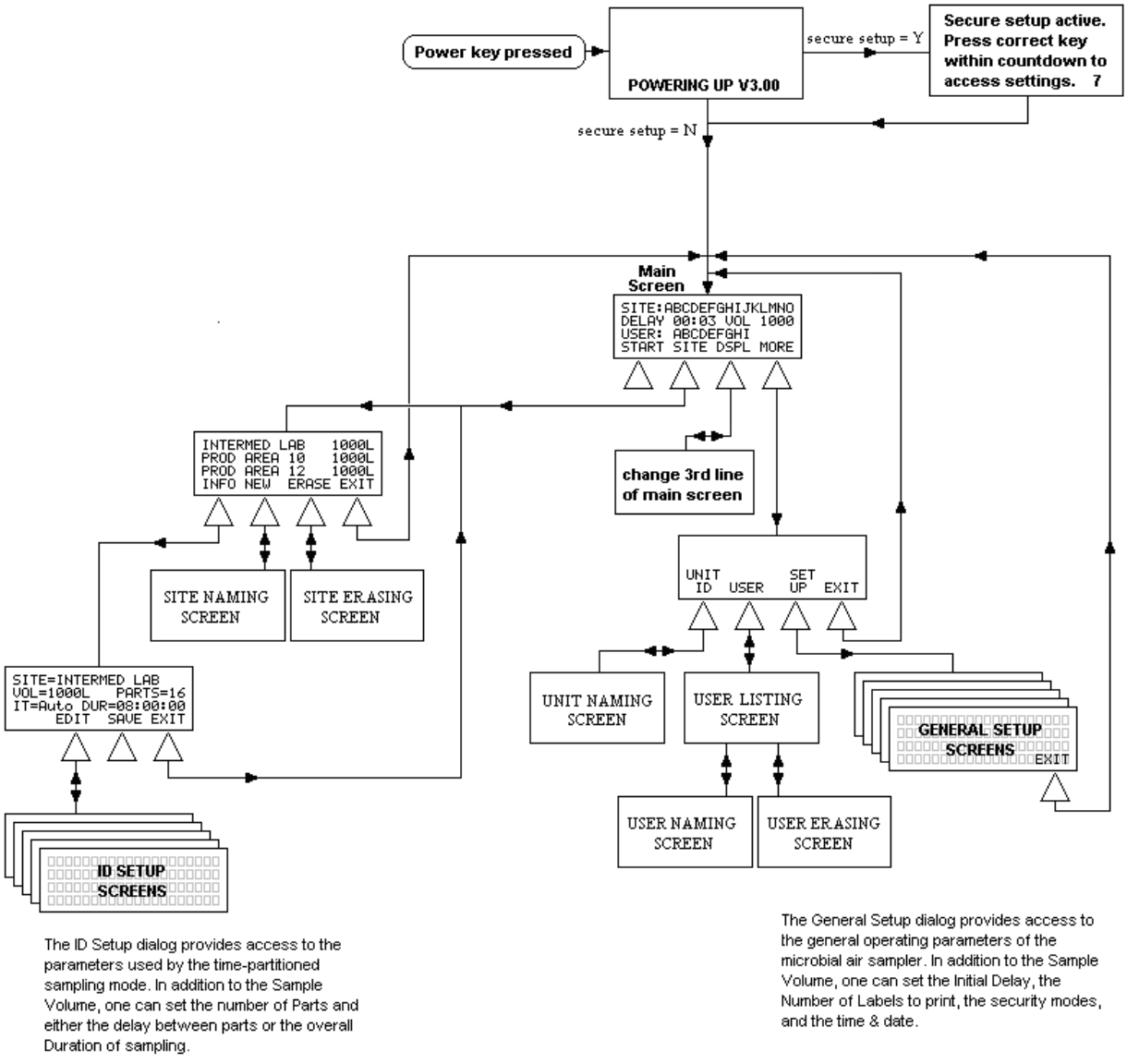
2.1.2 Extended-time Sampling

Some users might wish to extended-time sampling to monitor a work area over the duration of a time-consuming activity. Rather than collect samples on a number of petri dishes, this device allows samples to be broken into a number of subsamples separated by equal intervals. It allows the user to specify the total volume, the number of subsamples, and either the time between subsamples or the total duration of sampling.

If sampling is to be extended over a considerable length of time, the relevant settings are accessed by pressing [SITE][INFO][EDIT]. This allows sampling to be extended over an extended period of time by breaking the sample volume into several equal-sized parts, each separated by an inter-sample interval, or taken over a duration of up to 24 hours. The sampling parameters can be saved under a Site ID.

2.1.3 Operational Flow Diagram

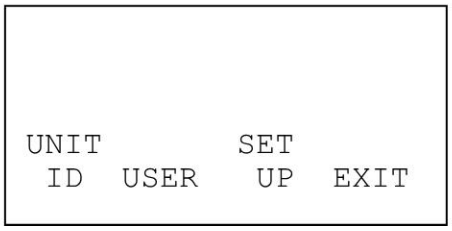
An operational diagram similar to a flow chart is provided here to give an idea of the intuitively simple operation of the CI-90. While this diagram does not explicitly detail every possible aspect of the microbial air sampler, it does describe the majority of possible operations.



Operating Flow Diagram

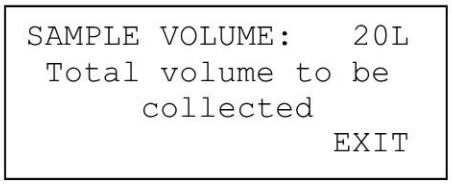
2.2 Setup menu options

The setup menu is entered from the main screen by pressing [MORE] followed by [SETUP]. The screen after pressing [MORE] appears below. The setup menu has a variety of options that can be set to control the sampling, alarms, and other features of the CI-95A. To ensure that these settings are retained, the user must press [EXIT] to return back to the main screen before turning power off. Pressing [EXIT] causes these settings to be stored in non-volatile memory. Thus, they are retained when power is off, the unit is unplugged, and even when the battery is disconnected.



2.2.1 Sample volume

The CI-95A has a number of preset sample volumes from which the user can choose. The minimum sample volume is 10 liters, which equates to a 6 second long sample time. The maximum sample volume is 6000 liters, which is 6 cubic meters and takes 60 minutes to complete. Sample volume choices available are 10, 12, 15, 20, 25, 30, 40, 50, 60, 80, 100, 125, 150, 200, 250, 300, 400, 500, 600, 800, 1000, 1100, 1250, 1500, 2000, 2500, 3000, 4000, 5000, and 6000 liters. An additional sample volume of INF is available (primarily as a maintenance feature) which runs the pump until the user presses [STOP].

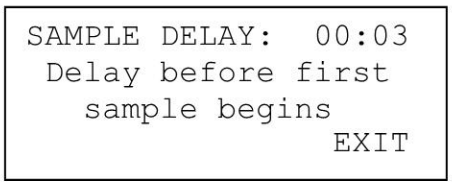


To select a sample volume, the user must first enter the setup menu, if not already there, and then use the up/down arrows as necessary to scroll the sample volume line to the top of the screen (as shown above). Once there, the current sample volume choice will blink, and the user can select the desired volume by using the left/right arrows to scroll through the available volumes. Holding any of the 4 direction keys down will conveniently cause them to auto-repeat. When the maximum or minimum volume has been reached the choices will roll over. Thus, when using the right arrow, 6000L will be followed by INF and then 10L. Similarly, when using the left arrow, 10L will be followed by INF and then 6000L.

2.2.2 Sample Delay

The CI-95A allows the user to set a sample delay time. Although the delay can be used for any purpose, it is typically used to give the user time to exit the area being sampled prior to the start of the sample. The CI-95A will start the pump 2 seconds before the end of the sample delay to get the flow up to speed for the start of the actual sample. The

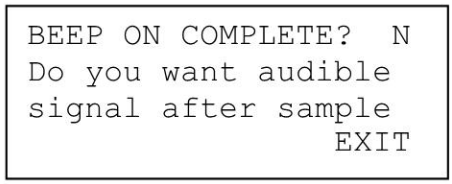
CI-95A has a range of sample delays from which the user can choose. The minimum sample delay is 3 seconds, and the maximum sample delay is 99 minutes 59 seconds. Delay values less than 00:03 are impossible to set. Sample delay choices are available in 1-second increments from 00:03 to 99:59.



To select the sample delay, the user must first enter the setup menu, if not already there, and then use the up/down arrows as necessary to scroll to the sample delay. The delay minutes and seconds are set separately. Once the cursor is on the sample delay minutes or seconds, the current value will flash. The user can select the desired delay by using the left/right arrows to scroll through the available values. When the minutes or seconds reach their limit the choices will roll over. Thus, when selecting the minutes with the right arrow, 99 minutes will be followed by 00. Similarly, when selecting seconds with the right arrow, 59 seconds will be followed by 00 or 03 (if minutes is currently 00). Using the left arrow will cause a roll over the other way.

2.2.3 Beep on complete?

The CI-95A allows the user to set an audible alert to signal the completion of a sample. If set, six loud beeps of short duration will occur at the end of a sample so that the user will know the sample ended. The bright green Sample LED will also flash until the user acknowledges the sample end by pressing [EXIT].



To select the beep on complete option, the user must first enter the setup menu, if not already there, and then use the up/down arrows as necessary to scroll to the BEEP ON COMPLETE field. The user can toggle this option on or off (Y or N) by using the left/right arrows.

2.2.4 Enable flow alarm?

The CI-95A allows the user to set a flow alarm that will detect an out-of-range flow condition. This guarantees all samples taken to be the correct sample volume within tolerance. The criteria for activating the flow alarm is a measured flow deviation from nominal of greater than ±10% for three consecutive seconds. The CI-95A's internal mass flow meter analog output is conditioned and converted into a digital signal representing the flow value. This digital value is monitored by the CI-95A's microprocessor and corrected using the stored flow calibration values. The flow value is converted and

displayed as the flow rate during sampling, and checked every second for alarm violation. When a flow alarm occurs, the CI-95A will stop sampling and display the message "FLOW FAILURE AT:" followed by the current date/time. An audible alert consisting of ten long beeps will notify the user of the alarm condition. Furthermore, the red alarm LED will continue flashing. After the user has recorded any relevant information, the CI-95A must be turned off and then back on to resume normal operation.

```
ENABLE FLOW ALARM? Y
Do you want audible
signal after error
                EXIT
```

To enable the flow alarm, the user must first enter the setup menu, if not already there, and then use the up/down arrows as necessary to scroll to the ENABLE FLOW ALARM field. The user can toggle this option on or off (Y or N) by using the left/right arrows.

If the flow alarm is not enabled (N), the unit will still go into flow alarm if the flow drops below approximately 70 LPM for 3 consecutive seconds. This serves as a preventive measure to very inaccurate sampling.

2.2.5 Secure setup?

To enable Secure Setup, the user must first enter the setup menu, if not already there, and then use the up/down arrows as necessary to scroll to the SECURE SETUP field. The user can toggle this option on or off (Y or N) by using the left/right arrows.

```
SECURE SETUP?      N
 Prevent changes to
 sample parameters
                EXIT
```

The Secure Setup feature of the CI-95A allows the user to lock out the [MORE] key. This prevents change of settings, unit ID, or user. The user can still, however, alter the site and main screen third line display. The key label "MORE" will not be visible, and pressing the [MORE] key will not have any effect. This does NOT prohibit changing settings via Site selection, but it does prohibit modification of Site parameters. When the CI-95A is powered up with Secure Setup enabled, the screen below will appear.

```
Secure setup active.
Press correct key
within countdown to
access settings.   7
```

This screen allows the user 7 seconds to bypass security by pressing a special key. This key is the far right menu key under the screen. If this is pressed prior to the

countdown number in the lower right corner reaching zero, then security is bypassed and the [MORE] key becomes visible and functional. It is important to note that the only way to cancel Secure Setup is to press the special key during the 7-second screen, then at some point entering the setup screen.

Upon pressing the [SETUP] key, the firmware will automatically change the Secure Setup setting to 'N'. If the user intends to retain Secure Setup, he must remember to change the setting back to 'Y'. The fact that the user entered the SETUP screen is interpreted by the firmware as intent to alter the setup, thus spoiling the security of the previous setup. This is why it automatically cancels the Secure Setup.

2.2.6 Secure sample?

The Secure Sample feature of the CI-95A allows the user to essentially lock the keyboard during a sample. Only the DSPL key will function and allow changing the information displayed on the main screen third line. This prevents the sample from being stopped prior to its completion, and prevents user access to any of the CI-95A's settings. When in Secure Sample mode the user can access all features of the CI-95A until the [START] key is pressed. After this, only the DSPL key functions, preventing the user from changing the site ID, the user ID, the unit ID, or any of the parameters available under the setup menu. The user, of course, can still stop the sample by pressing [POWER] to turn the unit off.

```
SECURE SAMPLE?     N
Prevent interruption
of sample in process
                 EXIT
```

To enable Secure Sample, the user must first enter the setup menu, if not already there, then use the up/down arrows as necessary to scroll to the SECURE SAMPLE field. The user can toggle this option on or off (Y or N) by using the left/right arrows.

2.2.7 Date format

The Date Format feature of the CI-95A allows the user to select either an MM/DD/YY or DD/MM/YY format for the date. All displays or printouts will be formatted according to the option selected.

```
DATE FORMAT MM/DD/YY

   US Date format
                 EXIT
```

To select a date format, the user must first enter the setup menu, if not already there, and then use the up/down arrows as necessary to scroll to the DATE FORMAT field. The user can toggle this option between MM/DD/YY and DD/MM/YY by using the left/right arrows.

2.2.8 Date/time

The CI-95A allows the user to set the current date and time. Once set, the CI-95A's internal real time clock will continue to keep the date and time. The real time clock is powered off the internal battery, but a backup capacitor provides enough power (over 30 minutes) to allow the battery to be changed without losing the date/time setting.

```
10/26/2005  10:55:30

Current Date & Time
                EXIT
```

To change the date/time, the user must first enter the setup menu, if not already there, and then use the up/down arrows as necessary to scroll to the date/time fields. There are six separate entry fields, one each for month, day, year, hours, minutes, and seconds. Once the cursor is on the desired entry field, the user can set the field by using the left/right arrows to scroll through the available values. The fields will roll over when they have reached a limit, except for the year field.

2.3 Setting the USER ID

2.3.1 Creating an ID

The CI-95A User ID's can be assigned a 1 to 9 character identification. The operator can enter up to 10 ID names. To create a User ID, press [MORE] from the main screen, then [USER] and observe the User screen appears. The currently selected User ID will be blinking on the top line.

```
User name 1
User name 2
User name 3
01   NEW  ERASE EXIT
```

To reach the ID entry screen, which will add a User ID in the user list below the currently selected ID, press [NEW] and observe the screen below appears. Note that if 10 ID's are already stored in memory, the [NEW] key is simply ignored.

```
1234567890#/.-ABCDEF
GHIJKLMNOPQRSTUVWXYZ
USER=_ _ _ _ _ _ _ _ _ _
BACK SPACE  NEXT  EXIT
```

To enter the desired name, use the left/right/up/down arrows to navigate the cursor to the desired character. Press [NEXT] to enter the character where the blinking underscore currently is in the user name. Continue this until the complete name has been entered.

The [SPACE] key can be used to enter a space character into the name. The [BACK] key will move the "blink" in the name to the left 1 character (with wraparound), but will not erase any character it was blinking. This is convenient for going back to edit characters. When finished, press [EXIT] to return to the User screen.

2.3.2 Selecting an ID

From the main screen, press [MORE] and [USER] to enter into the User screen. Then use the up/down arrows to scroll to the desired ID, placing it at the top of the screen where it will blink. The number at the lower left of the screen is the number of this selected ID. Press [EXIT] to finalize the selection and return to the MORE screen.

2.3.3 Deleting an ID

From the main screen, press [MORE] and [USER] and then scroll to the desired ID, which will then be blinking at the top of the screen. Press [ERASE] then [YES] to delete the ID and return to the User screen.

2.4 Setting the SITE ID

2.4.1 Creating an ID

The CI-95A location (Site) ID's can be assigned a 1 to 15 character identification. The user can enter up to 70 ID names. To create a Site ID, press [SITE] from the main screen and observe the Site screen appears. The currently selected ID will be blinking on the top line.

```
Location name 1  INF
Location name 2   50
Location name 3  100
INFO NEW  ERASE EXIT
```

To reach the ID entry screen, which will add a Site ID in the site list below the currently selected ID, press [NEW] and observe the screen below appears. Note that if 100 ID's are already stored in memory, the [NEW] key is simply ignored.

```
1234567890#/.-ABCDEF
GHIJKLMNOPQRSTUVWXYZ
ID = _______________
BACK SPACE NEXT EXIT
```

To enter the desired name, use the left/right/up/down arrows to navigate the cursor to the desired character. Press [NEXT] to enter the character where the blinking underscore currently is in the ID name. Continue this until the complete ID name has been entered. The [SPACE] key can be used to enter a space character into the ID name. The [BACK] key will move the "blink" in the ID name to the left 1 character (with wraparound), but will not erase any character it was blinking. This is convenient for going back to edit characters. When finished, press [EXIT] to return to the site screen.

2.4.2 Selecting an ID

From the main screen, press [SITE] and then scroll to the desired ID. The number at the lower left of the screen is the number of the currently highlighted ID at the top of the screen. While the up/down arrow keys will decrease/increase the scroll (ID number) by 1, the left/right arrow keys will decrease/increase by 10 (or to 0 and 100 if less than 10 away). Additionally, all arrow keys auto-repeat so that the list can be scrolled quickly. Press [EXIT] to select the highlighted ID and return to the main screen.

2.4.3 Deleting an ID

From the main screen, press [SITE] and then scroll to the desired ID. Press [ERASE] then [YES] to erase the highlighted ID and return to the site screen.

2.4.4 Viewing the Sample Settings for an ID

From the main screen, press [SITE] and then scroll to the desired ID. Press [INFO] to view the sample settings for the highlighted ID. In addition to the Sample Volume, the other values that are shown in this view include the time-extended sampling parameters that are stored with this ID.

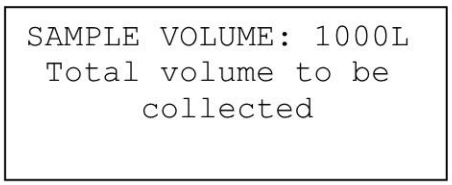
```
SITE=ABCDEFGHIJKLMNO
VOL=1500L  PARTS= 6
IT=Auto DUR=08:00:00
     EDIT  SAVE EXIT
```

The [SAVE] button will not be visible until some change has been made to the current system settings that differ from the stored settings. Press the [EDIT] button to enter the Site Parameters dialog that accesses these values. Be aware that certain selections block access to other parameters. For example, if the INF sample volume is selected, none of the other parameters will be available because they have no meaning since an infinite sample volume has no end. If a definite sample volume is selected, then the question of how many parts that sample should be broken into becomes relevant. However, if only a single part is chosen, none of the remaining parameters is needed.

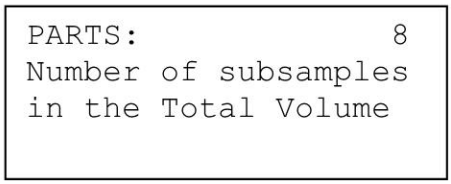
Pressing the [EXIT] button will return to the Site Selection screen.

2.4.5 Editing the Sample Settings for an ID

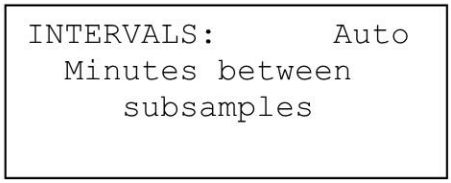
From the Site Selection screen, scroll to the desired ID, press [INFO] and then press [EDIT]. The parameter-setting dialog begins with the selection of the total sample volume. The minimum sample volume is 10 liters, which equates to a 6 second sample time. The maximum sample volume is 6000 liters, which is 6 cubic meters and takes 60 minutes to complete. Sample volume choices available are 10, 12, 15, 20, 25, 30, 40, 50, 60, 80, 100, 125, 150, 200, 250, 300, 400, 500, 600, 800, 1000, 1100, 1250, 1500, 2000, 2500, 3000, 4000, 5000, and 6000 liters. An additional sample volume of INF is available (primarily as a maintenance feature) which runs the pump until the user presses [STOP].



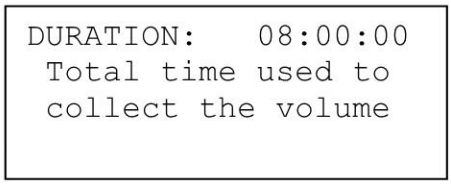
Use the Right and Left arrows to select the desired sample volume, and press the Down arrow to move on to the next parameter. Unless INF is chosen, the next parameter will be PARTS.



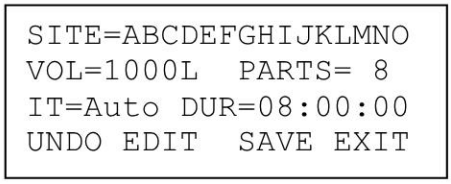
Use the Right and Left arrows to select the desired number of parts the sample volume should be broken into, and press the Down arrow to move on to the next parameter. Unless 1 is chosen, the next parameter will be INTERVALS.



Use the Right and Left arrows to select the desired number of minutes between subsamples, and press the Down arrow to move on to the next parameter. Only if Auto is chosen, the next parameter will be DURATION.



Duration is the total time, not counting the Initial Delay, that the sampler will use to collect the total volume. The [SAVE] button will not be visible unless some change has been made to the current system settings that differ from the stored settings.

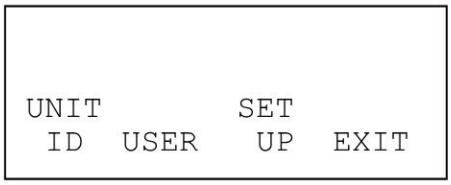


Press the [BACK] button to restore the original values stored under this Site ID. Press the [EDIT] to run through the dialog again with the currently displayed parameters, and press the [SAVE] button to save these values in this Site ID. Press the [EXIT] button to

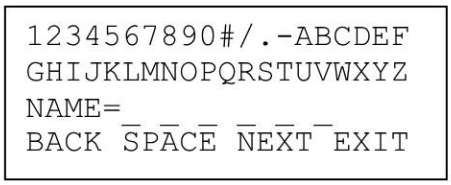
return to the Site Selection screen. The currently displayed sample parameters will remain in effect until others are selected even if they are not saved to the current ID.

2.5 Setting the UNIT ID

The CI-95A Unit ID can be assigned a 1 to 6 character identification. To create the Unit ID, press [MORE] and observe the following screen appears:



To reach the ID entry screen press [UNIT ID] and observe the following screen appears:



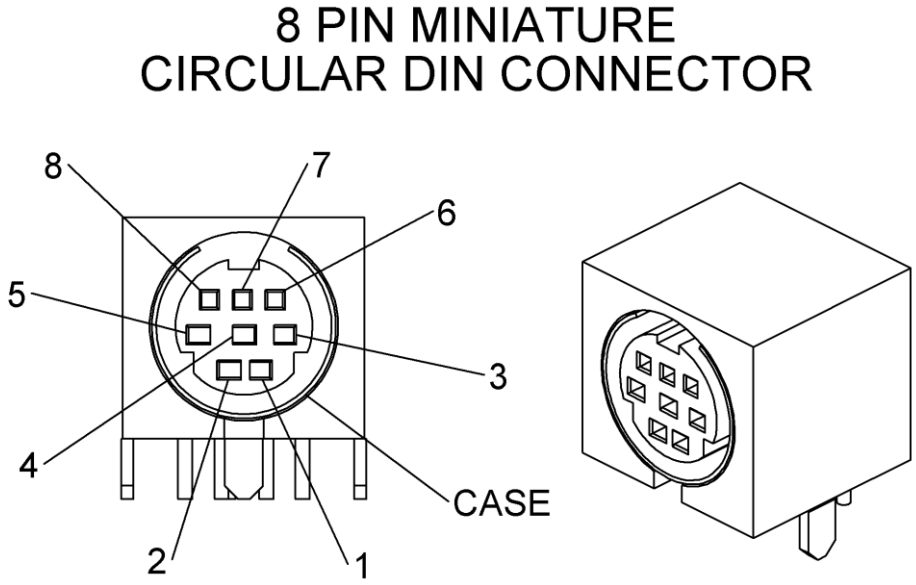
To enter the desired name, use the left/right/up/down arrows to navigate the cursor to the desired character. Press [NEXT] to enter the character where the blinking underscore currently is in the unit name. Continue this until the complete unit name has been entered. The [SPACE] key can be used to enter a space character into the unit name. The [BACK] key will move the "blink" in the unit name to the left 1 character (with wraparound), but will not erase any character it was blinking. This is convenient for going back to edit characters. When finished, press [EXIT] to return to the MORE screen.

Section 3: Auxiliary connections

3.1 RS-232 interface

The CI-95A has an RS-232 interface that allows the CI-95A to communicate with the serial port of a PC. There are two commands that are primarily used for maintenance, and two others that provide the ability to rapidly enter Site and User ID's into the unit. The Site and User ID names are created in the separately purchased program named CI-9x Loader, then downloaded serially into the CI-95A. This program runs on a Windows PC and communicates with the CI-95A through the serial port illustrated below.

Communication via the RS-232 port is at 9600 bps, 8-bit, 1 stop, no parity, no handshaking, and uses a special serial cable (Part Number 01206900).



PIN-1 N/C
PIN-2 RTS (HIGH)
PIN-3 TRANSMIT
PIN-4 GROUND
PIN-5 RECEIVE
PIN-6 N/C
PIN-7 N/C
PIN-8 N/C
CASE GROUND

3.2 RS-232 Commands

Each of the four RS-232 commands is only a single letter in length. They are listed below, along with their functional descriptions.

Command	Function
Y	Send model and software revision numbers, flow 90% and 100% A/D values, and flow digital pot setting
K	Receive Site ID strings into the CI-95A
k	Receive User ID strings into the CI-95A
o	Send the total time that the blower has been run

When the Y command is received the CI-95A responds by sending back the following:

CI-95A	model number
Software Revision 3.00	software revision number
209	flow 90% A/D value; 209 is typical
221	flow 100% A/D value; 221 is typical
010	flow digital pot setting; 010 is typical

The "CI-95A" is used by **CI9xV3Loader** (see below, for details) to identify which model of CLiMET instrument it is communicating with. All other information is provided for technicians and maintenance personnel during calibration and repair.

When the K command is received the CI-95A responds by first starting a 28 second timer, then storing the next 1500 characters it receives into non-volatile memory and setting the current site ID to the blank (000). If the timer ends before 1500 characters are received, it determines the last full 15 character ID that entered and sets it as the current site ID. This serves as an indication to the user that something has malfunctioned, since it routinely does it in about half the timer duration.

When the k command is received the CI-95A responds by first starting a 4 second timer, then storing the next 90 characters it receives into non-volatile memory and setting the current user ID to the blank (00). If the timer ends before 90 characters are received, it determines the last full 9 character ID that entered and sets it as the current user ID. As with the K command, if the current user is not set to blank (00), something has gone wrong with the download.

When the o command is received the CI-95A responds by sending back the following:

hhhhh hours, mm minutes of blower run time.	h and m are numerals 0-9

This command is normally used by a technician to determine the amount of run time on the blower.

3.3 CI9xV3 Loader

CI-9x Loader V3 (P/N 95035103) is a separate program that allows the user to load all 70 site ID's and all 10 user ID's from a PC without having to use the CI-90's alpha entry menu. Although the CI-90's alpha entry screen is a convenient, stand-alone way to enter ID names, it is time consuming to use the arrow keys to maneuver to each character entered. **CI9xV3Loader** offers a much faster method by utilizing a PC with its keyboard, along with the familiar Windows environment. The software allows the user to enter Site IDs and their associated sample parameters, and to store the lists in computer files for easy recall and loading into multiple Microbial Samplers.

To use **CI9xV3Loader**, one plugs the serial adapter cable that comes with program (CLiMET P/N 01219500) into the serial port of their PC. The other end is then plugged into the CI-90's RS-232 port, which is located on the rear panel next to the power plug. **CI9xV3Loader** is then started on the PC, the site and user ID's are entered into the program's site and user lists, and then the lists are separately downloaded into the CI-90 (the 90 must be on and not sampling). The list of sites and user ID's can also be saved as a named file for use at a later time. For detailed instructions on how to use **CI9xV3Loader**, please consult the manual that comes with the software.

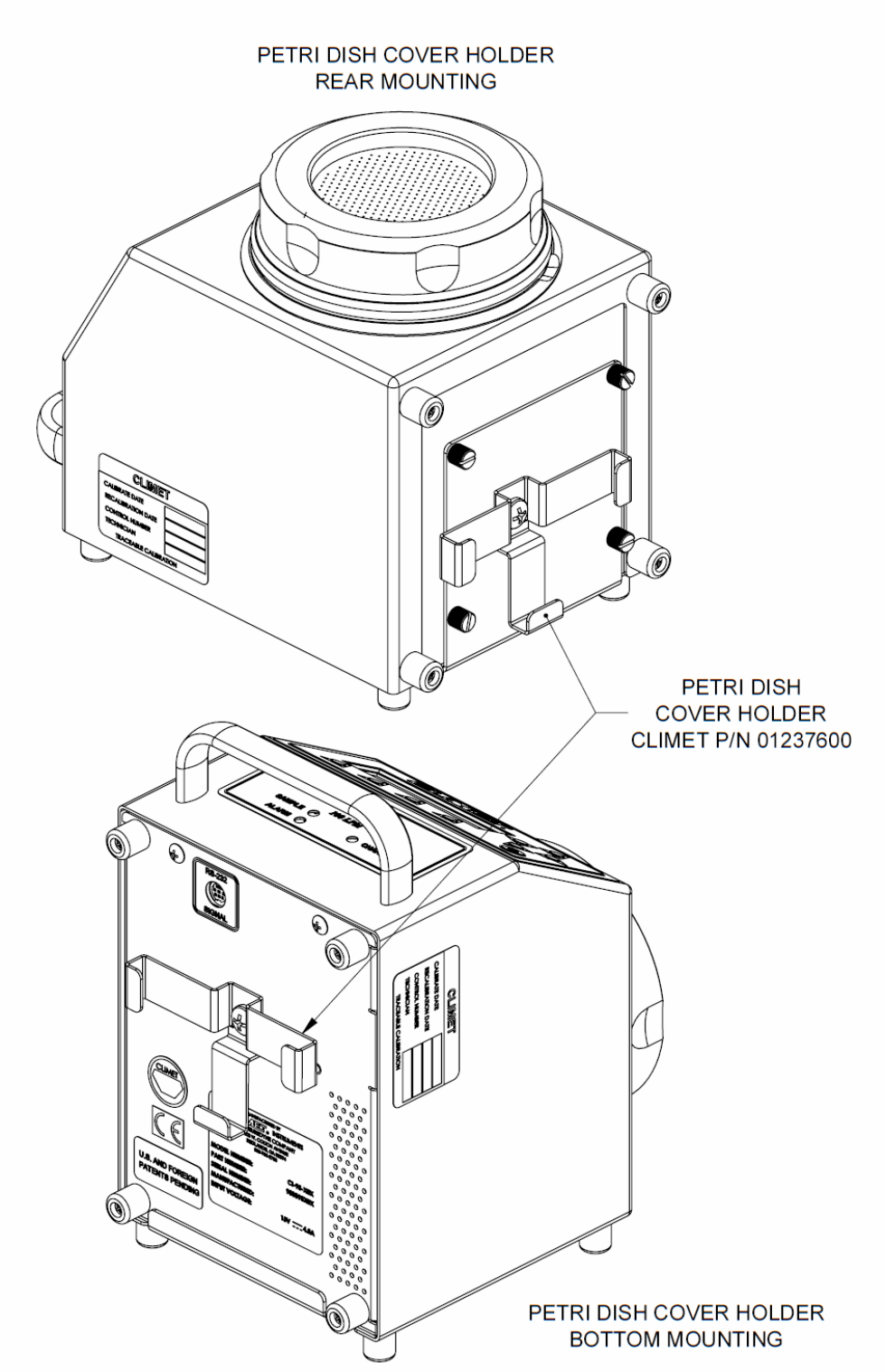
NOTE: *The earlier version of the **CI-9x Loader** software is not compatible with the Version 3 firmware described in this manual. The Version 3 firmware requires a new data format, including new information that is incompatible with earlier firmware versions.*

Section 4: Accessories

4.1 Petri dish cover holder

4.1.1 Attachment of Petri dish cover holder

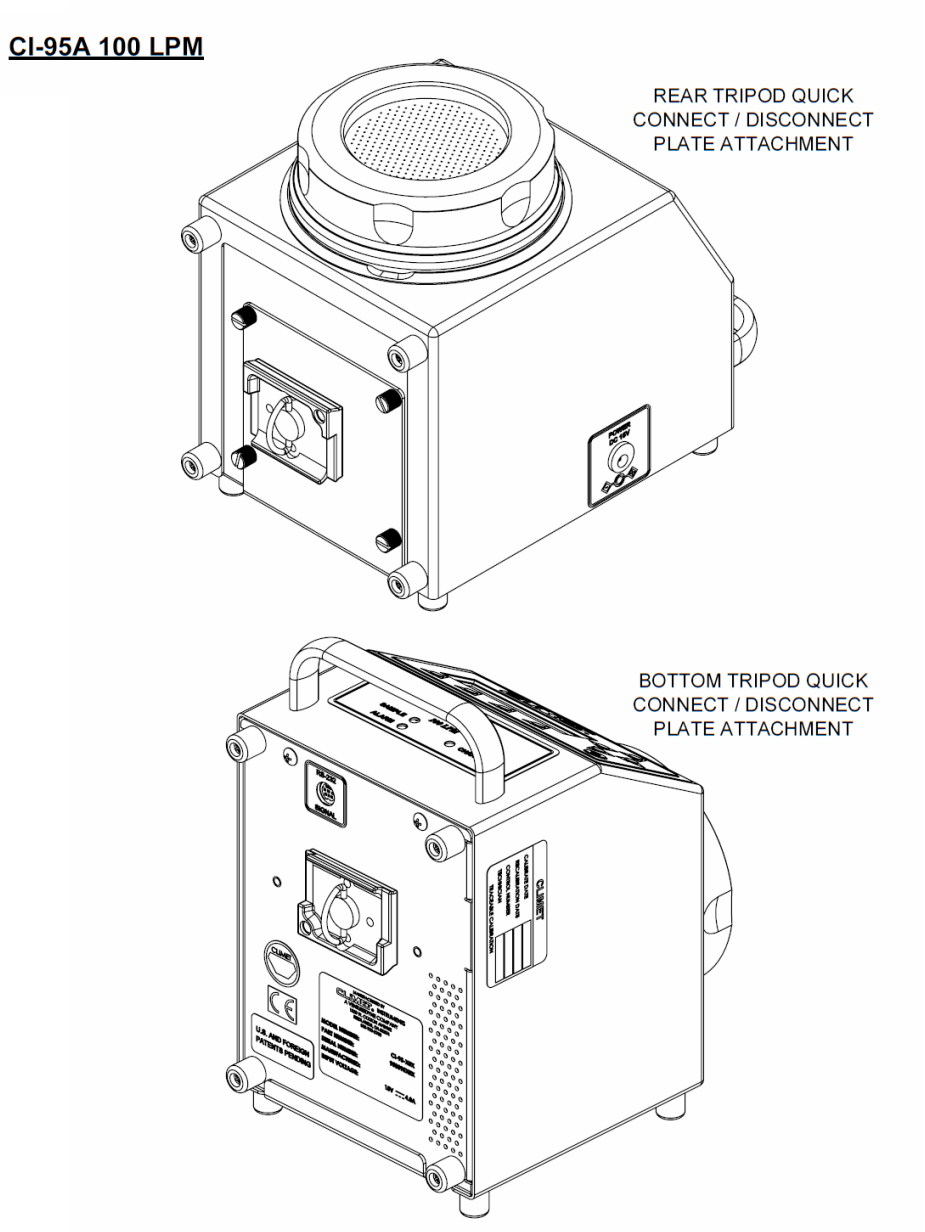
The petri dish cover holder can attach to either the back or bottom of the unit using the ¼-20 thread tripod mounts as shown in the illustration that follows. The petri dish cover holder (CLiMET #01237600) is secured using a pan head Phillips ¼-20 x 3/8 Lth. screw that is provided (CLiMET #60662400). Note that if the petri dish cover holder is secured to the back of the unit, it can not be placed on it's back feet anymore. This also applies to placing the unit on its bottom feet if the petri dish cover holder is secured to the bottom of the unit.


PETRI DISH COVER HOLDER
REAR MOUNTING
PETRI DISH
COVER HOLDER
CLIMET P/N 01237600
PETRI DISH COVER HOLDER
BOTTOM MOUNTING

4.2 Tripod

4.2.1 Recommended Tripod / Tripod head

The CI-95A microbial sampler has two locations where a tripod can be attached as shown earlier on page 7. CLiMET Instruments recommends that the Manfrotto #3001N basic tripod without head and the Manfrotto #486RC2 compact ball head with RC2 rapid connect system be used. The head includes a quick connect / disconnect plate that attaches to the CI-95A as shown below.



Manfrotto Head #486RC2

Manfrotto Tripod #3001N

Section 5: Service and maintenance

5.1 User maintenance

5.1.1 Battery replacement

To gain access to the battery, unscrew the four thumbscrews on the battery door. The battery rests in a fitted compartment attached to the base. The battery has a single 3-pin connector which mates to a panel mounted connector in the battery compartment. To free the battery from the enclosure all that is necessary is to unplug the 3-pin connector. The battery can then be removed. Replacement is a reversal of this procedure.

5.1.2 Long term storage

If the CI-95A is to be stored for three months or longer without use, the battery should be disconnected to prevent damage to the battery from a deep discharge. To gain access to the battery, unscrew the four thumbscrews on the battery door. The battery rests in a fitted compartment attached to the base. The battery has a single 3-pin connector which mates to a panel mounted connector in the battery compartment. To free the battery from the enclosure all that is necessary is to unplug the 3-pin connector. The battery can then be removed. Reconnect the battery again before use

5.2 Calibration service

The CI-95A, like any other electronic measurement equipment, should be calibrated at least annually. The purpose of the calibration is to establish that the unit is in tolerance, and that sample volume is therefore accurate.

The accuracy and consistency of your CI-95A can be degraded by unqualified and marginally experienced calibration services. To insure that the flow rate of the instrument is maintained to factory specifications, you may ship your unit to either our Eastern or Western service facility, or arrange for on-site service. For locations outside the U.S., consult your local distributor.

CLiMET's calibration service follows ANSI Z-540 and ISO 10012, providing both *as found* and *as left* measurements, as well as *in-tolerance* or *out-of tolerance* findings.

Our Service Center can be contacted by phone at 909-793-2788, by fax at 909-793-1738, or by email at service@CLiMET.com.

When shipping units, use the original shipping carton, a well padded shipping case, or a box that allows at least two inches of bubble wrap extending from the greatest protrusion on *all* sides of the instrument. Loose packing material, commonly referred to as *peanuts,* provides psychological comfort, but very little real protection.

Appendix — Feller Correction

There is a statistical analysis that corrects the observation to a *probable statistical total*. This compensates for the fact that the probability of a *colony forming unit (CFU)* passing through a given perforation increases with the actual concentration of microbes per cubic meter. What this means is that as the total number of CFUs passing through the perforated plate increases, the likelihood of a CFU passing through a hole that has already passed a CFU during the sample increases. The result is an undercount.

William Feller provides the correction in *An Introduction to Probability Theory and its Applications.* Vol 1. 3rd ed. New York: John Wiley and Sons, 1968. pp. 224-225.

The governing equation for this correction is:

$$Pr = N * [1/N + 1/(N-1) + 1/(N-2) + \ldots + 1/(N-r+1)]$$

Pr := Probable statistical total
N := Number of holes in perforated lid (Climet has 333 holes)
r := Number of CFUs observed on the incubated Petri dish

It is relatively easy to add a **Feller** function to an ***Excel*** spreadsheet. Simply execute the following steps:

- On the **Tools** menu, point to **Macro**, and then select **Visual Basic Editor**
- On the **Insert** menu in the **Microsoft Visual Basic** window, select **Module**
- In the **Module** window, type the code below

```
Function Feller(r)
    If r = 1 Then
        Feller = 1
    Else
        Feller = Feller(r - 1) + 333 / (334 - r)
    End If
End Function
```

- On the **File** menu, select **Close and Return to Microsoft Excel**

On the worksheet, insert the formula ***=Feller(A2)*** in the cell where you want the Probable Statistical Total to appear (assuming you have placed the observed value in cell A2).

The Feller Table below shows the corrected totals for every value one might observe with the Climet samplers. For example, if you obtain a sample on which you observe 105 colonies, you simply find 105 in column A in the table, and obtain 125.9 from the adjacent column B to the right.

Feller table for CI-90A and CI-95A

A	B	A	B	A	B	A	B
1	1.0	31	32.5	61	67.3	91	106.1
2	2.0	32	33.6	62	68.5	92	107.5
3	3.0	33	34.7	63	69.7	93	108.9
4	4.0	34	35.8	64	71.0	94	110.3
5	5.0	35	36.9	65	72.2	95	111.6
6	6.0	36	38.0	66	73.4	96	113.0
7	7.1	37	39.2	67	74.7	97	114.5
8	8.1	38	40.3	68	75.9	98	115.9
9	9.1	39	41.4	69	77.2	99	117.3
10	10.1	40	42.5	70	78.5	100	118.7
11	11.2	41	43.7	71	79.7	101	120.1
12	12.2	42	44.8	72	81.0	102	121.6
13	13.2	43	46.0	73	82.3	103	123.0
14	14.3	44	47.1	74	83.5	104	124.5
15	15.3	45	48.3	75	84.8	105	125.9
16	16.4	46	49.4	76	86.1	106	127.4
17	17.4	47	50.6	77	87.4	107	128.8
18	18.5	48	51.7	78	88.7	108	130.3
19	19.5	49	52.9	79	90.0	109	131.8
20	20.6	50	54.1	80	91.3	110	133.3
21	21.7	51	55.3	81	92.7	111	134.8
22	22.7	52	56.4	82	94.0	112	136.3
23	23.8	53	57.6	83	95.3	113	137.8
24	24.9	54	58.8	84	96.6	114	139.3
25	25.9	55	60.0	85	98.0	115	140.8
26	27.0	56	61.2	86	99.3	116	142.3
27	28.1	57	62.4	87	100.7	117	143.9
28	29.2	58	63.6	88	102.0	118	145.4
29	30.3	59	64.8	89	103.4	119	147.0
30	31.4	60	66.0	90	104.7	120	148.5

A = Colonies counted

B = Probable Total

Feller table for CI-90A and CI-95A (Cont.)

A	B	A	B	A	B	A	B
121	150.1	151	200.8	181	260.6	211	333.5
122	151.7	152	202.6	182	262.8	212	336.2
123	153.2	153	204.4	183	265.0	213	339.0
124	154.8	154	206.3	184	267.2	214	341.8
125	156.4	155	208.1	185	269.4	215	344.6
126	158.0	156	210.0	186	271.7	216	347.4
127	159.6	157	211.9	187	273.9	217	350.2
128	161.2	158	213.8	188	276.2	218	353.1
129	162.9	159	215.7	189	278.5	219	356.0
130	164.5	160	217.6	190	280.8	220	358.9
131	166.1	161	219.5	191	283.1	221	361.9
132	167.8	162	221.5	192	285.5	222	364.8
133	169.4	163	223.4	193	287.9	223	367.8
134	171.1	164	225.4	194	290.2	224	370.9
135	172.8	165	227.3	195	292.6	225	373.9
136	174.5	166	229.3	196	295.0	226	377.0
137	176.2	167	231.3	197	297.5	227	380.1
138	177.8	168	233.3	198	299.9	228	383.3
139	179.6	169	235.3	199	302.4	229	386.4
140	181.3	170	237.4	200	304.9	230	389.6
141	183.0	171	239.4	201	307.4	231	392.9
142	184.7	172	241.5	202	309.9	232	396.1
143	186.5	173	243.5	203	312.4	233	399.4
144	188.2	174	245.6	204	315.0	234	402.8
145	190.0	175	247.7	205	317.6	235	406.1
146	191.8	176	249.8	206	320.2	236	409.5
147	193.5	177	251.9	207	322.8	237	413.0
148	195.3	178	254.1	208	325.5	238	416.4
149	197.1	179	256.2	209	328.1	239	419.9
150	198.9	180	258.4	210	330.8	240	423.5

A = Colonies counted

B = Probable Total

Feller table for CI-90A and CI-95A (Cont.)

A	B	A	B	A	B	A	B
241	427.0	271	557.6	301	775.3	331	1627.3
242	430.7	272	563.0	302	785.8	332	1793.8
243	434.3	273	568.4	303	796.5	333	2126.8
244	438.0	274	574.0	304	807.6		
245	441.8	275	579.6	305	819.1		
246	445.6	276	585.4	306	831.0		
247	449.4	277	591.2	307	843.3		
248	453.3	278	597.2	308	856.1		
249	457.2	279	603.2	309	869.4		
250	461.1	280	609.4	310	883.3		
251	465.1	281	615.7	311	897.8		
252	469.2	282	622.1	312	912.9		
253	473.3	283	628.6	313	928.8		
254	477.5	284	635.2	314	945.4		
255	481.7	285	642.0	315	963.0		
256	486.0	286	649.0	316	981.5		
257	490.3	287	656.1	317	1001.0		
258	494.7	288	663.3	318	1021.9		
259	499.1	289	670.7	319	1044.1		
260	503.6	290	678.3	320	1067.8		
261	508.2	291	686.0	321	1093.5		
262	512.8	292	693.9	322	1121.2		
263	517.5	293	702.1	323	1151.5		
264	522.2	294	710.4	324	1184.8		
265	527.1	295	718.9	325	1221.8		
266	532.0	296	727.7	326	1263.4		
267	536.9	297	736.7	327	1311.0		
268	542.0	598	745.9	328	1366.5		
269	547.1	299	755.5	329	1433.1		
270	552.3	300	765.3	330	1516.3		

A = Colonies counted

B = Probable Total

EU Declaration of Conformity

EU Directives covered by this declaration:	EMCD 2014/30/EU
Standards Which Product Conforms To:	EN61326-1:2013 Class A
Manufacturer's Name:	Climet Instruments Company
Manufacturer's Address:	1320 West Colton Avenue Redlands CA 92374 909-793-2788
Equipment Description:	Microbial Sampler
Equipment Class:	Electrical Equipment Measurement Control & Laboratory Use – Industrial
Model Numbers:	CI-95A
European Contact:	Kay Walshaw Thermotron Industries UK Kent Science Park Sittingbourne, Kent ME9 8EF England

This declaration has been issued under the sole responsibility of the manufacturer. The object of the declaration is in conformity with relevant Union harmonization legislation

I, the undersigned, hereby declare that the equipment specified above conforms to the directives and standards.

Place: Redlands, California USA
Date: March 28, 2017

David L. Chandler
Engineering Manager

Attention

The attention of the purchaser, installer or user is drawn to the special measures and limitations which must be observed when the product is taken into service, in order to maintain compliance with the above directives. Details of the special measures and requirements are detailed in this product's user manual.

SUBJECT:	Single Dose / Multiple Dose Drug Vials or Ampules, Overwrapped Containers	REFERENCE #:	7065
DEPARTMENT	Clinical Operations	EFFECTIVE DATE:	05/01/2015
APPROVED BY:	VP Pharmacy Operations	REVIEWED DATE:	7/31/2018
		APPROVED DATE:	04/29/2015
REVISIONS:		REVISION DATE:	05/01/2015 01/29/2016 01/03/2017 06/07/2018

SCOPE

This policy and procedure applies to pharmacies or other entities under the ownership or control of BriovaRx Infusion Services, Inc. (the Company).

PURPOSE

To establish a uniform policy on shelf life and handling of all multiple dose vials, single dose medications or unit dose ampules, and overwrapped solution containers used for patient care.

DEFINITIONS/REFERENCES/REQUIREMENTS

Single dose drug products contain no preservatives. Single dose drug products may contain more than one dose.

Multiple dose drug products are preserved to help retard the growth of bacteria that may be inadvertently introduced with the penetration of the stopper by the needle. Multiple dose vials contain more than one dose.

Overwrapped solutions are those solutions or premixed medications that are packaged in plastic or foil to prevent loss of solution as part of the evaporation process. Examples include overwrapped packages of 24, 100ml 0.9% NaCl manufactured by Baxter, 1000ml containers of hydration, milrinone, Cipro, etc.

POLICY

Single dose containers are preferred over multiple dose containers. If this is not possible, the smallest multiple dose container available should be used.

PROCEDURE

1. Single Dose Drug Vials or Ampules

    a. Single dose (i.e. unit dose) glass ampules/syringes are specifically designed for single dose only. Any unused portions of medications must be discarded immediately.

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b. Opened single dose drug vials used in the preparation of parenteral nutrition (i.e. vials of electrolytes, trace elements) will remain in the ISO class 5 area, be labeled with the time and date of initial entry and disposed after six (6) hours of the initial entry or sooner per manufacturer guidelines.

c. Bulk containers used in the preparation of parenteral nutrition or reconstitution of medication (i.e. those solutions that are set up on an automated compounding device (ACD)) will remain in the ISO class 5 area, be labeled with the time and date or initial entry and be disposed of after six (6) hours of the initial entry.

d. Single dose drug vials used in the preparation of antibiotics, if not completely used, will be discarded.

    1) To avoid wastage, vials should be selected which meet the total amount required. For example, if compounding a 14 gram total dose of vancomycin, 2 x 5gm and 4 x 1gm should be selected.

e. A sterile syringe and needle or needleless device must be used to withdraw the required amount of medication from single dose vials.

f. For withdrawing medication from single dose glass ampule, use a 5 micron filter needle. The filter needle will prevent minute particles of glass from entering the syringe. Prior to administering the medication to the patient, the filter needle must be replaced with a regular sterile needle for parenteral injection or a needleless adapter.

2. Multiple Dose Drug Vials

a. Ideally, BULK antibiotic vials should only be used on one patient; they cannot be shared across multiple patients due to potential billing or reimbursement issues. Picking exact doses is important as shown below:

    1) To avoid wastage, vials should be selected which meet the total amount required. For example, if compounding a 14 gram total dose of ceftriaxone, 1 x 10gm and 4 x 1gm or 2 x 2gm should be selected.

b. Aseptic technique is always used. Wipe the top of the vial access port with sterile 70% isopropyl alcohol and allow it to dry for at least 10 seconds prior to withdrawing the fluid.

c. Visual inspection of the vial should be accomplished each time medication is withdrawn to determine that the stopper is intact and that no unusual particulate matter is in the vial. Check the vial for turbidity, discoloration, and integrity of rubber stopper seal.

d. A sterile unused vial adapter may be used for each bottle.

e. Avoid opening more than one multiple dose vial of the same medication at the same time.

f. Refrigeration of opened multiple dose vials is product specific (i.e., insulin, heparin, etc., will be refrigerated). Routine refrigeration of opened multiple dose vials is not recommended. Read the label.

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g. Multiple dose vials will be discarded when they are empty or when the manufacturer's expiration date is reached, whichever comes first.

   1) If the manufacturer does not provide guidelines as to when to discard a partially used multiple dose vial, the date used will be 28 days in the future from which the vial is first entered.

h. Multiple doses vials will have the date at which it should be discarded on the label with indelible ink.

3. Overwrapped solutions

   a. Overwrapped solutions that have had the overwrap opened will be discarded based on the manufacturer's recommendations. For example Baxter recommends that their 50ml overwrapped minibags be not used past 15 days once the overwrap is opened.

   b. Any remaining solutions in an open overwrap will be labeled or marked with a "Do not use beyond_____(write in date)".

   c. Beyond use dating on the overwrapped solution is to be taken into consideration when preparing a CSP utilizing the solution.

      Example: A 100ml Baxter Minibag Plus (MB+) overwrap is opened on 05/01/15. It is good for 30 days, so the "Do not use beyond" date would be 05/31/15.

      1) If the MB+ bags are used immediately for compounding, the BUD for the finished CSP is 05/31/15.

      2) If the opened MB+ bags are utilized at a later date for compounding, they will still expire 05/31/15, i.e. used to prepare a CSP on the 15th, the BUD on the finished CSP is still 05/31/15.

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SUBJECT:	Viable Air Impaction Testing	REFERENCE #:	9702
DEPARTMENT	Pharmacy Operations	EFFECTIVE DATE:	07/30/2018
APPROVED BY:	VP Pharmacy	REVIEWED DATE:	
		APPROVED DATE:	06/15/2018
REVISIONS:		REVISION DATE:	

SCOPE

This policy and procedure applies to pharmacies or other entities under the ownership or control of BriovaRx Infusion Services, Inc. (the Company).

PURPOSE

To define the procedure for routine active air sampling as well as re-testing for viable air particles following a scheduled sterile complex certification in which viable particle action levels were discovered; and outline the proper procedure for requesting, transporting, cleaning and operating the Climet CI-95A microbial air sampler.

DEFINITIONS/REFERENCES/REQUIREMENTS

Viable Air Sampling: Evaluation of airborne microorganisms using volumetric collection methods in the controlled air environments (LAFW's, buffer areas, ante-areas) for all compounding risk levels.

Sampling Method: Impaction will be the preferred method of volumetric air sampling and performed by properly trained individuals.

Volume of Sample: All samples will be 1000 liters of air.

Growth Media:

- **TSA -** Tryptic soy agar. Typically used to support the growth of bacteria. Normally incubated at 30-35 degrees centigrade for 48 – 72 hours
- **MEA:** Malt extract agar. Typically used to support the growth of fungi. Normally incubated at 26 – 30 degrees centigrade for 5 – 7 days.
- **SDA:** Sabouraud Dextrose Agar. Typically used to support the growth of fungi and yeast. Follow manufacturer's recommendation for incubation.

Climet CI-95A Microbial Air Sampler: The actual device that does the active air sampling. The unit is designed to sample air at a volume rate of 100 LPM (liters per minute). Manual provided as Exhibit 9702.E1

Competency Requirements: All staff performing active air sampling will be required to be trained on how to use the Climet CI-95A and successfully complete the Assessment of Microbial Air Sampling Competency Check List (Policy 9710.F7). The Pharmacy Manager/PIC at and at least one other

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pharmacy employee from each branch is required to be trained and competent on the method of active air sampling and use Climet CI-95A air sampling device.

Equipment Management : The Regional Clinical Pharmacists (RCP) will be responsible for the oversight of the Climet CI-95 devices and may assist the branches with scheduled quarterly air sampling, as well as any air sample re-testing resulting from positive air sample tests identified during 6 month clean room certifications.

USP<797> Table 2: attached as Appendix A

POLICY

The company will conduct impact air sampling in its controlled environments on a quarterly basis, alternating between scheduled, 6 month 3rd party certifications. Impact air samples will be obtained using the Climet CI-95A Microbial Air Sampler. Positive air sample results will require an immediate remediation plan. See Appendix A of this policy for USP <797> defined action levels.

PROCEDURE

A. Requesting the Climet CI-95A Microbial Air Sampler

Company will maintain four (4) Climet CI-95 air samplers, one (1) for each Region. The host branches that will maintain the samplers are:

- Kernersville, NC
- Orlando, FL
- Houston, TX
- Sacramento, CA

1. Request the unit by completing form 9702.F2: Microbial Air Sampler Request form

2. Email to AHS-Clinical – clinical@briovarxinfusion.com . A member of the Clinical team will coordinate the shipping of a Climet CI-95A unit from the host branch to the requesting branch.

B. Shipping and Receiving the Climet CI-95A Microbial Air Sampler

SAVE ALL THE PACKAGING MATERIAL INCLUDING THE BOX that the unit was shipped in.

1. The unit is always to be shipped in its original box with all the packing materials.

2. The receiving branch is to carefully unpack the unit on a stable surface and maintain all material/packaging.

3. The unit should remain at the testing branch until the testing results are received back from the lab. If a positive test is reported requiring further action, as defined by USP <797>, branch may need to repeat the test.

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4. After testing is completed and results are acceptable the branch is to ship the unit back to either the Regional host branch, or if directed by the RCP, to another branch within the region.

5. Before returning the unit:

   i. Thoroughly clean (see step C below: Cleaning and Disinfecting the unit.)

   ii. Remove the battery pack

   iii. Pack the unit and all ancillary equipment back into the original packaging

C. Cleaning and Disinfecting the Climet CI-95A Microbial Air Sampler

1. Prior to taking the Climet CI-95A into the sterile complex, the exterior of the unit must be completely wiped down with an acceptable cleaning and disinfecting agent. Acceptable cleaning/disinfecting products include: Super Sani Wipes, PreEmpt or Peridox. **DO NOT USE BLEACH** as this may corrode the unit. The following precautions are to be observed when cleaning the unit:

   - Turn the unit off and remove the power cord.
   - Make sure the red transit lid is in place to prevent fluid from entering the blower assembly.
   - Wipe the surface of the unit with a cloth or wipe, dampened with cleaning solution. **NEVER DIRECTLY SPRAY THE UNIT.**

2. Bring the unit into the sterile complex and in close proximity to where the test will be performed.

3. Remove the red transit lid.

4. The "Sample Head" may now be removed (see page 7 of the User's Manual).

5. Clean the sample head with PreEmpt or Peridox. Employee may also carefully wipe around the blower assembly - CAREFUL NOT TO GET ANY LIQUID DOWN IN THE BLOWER ASSEMBLY.

6. Use a lint free wipe dampened with sterile 70% isopropyl alcohol as the final wipe. Wipe the entire unit with sterile 70% isopropyl alcohol.

7. Make sure the unit has completely dried prior to testing.

8. Once your testing is complete, repeat the cleaning process and replace the red transit lid.

D. Operation of the Climet CI-95A Microbial Air Sampler

1. Prior to use, check that the Climet CI-95A calibration date is within one year of the last calibration date. There is a sticker on each unit that indicates the last calibration date and the recalibration date.

2. Ensure the test sample volume is set to 1000 L.

   a. The Climet CI-95A units will be shipped pre-set to the correct sample volume.

   - Double check this has not changed.
   - If the unit is found not set to 1000 L, follow the instructions in the user's manual to re-set the sample volume to the correct setting.

3. Ensure the correct positioning of the agar plate. The agar plate cover holder may be positioned In two (2) different locations. Depending on the sample the orientation of the holder may need to change. This should be completed prior to testing. A simple Phillips head screw driver will allow the removal of the center screw and relocate the dish lid holder. (See diagram of user's manual, page 25)

   - When sampling a room or a vertical laminar flow hood, the sample head will be oriented to the ceiling.
   - When sampling a horizontal flow hood, you may want the sample head orientation to be toward the screen of the hood.

E. AIR SAMPLE TESTING

A. Test areas outlined in branch air sampling map (policy 9701) quarterly between 6 month certifications.

B. Re-test any areas that failed during a 6 month certification testing. Ensure that the correct media is used during testing, i.e., if the anteroom failed the MEA air testing, the retest will require using MEA media in the same area that failed.

1. Starting your air sampling:

   a. Gather the appropriate number of agar plates to complete testing. **NOTE:** The Climet CI-95A only uses 90mm agar plates (petri dishes) and EMlabs is the preferred vendor. MSD also has 90mm TSA and SDA plates available for purchase and will serve as the back-up source for media agar plates.

   b. Spray gloved hands with sterile 70% isopropyl alcohol to prevent contaminating the agar sample.

   c. Remove the Sample Head and carefully place the agar plate (media side up) as demonstrated in the user's manual on page 7.

   d. Place the agar plate top in the holder as demonstrated on page 25 of the user's manual.

   e. Replace the sample head and START the sample. The Climet CI-95A will run at a rate of 100 LPM (liters per minute). A sample volume of 1000 L will take 10 minutes to complete.

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f. Once the sample is complete, the blower will automatically shut off and the unit will beep. The SAMPLE LED will continuously flash green.

g. Remove the Sample Head and retrieve the agar plate by carefully removing and immediately replace the lid.

h. Sanitized gloved hands with sterile 70% isopropyl alcohol.

i. Invert the sample and label with the date, media type, reference location and tester's initials.

j. Secure the lid with tape.

k. Repeat steps a-h for all other areas to be sampled, ensuring that the sampler head and tester's gloved hands are re-sanitized with sterile 70% isopropyl alcohol between each sample. Allow the unit to dry completely before running subsequent samples.

F. Media Sample Handling and Analysis

EMLab is the preferred vendor for reading media air samples. Refer to policy 9702.A1 to establish individual branch login username and password and to gain access to the EMLab website where branch can order media, download forms, and view lab results.

1. Prepare samples for shipping to EMLab.

   a. After obtaining samples, inverting and taping the lid, place each sample into an individual zip-lock baggie.

   b. Place agar plates and into insulated shipping box with sufficient bubble wrap to protect the plates during shipping.

   c. Add an ice block to prevent the shipment from getting too hot.

   d. Complete shipping forms as outline in policy 9702.A1.

3. EMLab will incubate the samples and provide a report on test results. Should a sample test positive for microbial contamination, EMLab will provide the of the number of colony forming units (CFU) and identity of units.

4. Remediation plans and re-testing are to be completed as outlined in policy 9701 and documented (form 9583.F1.)

RECORDS

FORMS

9710.F7 - Assessment of Microbial Air Sampler Competency Check List
9702.F2 - Microbial Air Sampler Request Form
9702.A1 - EMLab: Surface and Active Air Sampling Services
9702.E1 - Climet Cl-95A Manual
9583.F1 - Sterile Complex Remediation Action Plan Form

APPENDIX A

Reference: USP<797>

Table 2. Recommended Action Levels for Microbial Contamination

(cfu per cubic meter [1000 liters] of air per plate)

Classification	Air Sample
ISO Class 5	> 1
ISO Class 7	> 10
ISO Class 8 or worse	> 100

Any cfu count that exceeds its respective action level (see *Table 2*) should prompt a re-evaluation of the adequacy of personnel work practices, cleaning procedures, operational procedures, and air filtration efficiency within the aseptic compounding location. An investigation into the source of the contamination shall be conducted. Sources could include HVAC systems, damaged HEPA filters, and changes in personnel garbing or work practices. The source of the problem shall be eliminated, the affected area cleaned, and resampling performed.

Counts of cfu are to be used as an approximate measure of the environmental microbial bio burden. Action levels are determined on the basis of cfu data gathered at each sampling location and trended over time. The numbers in *Table 2* should be used only as guidelines. Regardless of the number of cfu identified in the pharmacy, further corrective actions will be dictated by the identification of microorganisms recovered (at least the genus level) by an appropriate credentialed laboratory of any microbial bio burden captured as a cfu using an impaction air sampler.

Highly pathogenic microorganisms (e.g., Gram-negative rods, coagulase positive staphylococcus, molds and yeasts) can be potentially fatal to patients receiving CSPs and must be immediately remedied, regardless of cfu count, with the assistance of a competent microbiologist, infection control professional or industrial hygienist.

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SUBJECT:	Certification of Aseptic Technique - Gloved Fingertip Testing	REFERENCE #:	9705
DEPARTMENT	Pharmacy Operations	EFFECTIVE DATE:	10/01/2014
APPROVED BY:	VP of Pharmacy	REVIEWED DATE:	09/12/2014 01/13/2017 06/07/2018
		APPROVED DATE:	09/26/2014
REVISIONS:		REVISION DATE:	01/13/2017 01/19/2018 06/07/2018

SCOPE

This policy and procedure applies to pharmacies or other entities under the ownership or control of BriovaRx Infusion Services, Inc. (the Company).

PURPOSE

To reduce the risk of touch contamination during sterile compounding by periodically testing and validating compounding personnel competency in the proper technique for hand hygiene and gloving.

POLICY

1. Gloved fingertip sampling shall be used to evaluate the competency of personnel in performing hand hygiene and garbing procedures in addition to educating compounding personnel on proper work practices.

2. New employees will be required to successfully complete three (3) separate gloving competency evaluations and initial gloved fingertip testing before being allowed to compound sterile products.

3. Employees that compound low and medium risk level compounded sterile preparations shall perform gloved fingertip testing as a series with media fill test at time of hire and annually as outlined in Company policy.

4. Employees that compound high risk level compounded sterile preparations shall perform gloved fingertip testing as a series with media fill test, at time of hire and every 6 months as outlined in Company policy.

PROCEDURE

Supplies:

a. Trypticase soy agar (TSA) with lecithin and polysorbate 80 agar plates

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b. For High Risk compounding facilities, Malt extract agar plates should be used (supports growth of fungi.)

1. New Employee Fingertip glove testing

Prior to performing any sterile compounding, new personnel must perform three (3) separate gowning and gloving procedures, and then perform a fingertip test after each.

After washing hands and completing the gowning process, the employee will enter the cleanroom, apply alcohol based hand wash with persistent activity and don sterile gloves.

a. Gloved hands are NOT to be sprayed with sterile 70% IPA.

b. Open agar plates using aseptic technique in the ISO 5 environment.

c. Gently press all finger tips/thumb on plate testing surface.

d. Repeat the same process for opposite hand on a separate plate

e. Cover agar plate and write today's date and initial your container top using a permanent marker and place in the incubator.

f. Agar plates should be taped and inverted.

g. Discard sampled gloves, de-garb, and complete proper hand hygiene.

h. TSA with lecithin and polysorbate 80 plates are to be incubated at 30-35°C for 48-72 hours.

i. This process will be repeated for a total of three (3) samplings.

j. The colony forming unit (cfu) count for each test must be zero in order to pass.

2. Initial and Annual Fingertip glove testing will be performed **immediately** after completing media fill test:

a. Gloved hands are NOT to be sprayed with sterile 70% IPA.

b. Open agar plates using aseptic technique in the ISO 5 environment.

c. Gently press all finger tips/thumb on plate testing surface.

d. Repeat the same process for opposite hand on a separate plate

e. Cover agar plate and write today's date and initial your container top using a permanent marker and place in the incubator.

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f. Agar plates should be taped and inverted.

g. Discard sampled gloves, de-garb, and complete proper hand hygiene.

h. TSA with lecithin and polysorbate 80 are to be incubated at 30-35°C for 48-72 hours.

i. The cfu count must be less than or equal to three to pass.

3. The Pharmacy Manager/PIC or designee will review the results and record in QA log.

> Negative results will show no growth.
> Positive results will show colonization on the plate

a. Positive results must be reported to Pharmacy Manager/PIC immediately

b. The employee with positive results is to be re-tested as soon as possible.

c. A subsequent positive result will require the employee to be re-validated on aseptic process and re-tested on glove sterility.

d. The employee will not be allowed to compound CSP until they have successfully completed the aseptic and sterility testing.

4. Revalidation testing will occur as outlined above or more often as determined by the Pharmacy Manager/PIC.

RECORDS

Employee competency records

FORMS

9710F6 Gloved Fingertip Log

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SUBJECT:	EMLab P&K: Surface, Active Air Sampling Services	REFERENCE #:	9702.A1
DEPARTMENT	Pharmacy Operations	EFFECTIVE DATE:	07/30/2018
APPROVED BY:	VP Pharmacy	REVIEWED DATE:	
		APPROVED DATE:	06/11/2018
REVISIONS:		REVISION DATE:	

SCOPE

This policy and procedure applies to pharmacies or other entities under the ownership or control of BriovaRx Infusion Services, Inc. (the Company).

PURPOSE

To identify an established laboratory service that can provide USP 797 analysis of surface and active air media samples. The laboratory will provide incubation, identification and reporting services of the samples submitted. The laboratory will also be a source of media and supplies for our testing purposes.

DEFINITIONS/REFERENCES/REQUIREMENTS

EMLab P&K, a Test America Company: The UHG approved vendor we have contracted with to provide USP 797 analysis of surface and active air sampling. This sampling is required by USP 797 and is part of our Environmental Monitoring policy.

Chain of Custody Form (COC): The form required to submit media samples to EMLab.

Active Air Sampling: Air samples collected with an active air sampling device that samples 1000 liters of air via an "impaction" method.

POLICY

All active air sampling performed in-house will be required to be submitted to EMlab for incubation and identification should any samples become positive for growth. Branch location will need to contact EMlab initially to request user name and password to access their website. All steps can be completed online including ordering the media, downloading the "COC" form that is required to be submitted with each sample, as well as viewing sample results.

EMLab P&K have locations across the country:

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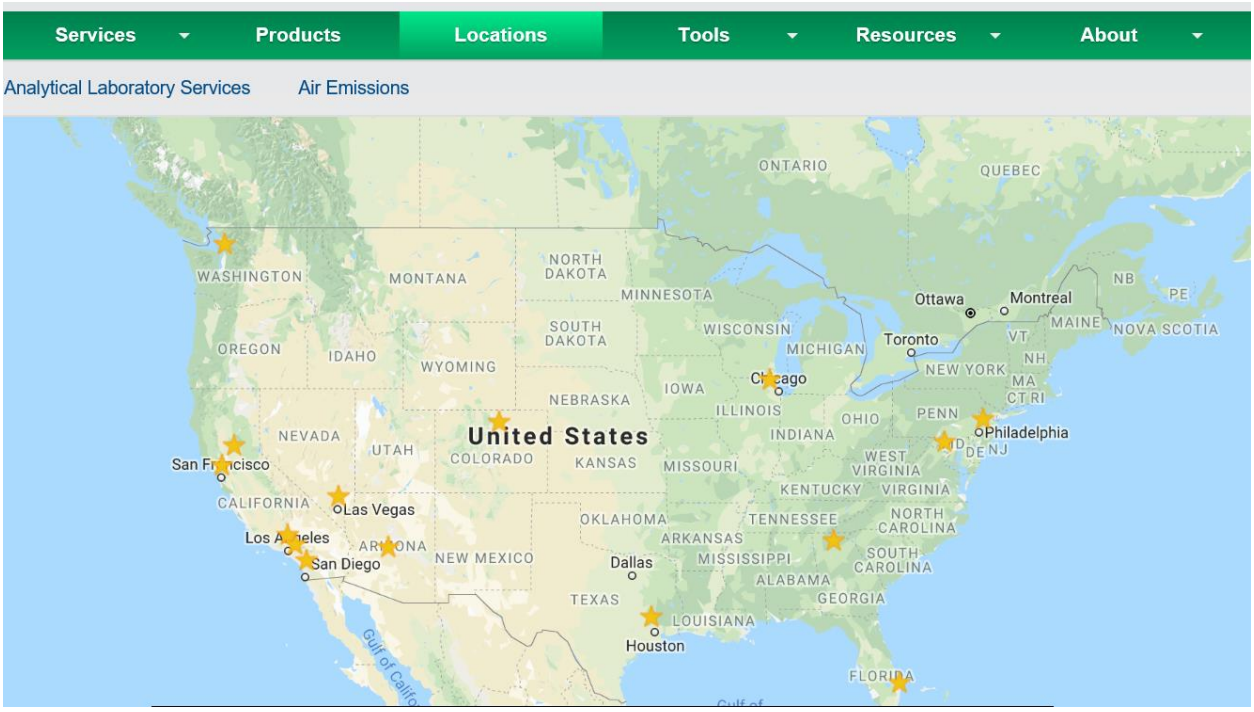

EMLab P&K locations

Website: https://emlab.com

Login : https://www.emlab.com/app/main/Login.po

CONTACTS:

Initial contact to set up accounts, and technical assistance:

Angela Heatherington, Project Manager

1501 West Knudsen Drive, Phoenix AZ 85027

Phone: 623-298-1014

Email: ahetherington@emlabpk.com

Northwest Regional Account Manager

Alex Pratt

6000 Shoreline Court, Suite 205, South San Francisco, CA 94080-7606

Phone: 858-354-1379

Email: apratt@emlabpk.com

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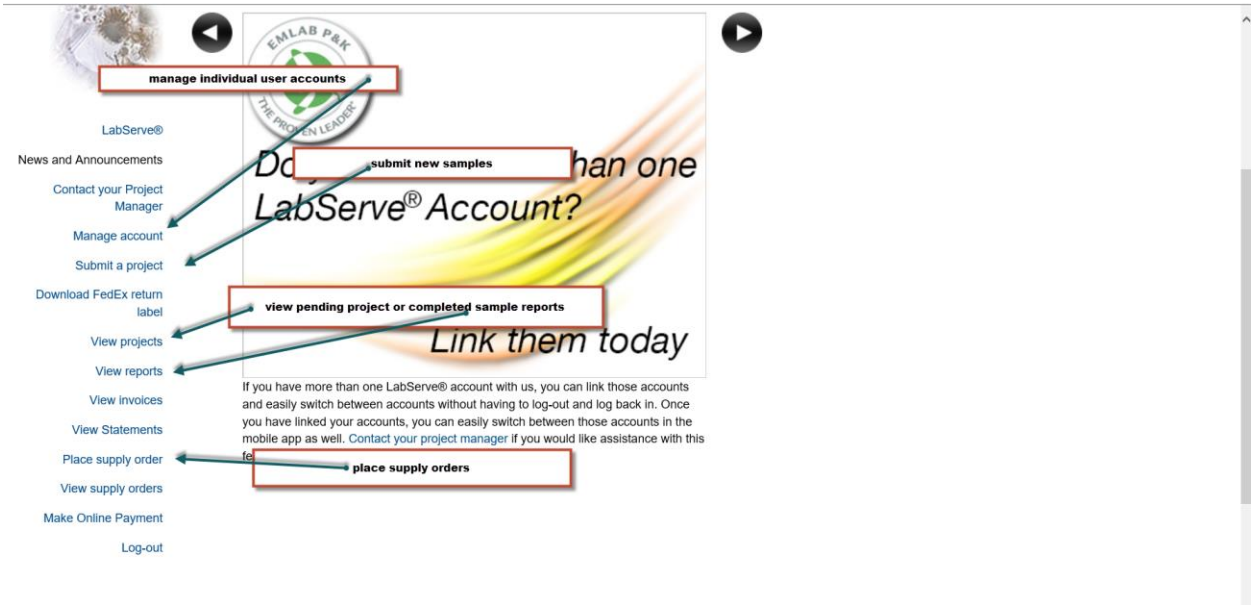
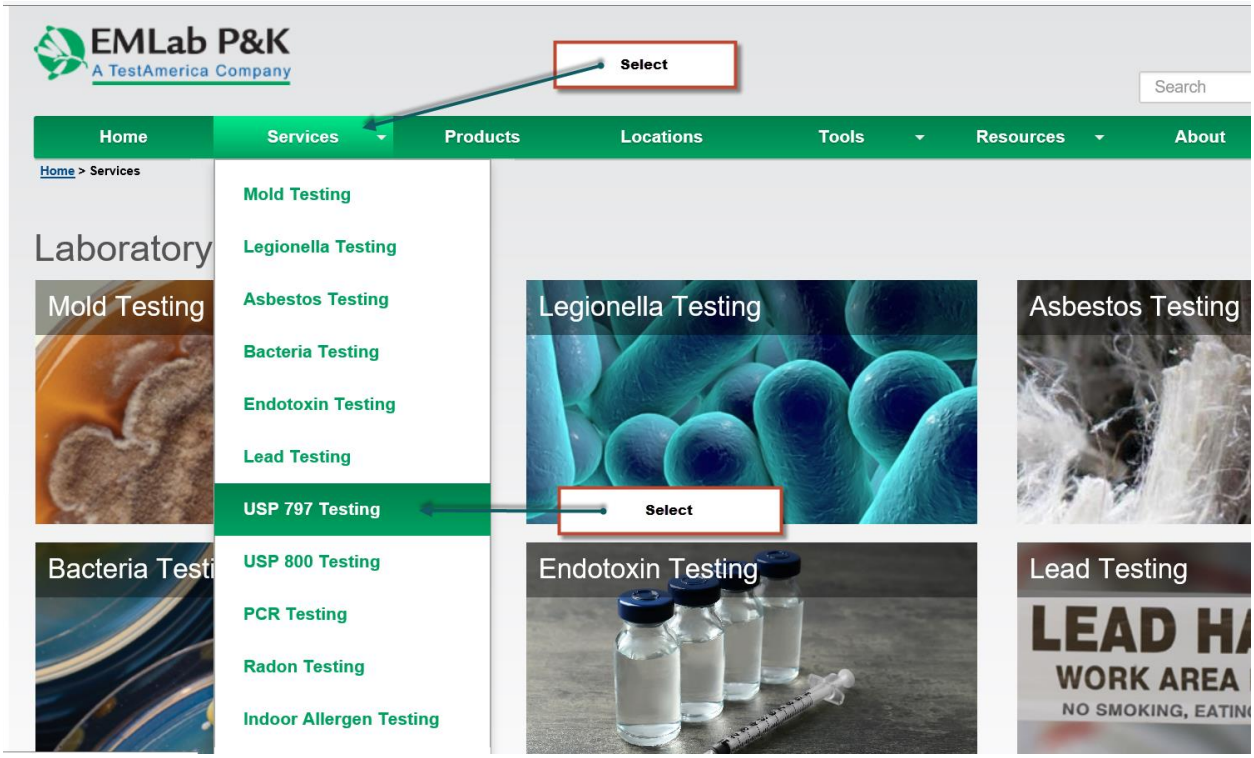
Everything can be performed on the EMLab web page: https://www.emlab.com

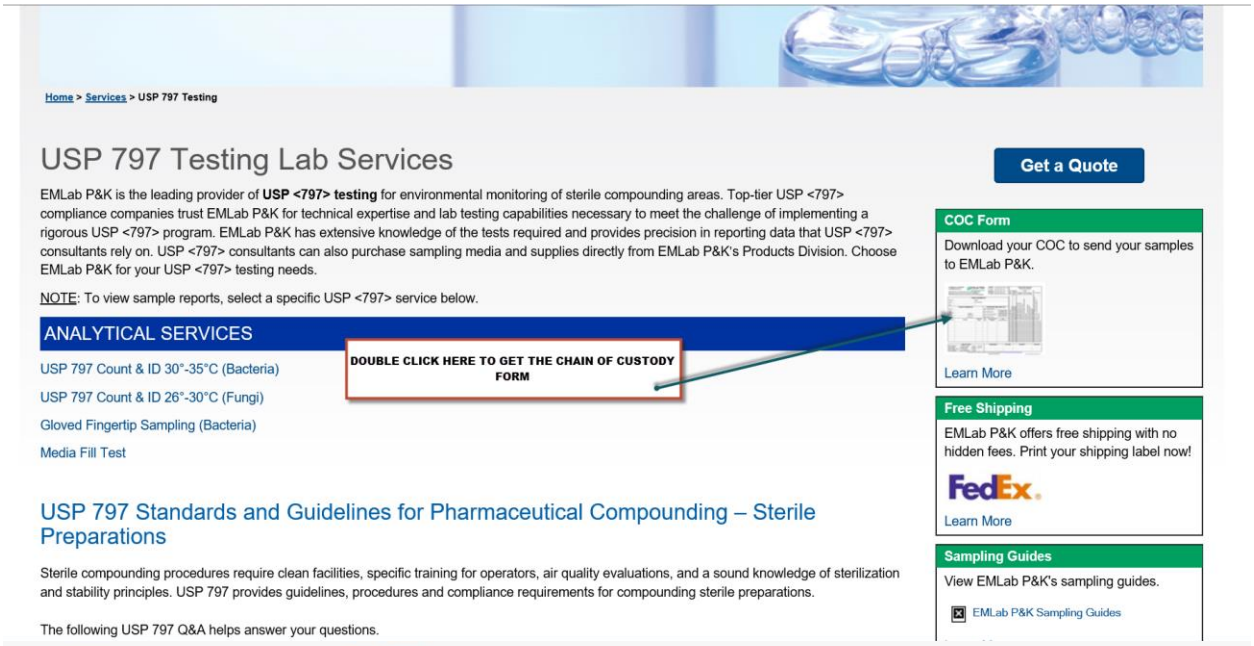


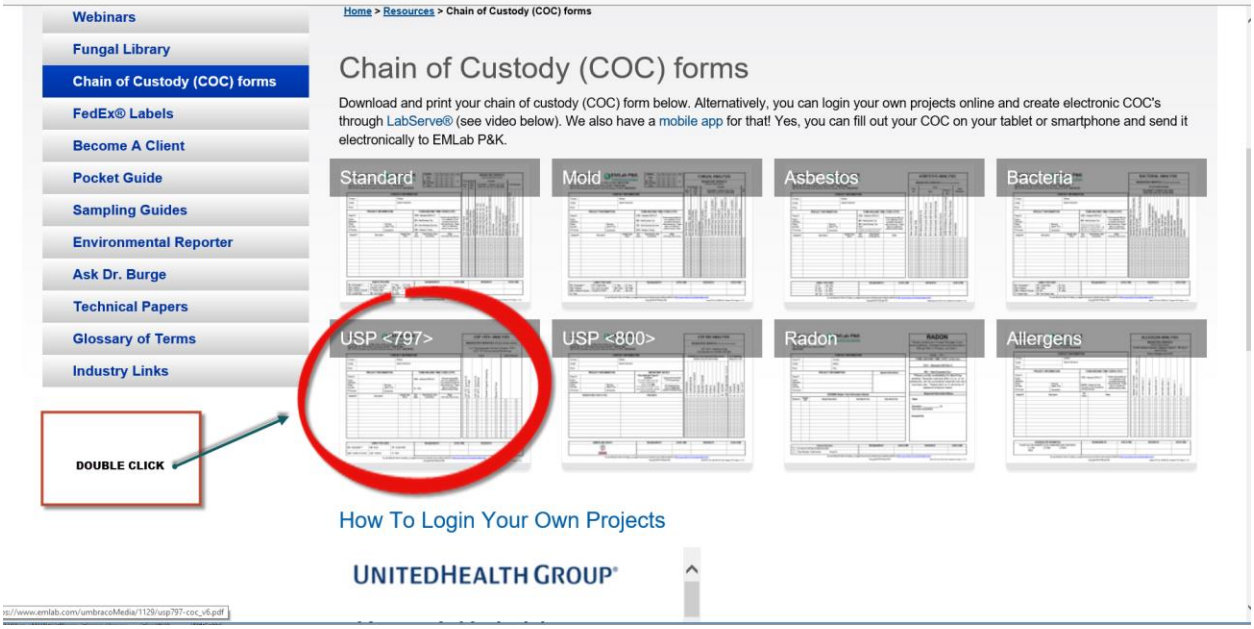
To submit a sample:

Click the drop down menu: ”Services”, then click “USP 797 Testing”.

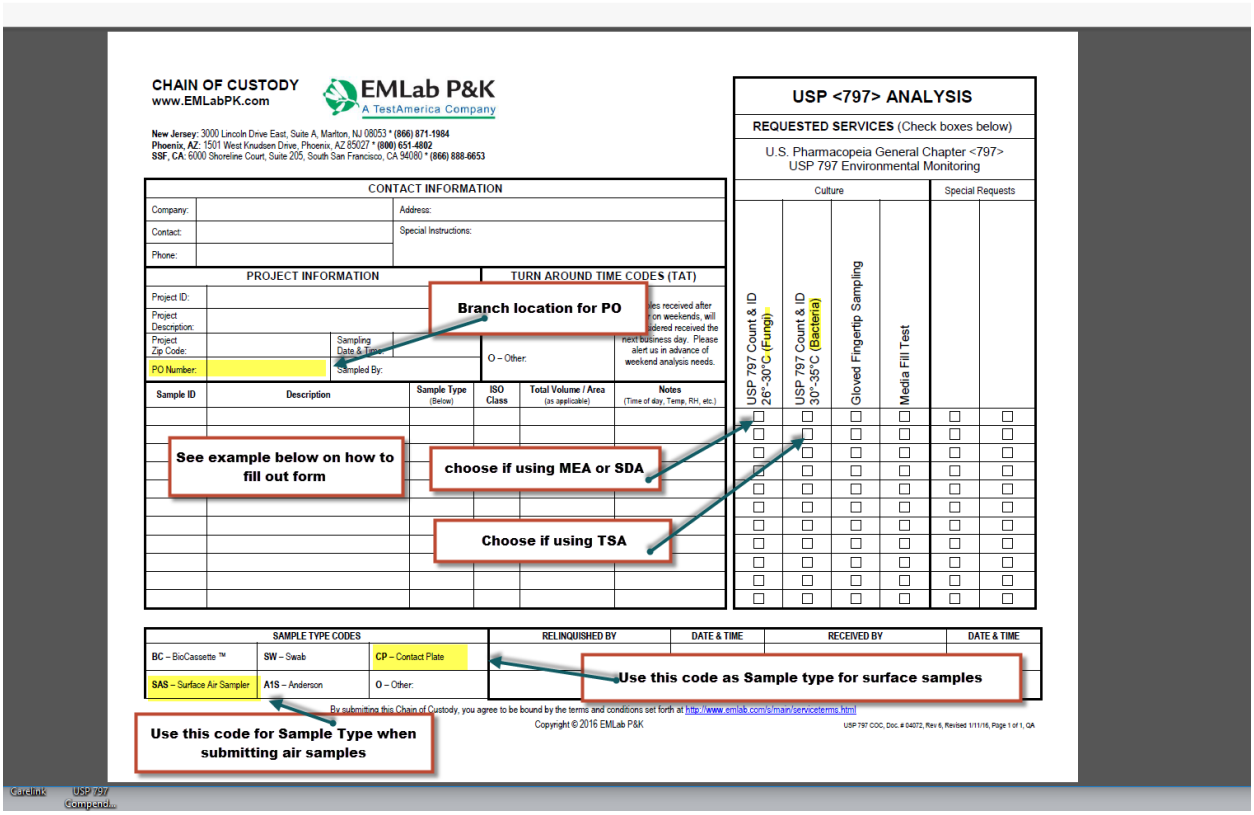


Download and print the “Chain of Custody” form:

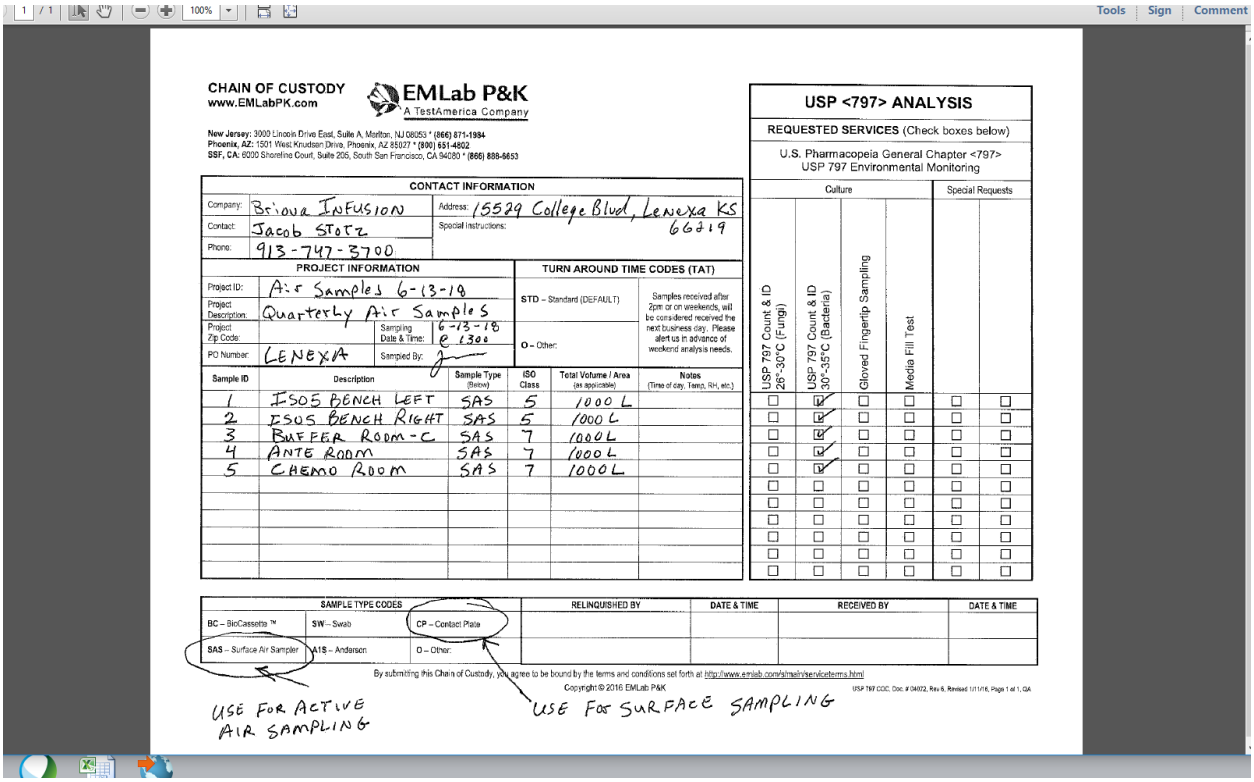




CHAIN OF CUSTODY FORM:



EXAMPLE ON HOW TO FILL THE FORM OUT:



CHAIN OF CUSTODY
www.EMLabPK.com

EMLab P&K
A TestAmerica Company

New Jersey: 3000 Lincoln Drive East, Suite A, Marlton, NJ 08053 * (866) 871-1994
Phoenix, AZ: 1501 West Knudsen Drive, Phoenix, AZ 85027 * (800) 651-4802
SSF, CA: 6000 Shoreline Court, Suite 205, South San Francisco, CA 94080 * (866) 888-8653

CONTACT INFORMATION

Company:	Briova Infusion	Address:	15529 College Blvd, Lenexa KS 66219
Contact:	Jacob Stotz	Special Instructions:	
Phone:	913-747-3700		

PROJECT INFORMATION

Project ID:	Air Samples 6-13-18		
Project Description:	Quarterly Air Samples		
Project Zip Code:		Sampling Date & Time:	6-13-18 @ 1300
PO Number:	LENEXA	Sampled By:	

TURN AROUND TIME CODES (TAT)

STD – Standard (DEFAULT)

O – Other:

Samples received after 2pm or on weekends, will be considered received the next business day. Please alert us in advance of weekend analysis needs.

Sample ID	Description	Sample Type (Below)	ISO Class	Total Volume / Area (as applicable)	Notes (Time of day, Temp, RH, etc.)
1	ISO5 BENCH LEFT	SAS	5	1000 L	
2	ISO5 BENCH RIGHT	SAS	5	1000 L	
3	BUFFER ROOM-C	SAS	7	1000L	
4	ANTE ROOM	SAS	7	1000 L	
5	CHEMO ROOM	SAS	7	1000L	

USP <797> ANALYSIS

REQUESTED SERVICES (Check boxes below)

U.S. Pharmacopeia General Chapter <797>
USP 797 Environmental Monitoring

Culture				Special Requests	
USP 797 Count & ID 26°-30°C (Fungi)	USP 797 Count & ID 30°-35°C (Bacteria)	Gloved Fingertip Sampling	Media Fill Test		
☐	☑	☐	☐	☐	☐
☐	☑	☐	☐	☐	☐
☐	☑	☐	☐	☐	☐
☐	☑	☐	☐	☐	☐
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☐	☐	☐	☐	☐	☐
☐	☐	☐	☐	☐	☐
☐	☐	☐	☐	☐	☐
☐	☐	☐	☐	☐	☐

SAMPLE TYPE CODES

BC – BioCassette ™ | SW – Swab | CP – Contact Plate
SAS – Surface Air Sampler | AIS – Anderson | O – Other:

RELINQUISHED BY	DATE & TIME	RECEIVED BY	DATE & TIME

By submitting this Chain of Custody, you agree to be bound by the terms and conditions set forth at http://www.emlab.com/emlab/serviceterms.html

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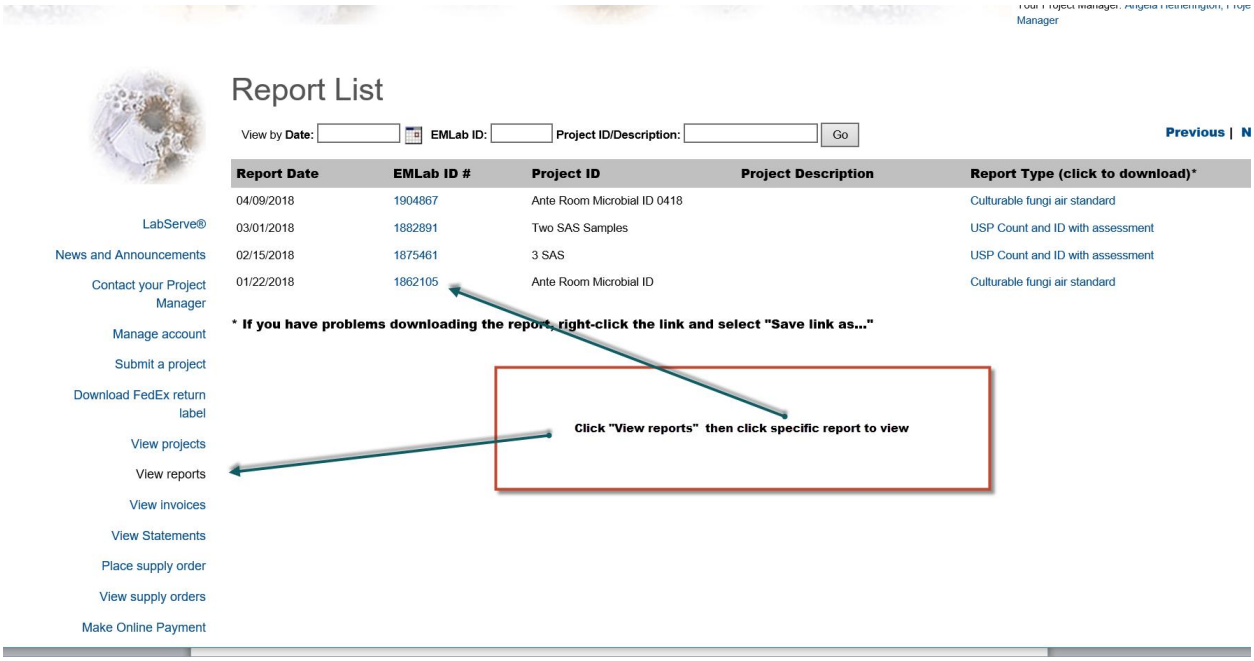
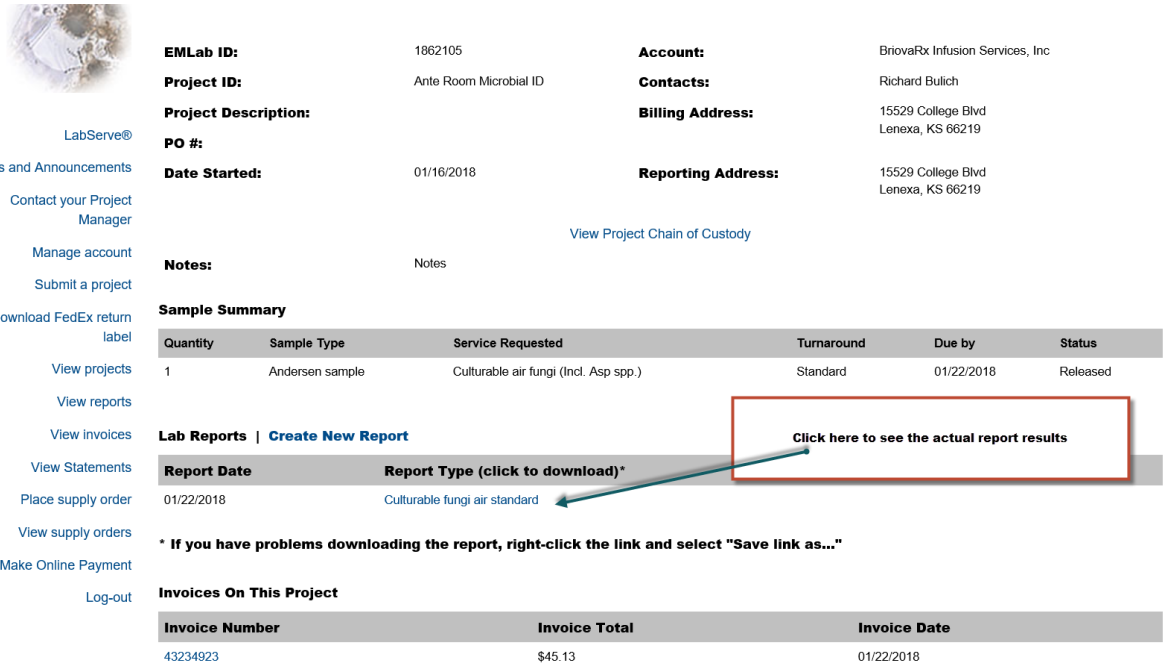
USP 797 COC Doc # 04072, Rev 6, Revised 1/11/16, Page 1 of 1, QA

USE FOR ACTIVE AIR SAMPLING

USE FOR SURFACE SAMPLING

VIEWING REPORTS:





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View Statements
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View supply orders
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EMLab ID: 1862105 **Account:** BriovaRx Infusion Services, Inc
Project ID: Ante Room Microbial ID **Contacts:** Richard Bulich
Project Description: **Billing Address:** 15529 College Blvd Lenexa, KS 66219
PO #:
Date Started: 01/16/2018 **Reporting Address:** 15529 College Blvd Lenexa, KS 66219

View Project Chain of Custody

Notes: Notes

Sample Summary

Quantity	Sample Type	Service Requested	Turnaround	Due by	Status
1	Andersen sample	Culturable air fungi (Incl. Asp spp.)	Standard	01/22/2018	Released

Lab Reports | **Create New Report**

Click here to see the actual report results

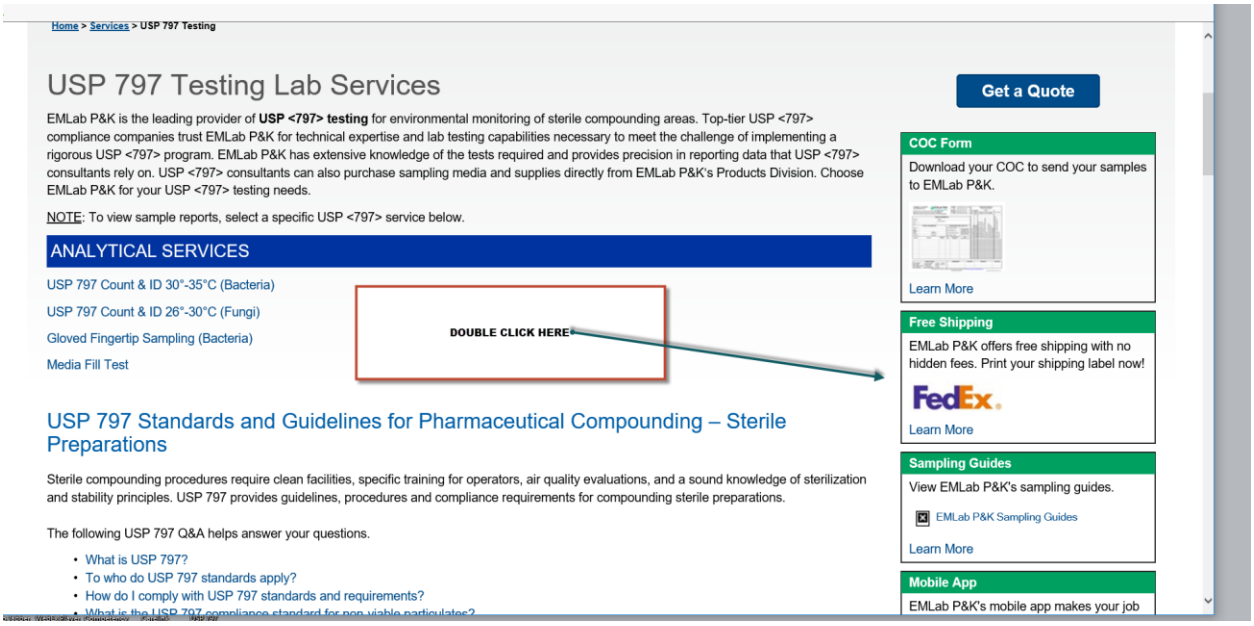
Report Date	Report Type (click to download)*
01/22/2018	Culturable fungi air standard

*** If you have problems downloading the report, right-click the link and select "Save link as..."**

Invoices On This Project

Invoice Number	Invoice Total	Invoice Date
43234923	$45.13	01/22/2018

EMLab will pay for Fed Ex shipping of samples to their lab.



Home > Services > USP 797 Testing

USP 797 Testing Lab Services

EMLab P&K is the leading provider of **USP <797> testing** for environmental monitoring of sterile compounding areas. Top-tier USP <797> compliance companies trust EMLab P&K for technical expertise and lab testing capabilities necessary to meet the challenge of implementing a rigorous USP <797> program. EMLab P&K has extensive knowledge of the tests required and provides precision in reporting data that USP <797> consultants rely on. USP <797> consultants can also purchase sampling media and supplies directly from EMLab P&K's Products Division. Choose EMLab P&K for your USP <797> testing needs.

NOTE: To view sample reports, select a specific USP <797> service below.

ANALYTICAL SERVICES

USP 797 Count & ID 30°-35°C (Bacteria)
USP 797 Count & ID 26°-30°C (Fungi)
Gloved Fingertip Sampling (Bacteria)
Media Fill Test

DOUBLE CLICK HERE

Get a Quote

COC Form
Download your COC to send your samples to EMLab P&K.
Learn More

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Sampling Guides
View EMLab P&K's sampling guides.
EMLab P&K Sampling Guides
Learn More

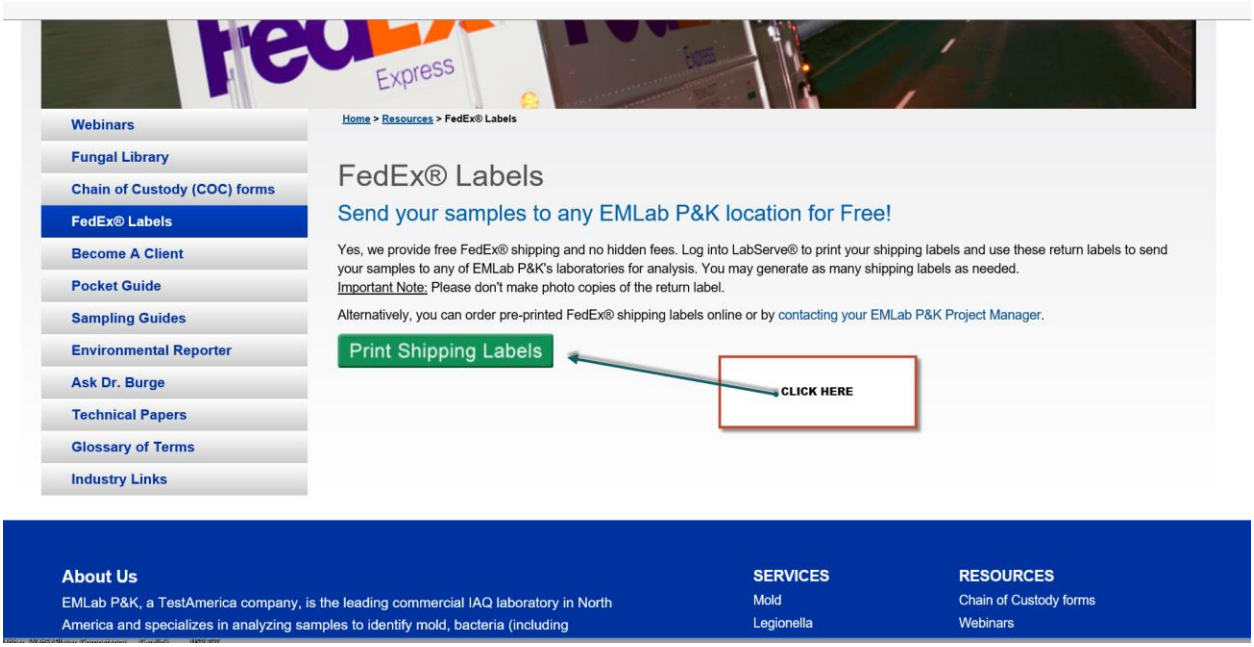
Mobile App
EMLab P&K's mobile app makes your job

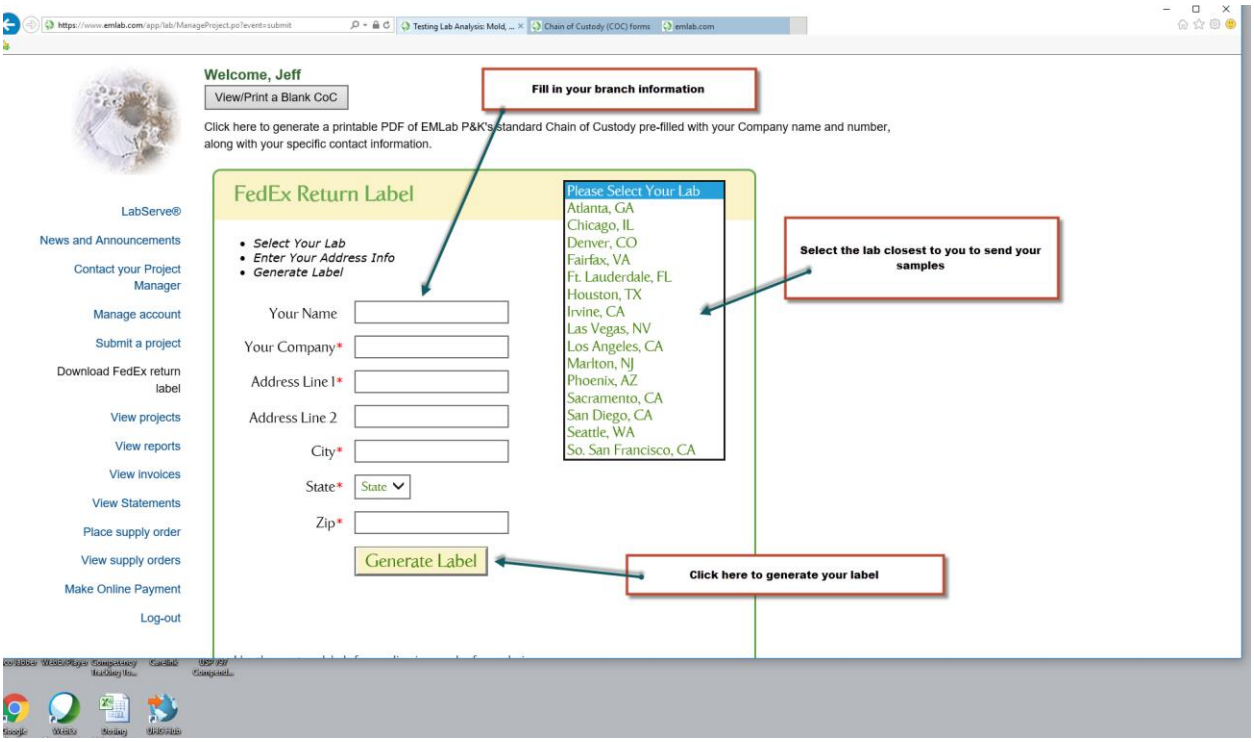
USP 797 Standards and Guidelines for Pharmaceutical Compounding – Sterile Preparations

Sterile compounding procedures require clean facilities, specific training for operators, air quality evaluations, and a sound knowledge of sterilization and stability principles. USP 797 provides guidelines, procedures and compliance requirements for compounding sterile preparations.

The following USP 797 Q&A helps answer your questions.

- What is USP 797?
- To who do USP 797 standards apply?
- How do I comply with USP 797 standards and requirements?
- What is the USP 797 compliance standard for non-viable particulates?





FedEx® Labels

Send your samples to any EMLab P&K location for Free!

Yes, we provide free FedEx® shipping and no hidden fees. Log into LabServe® to print your shipping labels and use these return labels to send your samples to any of EMLab P&K's laboratories for analysis. You may generate as many shipping labels as needed.
Important Note: Please don't make photo copies of the return label.

Alternatively, you can order pre-printed FedEx® shipping labels online or by contacting your EMLab P&K Project Manager.

Print Shipping Labels

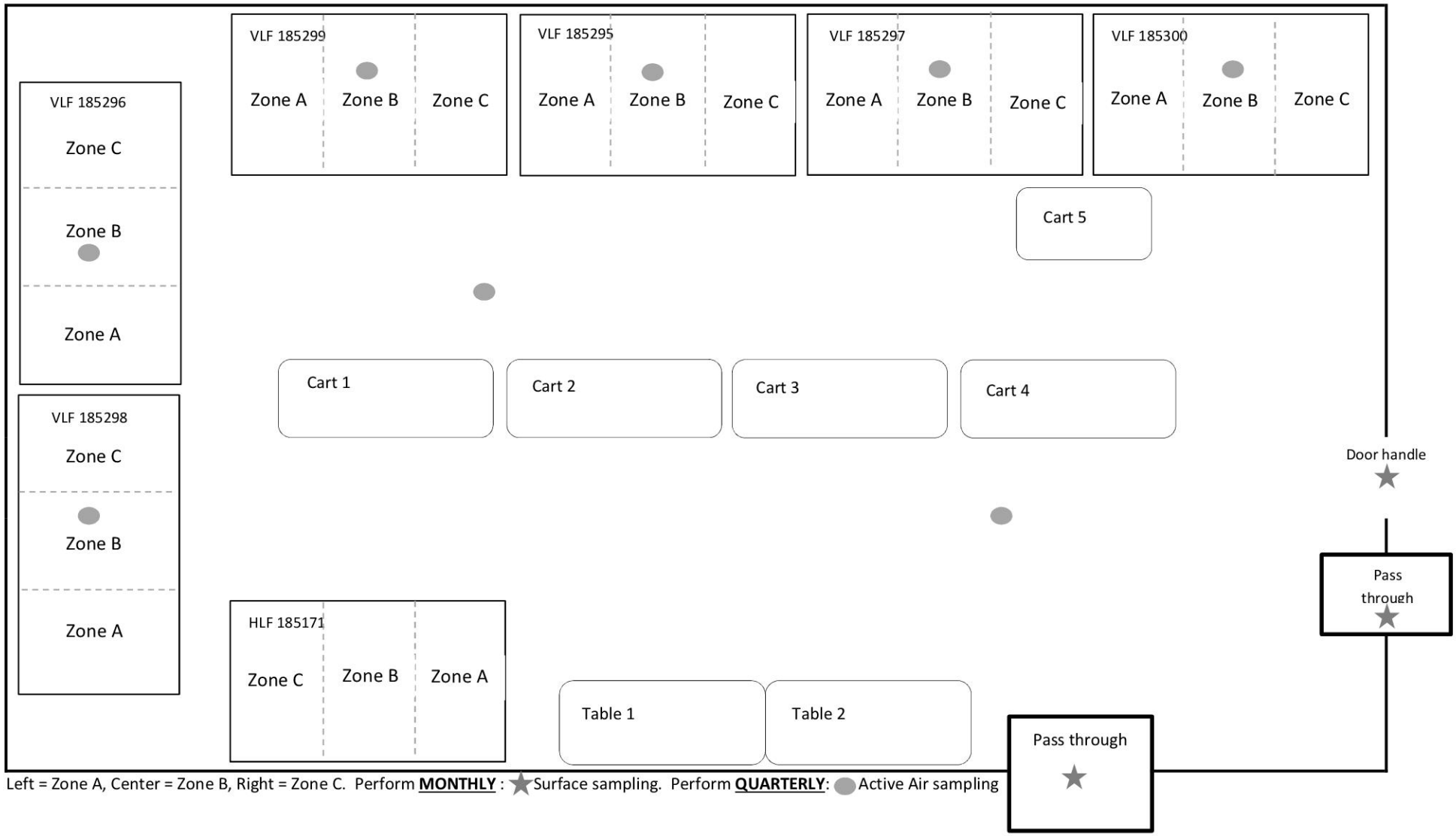
Shipping

Samples should be shipped to the laboratory for overnight delivery. Protect samples from physical damage and avoid/address potential extremes (e.g. in hot season use cooler and add cold packs).

BriovaRx Infusion Services – Miramar Cleanroom Map for Surface and Active Air Sampling

Hood Rotation (Surface only): Zone A - January, April, July & October. Zone B - February, May, August & November. Zone C - March, June, September & December

Other Rotation (Surface only): Cart 1, Cart 4, Table 1: Jan, Apr, Jul & Oct. Cart 2, Cart 6, Table 2: Feb, May, Aug & Nov. Cart 3, Cart 5, Shelf A: Mar, Jun, Sep & Dec.

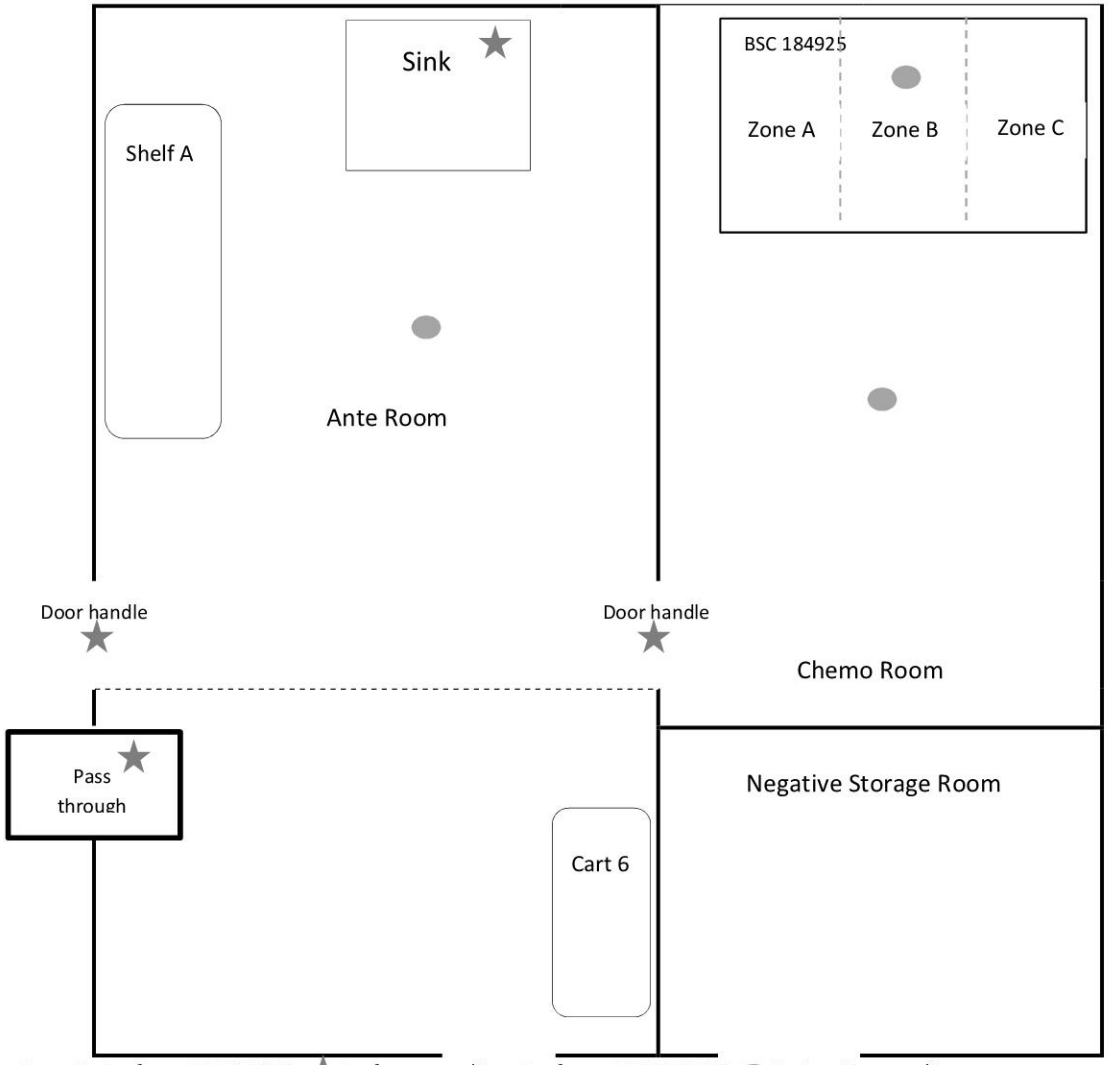


Left = Zone A, Center = Zone B, Right = Zone C. Perform **MONTHLY** : ★Surface sampling. Perform **QUARTERLY**: ●Active Air sampling

BriovaRx Infusion Services – Miramar *Ante Room & Chemo Room* Map for Surface and Active Air Sampling

Hood Rotation (Surface only): Zone A - January, April, July & October. Zone B - February, May, August & November. Zone C - March, June, September & December

Other Rotation (Surface only): Cart 1, Cart 4, Table 1: Jan, Apr, Jul & Oct. Cart 2, Cart 6, Table 2: Feb, May, Aug & Nov. Cart 3, Cart 5, Shelf A: Mar, Jun, Sep & Dec.



Left = Zone A, Center = Zone B, Right = Zone C. Perform **MONTHLY** : ★ Surface sampling. Perform **QUARTERLY**: ● Active Air sampling

STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES
INV797-Sterile Compounding

File # 21072
Insp # 166381

NAME	PERMIT NUMBER	DATE OF INSPECTION
OPTUM INFUSION SERVICES 203, INC	27913	01/30/2020
DOING BUSINESS AS		
STREET ADDRESS 9984 PREMIER PARKWAY	**TELEPHONE #**	**EXT**
CITY MIRAMAR	**COUNTY** BROWARD	**STATE/ZIP** FL/33025

Additional Information

Business Operation Hours

M-T-W-TH-F Y	Weekly Hours 8:30 am to 5:30
Monday N	Tuesday N
Wednesday N	Thursday N
Friday N	Saturday N
Sunday N	

Registered Pharmacist / Intern / Tech

License # PS49270	Licensee Name Shirley Elisbrun Adams
License Type Registered Pharmacists	
License # PS36287	Licensee Name Vincent Ekebu
License Type Registered Pharmacists	
License # PS52096	Licensee Name Jacqueline Rodriguez
License Type Registered Pharmacists	
License # PS21110	Licensee Name Manuela Vega-Rivera
License Type Registered Pharmacists	
License # PS28016	Licensee Name Enrique Hernandez
License Type Registered Pharmacists	
License # PS38581	Licensee Name Leslie Nazario
License Type Registered Pharmacists	
License # RPT38111	Licensee Name Gsa Gsa Alexandria Talamas
License Type Registered Pharmacists	
License # PS46873	Licensee Name Mary Jo Giles
License Type Registered Pharmacists	

ACS Manager

Optional Information

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FRENI, LAWRENCE	License #

KLEINMAN, IRA	License #
KRAMM, EDWARD P	License #
KRAMM, KATHEE M	License #
WILKINS, JOHN	License #
YORK, CHRISTOPHER	License #

RX DPT MGR/COR/POR

GILES, MARY JO B	License # 46873

Special Sterile Compounding

OPTUM INFUSION SERVICES 203, INC.	License # 18740

INV797 - Sterile Compounding

LOW RISK

1. Low risk CSP's are properly identified: Aseptic manipulations within an ISO Class 5 environment using three or fewer sterile products and no more than two entries into any container. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Low-Risk Level CSPs]	Yes
2. Low Risk CSP's, in absence of passing sterility test, stored not more than 48 hours at controlled room temperature, 14 days at cold temperature, or 45 days in solid frozen state at -25° to -10° or colder. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Low-Risk Level CSPs]	Yes
3. Low Risk CSP's with 12 hour BUD are properly identified and comply with all four specific criteria. 1. PEC in Segregated Compounding area 2. Away from windows, doors , high traffic areas 3. Hygiene & garbing required, sinks not adjacent to PEC. 4. Cleaning & Disinfecting, Personnel training, Competency evaluation, Garbing, Aseptic work practices, Viable and non-viable environmental sampling apply. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Low-Risk Level CSPs]	N/A

MEDIUM RISK

4. Medium Risk CSP's are properly identified: Aseptic manipulations within an ISO Class 5 environment using prolonged and complex mixing and transfer, more than three sterile products and entries into any container, and pooling ingredients from multiple sterile products to prepare multiple CSPs. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Medium-Risk Level CSPs]	Yes
5. Medium Risk CSP's, In absence of passing sterility test, stored not more than 30 hours at controlled room temperature, 9 days at cold temperature, or 45 days in solid frozen state at -25° to -10° or colder. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Medium-Risk Level CSPs]	Yes

HIGH RISK

6. Presterilization procedures for high-risk level CSPs, such as weighing and mixing, are completed in no worse than an ISO Class 8 environment. [ENVIRONMENTAL QUALITY AND CONTROL : Placement of Primary Engineering Controls Within ISO Class 7 Buffer Areas]	
7. High Risk CSP's are properly identified: Confirmed presence of nonsterile ingredients and devices, or confirmed or suspected exposure of sterile ingredients for more than one hour to air quality inferior to ISO Class 5 before final sterilization. [CSP MICROBIAL CONTAMINATION RISK LEVELS : High-Risk Level CSPs]	
8. High Risk CSP's, in absence of passing sterility test are not stored more than 24 hours at controlled room temperature, 3 days at cold temperature, or 45 days in solid frozen state at -25° to -10° or colder. [CSP MICROBIAL CONTAMINATION RISK LEVELS : High-Risk Level CSPs]	
9. A 0.2-µm certified sterilizing membrane filter is used that is chemically and physically compatible with the CSP. Filtration is completed rapidly without filter replacement. Sterilization method is verified to achieve sterility for the quantity and type of containers. [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Sterilization of High-Risk Level CSPs by Filtration]	
10. Sterilization method used has documentation that acceptable strength and purity of ingredients and integrity of containers is maintained. [CSP MICROBIAL CONTAMINATION RISK LEVELS : High-Risk Level CSPs]	
11. The manufacturer recommended filter integrity (e.g., bubble point) test is performed and documented for all sterilizing filters after filtering CSPs. [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Sterilization of High-Risk Level CSPs by Filtration]	
12. Autoclave cycle has been verified using appropriate biological indicators. Solutions are passed through a 1.2-µm or smaller filter into final containers to remove particulates before sterilization. [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Sterilization of High-Risk Level CSPs by Steam]	
13. Dry heat ovens used for sterilization have filtered forced air. Only those items that will be damaged by steam are sterilized by dry heat. [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Sterilization of High-Risk Level CSPs by Dry Heat]	
14. The description of dry heat sterilization conditions and duration for specific CSPs is included in written documentation in the compounding facility. The effectiveness of dry heat sterilization is verified using appropriate biological indicators and other confirmation. [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Sterilization of High-Risk Level CSPs by Dry Heat]	
15. Dry heat depyrogenation is used to render glassware or containers, such as vials free from pyrogens as well as viable microbes. The description of the dry heat depyrogenation cycle and duration for specific load items is included in written documentation in the compounding facility. The effectiveness of the dry heat depyrogenation cycle is verified using endotoxin challenge vials (ECVs). [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Depyrogenation by Dry Heat]	
16. Sterility testing is completed for all High-risk level CSPs prepared in batches of more than 25 identical containers, or exposed longer than 12 hours at 2° to 8°, and 6 hours at warmer than 8° before being sterilized. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Sterility Testing]	

USP <71> STERILITY TESTING (Outsourced)

17. Outsourced sterility testing results indicate that it is compliant with USP<71>. A method not described in the USP may be used if validation demonstrates that the alternative is at least as effective and reliable. [STERILITY TEST USP<71>]	
18. Outsourced: The number of articles tested are appropriate according to USP<71>. [STERILITY TEST USP<71> : Number of Articles to Be Tested]	
19. Outsourced: The volume/quantity tested is according to USP<71>. [STERILITY TEST USP<71> : Number of Articles to Be Tested]	
20. Outsourced: A USP<71> method suitability test has been done with appropriate inoculum, additives and rinses. [STERILITY TEST USP<71> : Method Suitability Test]	

21. Outsourced: Sterility testing reports are reviewed and appropriate actions taken and documented. [FINISHED PREPARATION RELEASE CHECKS AND TESTS]	

USP <71> STERILITY TESTING

22. On site: Membrane filtration is used if appropriate. (The technique of membrane filtration is used whenever the nature of the product permits; that is, for filterable aqueous preparations, for alcoholic or oily preparations, and for preparations miscible with, or soluble in, aqueous or oily solvents, provided these solvents do not have an antimicrobial effect in the conditions of the test.) Filters are rinsed according to USP<71>. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Sterility Testing]	
23. On site: Direct inoculation is done only when membrane filtration cannot be carried out. Volume to be inoculated does not exceed 10% of the culture media volume. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Sterility Testing]	
24. On site: The number of articles tested are appropriate according to USP<71>. [STERILITY TEST USP<71> : Number of Articles to Be Tested]	
25. On site: The volume/quantity tested is according to USP<71>. [STERILITY TEST USP<71> : Number of Articles to Be Tested]	
26. On site: A growth promotion test has been done on the media with the 5 specified organisms (not more than 100 CFU) according to USP<71>. [STERILITY TEST USP<71> : Growth Promotion Test of Aerobes, Anaerobes, and Fungi]	
27. On site: A USP<71> method suitability test has been done with appropriate inoculum, additives and rinses. [STERILITY TEST USP<71> : Method Suitability Test]	
28. On site: TSB or SCD is incubated at 20-25 C for 14 days (2 incubators present). [STERILITY TEST USP<71> : Culture Media and Incubation Temperatures]	
29. On site: FTM is incubated at 30-35 C for 14 days (2 incubators present). [STERILITY TEST USP<71> : Culture Media and Incubation Temperatures]	
30. On site: Sterility testing is documented including lot numbers and expiration dates of media. [FINISHED PREPARATION RELEASE CHECKS AND TESTS]	
31. On site: Sterility testing reports are reviewed and appropriate actions taken and documented. [FINISHED PREPARATION RELEASE CHECKS AND TESTS]	

ENDOTOXIN TESTING

32. Endotoxin testing is conducted for High-risk level CSP's that are prepared in batches of more than 25 identical containers, or exposed longer than 12 hours at 2° to 8°, and 6 hours at warmer than 8°, before being sterilized or in multidose containers for administration to multiple patients. (excluding those for inhalation and ophthalmic administration) [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Bacterial Endotoxin (Pyrogen) Testing]	
33. Endotoxin testing process indicates that it is compliant with USP<85>. [BACTERIAL ENDOTOXINS TEST USP<85>]	
34. High Risk CSP's are within allowable limits for bacterial endotoxins. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Bacterial Endotoxin (Pyrogen) Testing]	

IMMEDIATE USE COMPOUNDING

35. Immediate-use compounding complies with all six specified criteria. 1. Low-risk sterile nonhazardous products or diagnostic radiopharmaceutical products from the manufacturers' original containers. Anti-neoplastics shall not be prepared as immediate-use CSPs because they are hazardous drugs. 2. Unless required for the preparation, the compounding procedure is a continuous process not to exceed 1 hour. 3. During preparation, aseptic technique is followed and, if not immediately administered, the finished CSP is under continuous supervision to minimize the potential for contact with nonsterile surfaces, introduction of particulate matter or biological fluids, mix-ups with other CSPs, and direct contact of outside surfaces. 4. Administration begins not later than 1 hour following the start of the preparation of the CSP. 5. Unless immediately and completely administered by the person who prepared it or immediate and complete administration is witnessed by the preparer, the CSP shall bear a label listing patient identification information, the names and amounts of all ingredients, the name or initials of the person who prepared the CSP, and the exact 1-hour BUD and time. 6. If administration has not begun within 1 hour following the start of preparing the CSP, the CSP shall be promptly, properly, and safely discarded. [IMMEDIATE-USE CSPs]	N/A

SINGLE/MULTIPLE DOSE CONTAINER BUD

36. Beyond-use date does not exceed 28 days for multiple-dose containers after initial opening or entry, unless specified otherwise by the manufacturer. [SINGLE-DOSE AND MULTIPLE-DOSE CONTAINERS]	Yes
37. Beyond-use time does not exceed 6 hours for closure sealed single-dose containers in ISO Class 5 or cleaner air after initial opening or entry, unless specified otherwise by the manufacturer. [SINGLE-DOSE AND MULTIPLE-DOSE CONTAINERS]	Yes
38. Beyond-use time does not exceed 1 hour for closure sealed single-dose containers after being opened or entered in worse than ISO Class 5 air. [SINGLE-DOSE AND MULTIPLE-DOSE CONTAINERS]	N/A
39. Single-dose ampules are discarded immediately after use. [SINGLE-DOSE AND MULTIPLE-DOSE CONTAINERS]	Yes

HAZARDOUS DRUGS

40. A pressure indicator is installed and differential pressures are monitored and documented daily for hazardous buffer room. [HAZARDOUS DRUGS AS CSPs]	Yes
41. Hazardous drug buffer room is at least 0.01 inch water column negative pressure with 30 ACPH of HEPA filtered air. [HAZARDOUS DRUGS AS CSPs]	Yes
42. At least 0.01 inch water column negative pressure and 12 air changes per hour in non-cleanrooms in which CACIs are located. FAC: USP Chapter 797 requires that: "When closed-system vial-transfer devices (CSTDs) (i.e., vial-transfer systems that allow no venting or exposure of hazardous substance to the environment) are used, they shall be used within an ISO Class 5 environment of a BSC or CACI. The use of the CSTD is preferred because of their inherent closed system process. In facilities that prepare a low volume of hazardous drugs, the use of two tiers of containment (e.g., CSTD within a BSC or CACI that is located in a non-negative pressure room) is acceptable." For purpose of said provision, a "low volume of hazardous drugs" is defined as less than 40 doses per month. [HAZARDOUS DRUGS AS CSPs]	N/A
43. Personnel compounding hazardous drugs wear appropriate personal protective equipment. [HAZARDOUS DRUGS AS CSPs]	Yes
44. Hazardous drugs are handled with caution at all times using appropriate chemotherapy gloves during receiving, distribution, stocking, inventorying, preparing for administration, and disposal. Spill kits are available. [HAZARDOUS DRUGS AS CSPs]	Yes
45. Hazardous drugs are prepared in an ISO Class 5 environment (BSC or CACI) with protective engineering controls in place, following aseptic practices specified for the appropriate contamination risk levels. [HAZARDOUS DRUGS AS CSPs]	Yes

46. Hazardous drugs are stored separately from other inventory in a manner to prevent contamination and personnel exposure. [HAZARDOUS DRUGS AS CSPs] *Negative pressure storage room.*	Yes
47. Access to hazardous drug preparation areas is limited to authorized compounding personnel. [HAZARDOUS DRUGS AS CSPs]	Yes
48. Annual documentation of hazardous drug training of personnel regarding storage, handling, containment techniques and disposal of hazardous drugs is available. [HAZARDOUS DRUGS AS CSPs]	Yes
49. Compounding personnel of reproductive capability have confirmed in writing that they understand the risks of handling hazardous drugs. [HAZARDOUS DRUGS AS CSPs]	Yes
50. Facility maintains appropriate disposal containers for all hazardous waste. [HAZARDOUS DRUGS AS CSPs]	Yes

FACILITY DESIGN AND CERTIFICATION

51. Certification and testing of primary (LAFWs, BSCs, CAIs and CACIs) and secondary engineering controls (buffer and ante areas) have been performed by a qualified individual no less than every six months and whenever the device or room is relocated, altered, or major service to the facility is performed. Corrective action for deficiencies are documented. Certification procedures such as those outlined in the CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2006) are conducted under dynamic conditions. [ENVIRONMENTAL QUALITY AND CONTROL : Environmental Nonviable Particle Testing Program] *4/25/2019 and 10/23/2019 MTA certified ISO 7 anteroom, IV room, and ISO 7 HD room; 7 X ISO LFW's (one PEC horizontal flow, six vertical flow - Three TPN hoods are VLFH's) and 1 X Class II A2 BSC.*	Yes
52. Primary engineering controls provide unidirectional (i.e., laminar) HEPA filtered air. Air pattern analysis via smoke studies are conducted at the critical site to demonstrate unidirectional airflow and sweeping action over and away from the product under dynamic conditions.[ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls] *Smoke study videos done by certification company on 10/24/2019 indicate there were no employees simulating compounding; One of the VLFH's demonstrates smoke flow doesn't reach DCA; a video of HLFW demonstrates ebbs. There are three VLFH's that contain Pinnacle TPN machines used to compound TPNs; there are NO components attached to any of the Pinnacles, NO employees simulating compounding. There were NO LVP's, tubing, drugs attached to pinnacles during smoke studies.*	No
53. The primary engineering controls are placed within a buffer area in such a manner as to avoid conditions that could adversely affect their operation. The PEC is placed out of the traffic flow and in a manner to avoid disruption from the HVAC system and room cross drafts. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
54. All HEPA filters are leak tested after installation and every six months thereafter. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes

ISOLATORS

55. CAIs are proven to maintain ISO Class 5 air when particle counts are sampled 6 to 12 inches upstream of critical site exposure areas during performance of normal inward and outward transfer of materials, and compounding manipulations when such CAIs are located in air quality worse than ISO Class 7. [ENVIRONMENTAL QUALITY AND CONTROL : Placement of Primary Engineering Controls Within ISO Class 7 Buffer Areas]	
56. Adequate recovery time for isolators to achieve ISO Class 5 air quality is allowed after material transfer before and during compounding operations. [ENVIRONMENTAL QUALITY AND CONTROL : Placement of Primary Engineering Controls Within ISO Class 7 Buffer Areas]	
57. Personnel garbing requirements are followed for CAIs unless manufacturer provides written documentation based on validated testing that any components of PPE are not required to maintain sterility of CSPs. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	

FACILITY DESIGN AND CERTIFICATION (Secondary Engineering Controls)

58. Facility has pressure gauges or velocity meters to monitor the pressure differential or airflow between the buffer area and ante-area, and the ante-area and the general environment outside the compounding area. The results are reviewed and documented on a log at least daily or by a continuous recording device. The pressures differentials meet or exceed 5 Pa (0.02 inch water column (w.c.)). Alternatively, in facilities where low- and medium-risk level CSPs are prepared, differential airflow is maintained at a minimum velocity of 0.2 meter/second (40 fpm) across a line of demarcation between buffer area and ante-area. [ENVIRONMENTAL QUALITY AND CONTROL : Pressure Differential Monitoring] *Differential pressure values are documented daily and electronically monitored through JLL . January 2020 records indicate anteroom and IV room pressures were at "0.01 or 0.00 on 11 days (Jan 1,3,6,7,8,10,13,16,21,22,24 and 27). Uknown if loss of pressure is due opening/closing door, duration of excursion. Per JLL representative, alerts are sent at an hour after initial excursion.*	No
59. Clean rooms for nonhazardous and nonradioactive CSPs are supplied with HEPA filtered air that enters from ceilings with return vents low on walls, and that provides not less than 30 air changes per hour or qualifies for exception in 64B16-27.797(4)(c). [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
60. Activities and tasks carried out within the buffer area are limited to only those necessary when working within a controlled environment. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
61. Only the furniture, equipment, supplies, and other material required for the compounding activities to be performed are brought into the buffer room. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
62. Surfaces and essential furniture in buffer rooms or zones and clean rooms are nonporous, smooth, non-shedding, impermeable, cleanable, and resistant to disinfectants. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
63. The surfaces of ceilings, walls, floors, fixtures, shelving, counters, and cabinets in the buffer area are smooth, impervious, free from cracks and crevices, and non-shedding, thereby promoting cleanability, and minimizing spaces in which microorganisms and other contaminants may accumulate. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
64. Ceiling tiles are caulked around each perimeter and to walls to seal them to the support frame. The exterior lens surface of ceiling lighting fixtures is smooth, mounted flush, and sealed. All other penetrations through the ceiling or walls are sealed. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
65. The buffer area does not contain sources of water (sinks) or floor drains. Work surfaces are constructed of smooth, impervious materials, such as stainless steel or molded plastic, so that they are easily cleaned and disinfected. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
66. Storage shelving, counters, cabinets and carts/casters in the buffer area are smooth, impervious, free from cracks and crevices, non-shedding, non-porous, cleanable, and disinfectable. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
67. When devices (e.g., computers and printers) and objects (e.g., carts and cabinets) are placed in buffer areas, air quality is verified by particle counts on certification. [ENVIRONMENTAL QUALITY AND CONTROL : ISO Class 5 Air Sources, Buffer Areas, and Ante-Areas] *Certifcation report does not indicate TPN Pinnacle machines (3) located in VLFH's were operational (drugs, LVP bags, sterile tubing not in hoods during certification).*	No

QUALITY AND CONTROL

68. An appropriate environmental sampling plan has been developed for airborne viable particles based on a risk assessment of compounding activities performed. Volumetric air sampling is conducted every six months and sites include locations within each ISO Class 5 environment and in the ISO Class 7 and 8 areas, and the areas at greatest risk of contamination (e.g., work areas near the ISO Class 5 environment, counters near doors, pass-through boxes). The plan includes sample locations, method of collection, frequency of sampling, volume of air sampled, and time of day as related to activity in the compounding area and action levels. [ENVIRONMENTAL QUALITY AND CONTROL : Environmental Viable Airborne Particle Testing Program—Sampling Plan]	Yes
69. Evaluation of airborne microorganisms using volumetric collection methods in the controlled air environments is performed by properly trained individuals for all compounding risk levels. [ENVIRONMENTAL QUALITY AND CONTROL : Viable Air Sampling] *Quarterly active air sampling (twice by third party, twice in-house), per EM policy.*	Yes
70. Volumetric air sampling using malt extract agar (MEA) or some other media that supports the growth of fungi is used in high-risk level compounding environments. [ENVIRONMENTAL QUALITY AND CONTROL : Growth Media]	N/A
71. For low-risk level CSPs with 12-hour or less BUD, air sampling is performed at locations inside the ISO Class 5 environment and other areas that are in close proximity to the ISO class 5 environment. [ENVIRONMENTAL QUALITY AND CONTROL : Viable Air Sampling]	N/A
72. The number of discrete colonies of microorganisms is counted and reported as colony-forming units (cfu) and documented on an environmental monitoring form. Counts from air monitoring are transformed into cfu/cubic meter of air and evaluated for adverse trends. [ENVIRONMENTAL QUALITY AND CONTROL : Incubation Period]	Yes
73. Surface sampling is accomplished in all ISO classified areas on a periodic basis using TSA contact plates with lecithin and polysorbate 80 and/or swabs and is done at the conclusion of compounding. [ENVIRONMENTAL QUALITY AND CONTROL : Surface Cleaning and Disinfection Sampling and Assessment] *Facility is conducting monthly surface sampling, per policy.*	Yes
74. Sampling data is collected and reviewed on a periodic basis as a means of evaluating the overall state of control of the compounding environment. [ENVIRONMENTAL QUALITY AND CONTROL : Action Levels, Documentation and Data Evaluation]	Yes
75. Competent microbiology personnel are consulted if an environmental sampling consistently shows elevated levels of microbial growth. If any mold, yeast, coagulase positive staphylococcus, or gram negative rods are detected immediate remediation and investigation into the cause and source was conducted. [ENVIRONMENTAL QUALITY AND CONTROL : Action Levels, Documentation and Data Evaluation]	N/A
76. Surfaces in the LAFWs, BSCs, CAIs, and CACIs are cleaned and disinfected frequently, including at the beginning of each work shift, before each batch preparation is started, every 30 minutes during continuous compounding periods of individual CSPs, when there are spills, and when surface contamination is known or suspected from procedural breaches. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
77. Cleaning and disinfecting occurs before compounding is performed. Items are removed from all areas to be cleaned, and surfaces are cleaned by removing loose material and residue from spills, e.g., water-soluble solid residues are removed with Sterile Water and low-shedding wipes. This shall be followed by wiping with a residue-free disinfecting agent, such as sterile 70% IPA, which is allowed to dry before compounding begins. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
78. Cleaning and disinfecting agents and methods of application are in accordance with written SOPs and followed by custodial and/or compounding personnel. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
79. Cleaning materials, such as wipes, sponges, and mops, are non-shedding, preferably composed of synthetic micro fibers, and dedicated to use in the buffer area, ante-area, and segregated compounding areas and are not removed from these areas except for disposal. If cleaning materials are reused (e.g., mops), there are procedures based on manufacturer recommendations that ensure that the effectiveness of the cleaning device is maintained and repeated use does not add to the bioburden of the area being cleaned. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
80. Supplies and equipment removed from shipping cartons are wiped with a suitable disinfecting agent (e.g., sterile 70% IPA). [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
81. Disinfectant sprayed or wiped on a surface to be disinfected is allowed to dry, and during this time the item is not be used for compounding purposes. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
82. Sterile 70% IPA pads are used to disinfect the sterile entry points of packages and devices. Wetted gauze pads or other particle-generating material are not appropriate. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes

QUALITY AND CONTROL (Secondary Engineering Controls)

83. Work surfaces in ISO Class 7 and 8 areas and segregated compounding areas are cleaned at least daily. IPA (70% isopropyl alcohol) remains on surfaces to be disinfected for at least 30 seconds before such surfaces are used to prepare CSPs. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
84. Floors in ISO Class 7 and 8 areas are mopped daily by trained personnel at a time when no aseptic operations are in progress using approved agents and procedures described in written SOP's. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
85. Shelving, walls, and ceilings in ante-areas and buffer areas are cleaned and disinfected at least monthly. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes

PERSONNEL CLEANSING, GARBING & COMPETENCY EVALUATION

86. Personnel preparing CSP's are free from rashes, sunburn, weeping sores, conjunctivitis, and active respiratory infections. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	Yes
87. Compounding personnel remove personal outer garments; cosmetics; artificial nails; hand, wrist, and body jewelry that can interfere with the fit of gowns and gloves; and visible body piercing above the neck. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	Yes
88. Facility has adequate supplies to meet PPE requirements of USP<797>. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	Yes
89. Garbing and hand hygiene are accomplished in the ante-area in order of dirtiest to cleanest: shoes or shoe covers, head and facial hair covers, face mask, fingernail cleansing, hand and forearm washing and drying; non-shedding gown. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	Yes
90. Sterile gloves are donned in the buffer room/isolator after hand cleansing with an alcohol-based product with persistent activity and hands are allowed to dry. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	Yes
91. Gloves are routinely disinfected with sterile 70% IPA after contacting nonsterile objects. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	Yes
92. Personnel repeat garbing and hand hygiene after they are exposed to direct contact contamination or worse than ISO Class 8 air. Gowns may be hung in the anteroom and reused during the same workshift. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	Yes

93. Low/Medium Risk media-fill tests that closely simulate the most challenging or stressful conditions encountered during compounding are completed at least annually by compounding personnel. Media-filled vials are appropriately incubated for 14 days. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Medium-Risk Level CSPs]	Yes
94. High Risk Media-fill tests that closely simulate the most challenging or stressful conditions encountered during compounding have been completed at least semiannually by compounding personnel. Media-filled vials are appropriately incubated for 14 days. [CSP MICROBIAL CONTAMINATION RISK LEVELS : High-Risk Level CSPs]	N/A
95. Documentation indicates compounding personnel have successfully completed didactic training, passed written competency assessments, undergone skill assessment using observational audit tools (hand hygiene, garbing, aseptic technique) and media-fill testing annually or semiannually (high risk) and before any compounding personnel begin to prepare CSPs . [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures]	Yes
96. Compounding personnel who fail written tests, observational audits, or whose media-fill test vials have one or more units showing visible microbial contamination, are reinstructed and re-evaluated by expert compounding personnel to ensure correction of all aseptic work practice deficiencies. Corrective action is documented. Compounding personnel pass all evaluations prior to resuming compounding of sterile preparations. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures]	N/A
97. Other cleaning personnel performing cleaning and disinfecting procedures (e.g. environmental) are thoroughly trained in proper hand hygiene, and garbing, cleaning, and disinfection procedures by a qualified aseptic compounding expert. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures]	N/A
98. Compounding personnel and other personnel responsible for cleaning routinely undergo performance evaluation of proper hand hygiene, garbing, and all applicable cleaning and disinfecting procedures conducted by a qualified aseptic compounding expert. Visual observation of hand hygiene, garbing and cleaning is documented and maintained to provide a permanent record and long-term assessment of personnel competency. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures]	Yes
99. Immediately after the compounder completes the hand hygiene and garbing procedure, the evaluator collects a gloved fingertip and thumb sample from both hands of the compounder onto appropriate agar plates. The plates are incubated at 30-35° for 2–3 days. All compounding personnel have successfully completed an initial competency evaluation and gloved fingertip/thumb sampling procedure (0 cfu) no less than three times before initially being allowed to compound CSPs for human use. [ENVIRONMENTAL QUALITY AND CONTROL : Gloved Fingertip Sampling]	Yes
100. Re-evaluation of glove fingertip testing onto appropriate agar plates (Trypticase soy agar (TSA) with lecithin and polysorbate 80) for all compounding personnel occurs at least annually for low- and medium-risk level CSPs and semiannually for high-risk level CSPs before being allowed to continue compounding CSPs. Gloves shall not be disinfected with sterile 70% IPA prior to testing. The cfu action level is based on the total number of cfu on both gloves and not per hand. [ENVIRONMENTAL QUALITY AND CONTROL : Gloved Fingertip Sampling]	Yes

VERIFICATION

101. Labels of CSPs contain name and address of pharmacy, correct names and amounts or concentrations of ingredients, total volumes, beyond-use dates, storage conditions, and route(s) of administration. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Identity and Strength Verification of Ingredients]	Yes
102. Facility has documentation that procedures have been followed to ensure sterility, purity, correct identities and amounts of ingredients, and stability. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Inspection of Solution Dosage Forms and Review of Compounding Procedures]	Yes
103. CSP's are visually inspected for abnormal particulate matter and color, and intact containers and seals. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Inspection of Solution Dosage Forms and Review of Compounding Procedures]	Yes
104. Beyond Use Dates are assigned using direct stability-indicating assays or authoritative literature that supports the assigned BUD. [STORAGE AND BEYOND-USE DATING : Determining Beyond-Use Dates]	Yes
105. Storage time of assembled bag and vial systems are according to the manufacturer recommendations. (eg Minibag plus, Addvantage, Add-ease) [STORAGE AND BEYOND-USE DATING : Proprietary Bag and Vial Systems]	N/A

DISPENSING/DISTRIBUTION

106. Facility has written procedures for proper packaging, storage, and transportation conditions to maintain sterility, quality, purity, and strength of CSPs. [MAINTAINING STERILITY, PURITY, AND STABILITY OF DISPENSED AND DISTRIBUTED CSPs :] *Refrigerated CSP's are shipped same day or overnight via courier and are required to maintain temp of 2 to 8 celcius and shall not exceed 8 degrees C longer than 8 hours prior to patient receiving CSP. Policy does not indicate how temperature of CSP is known during transit or upon delivery.*	No
107. Modes of transport are used that maintain appropriate temperatures and prevent damage to CSPs. [MAINTAINING STERILITY, PURITY, AND STABILITY OF DISPENSED AND DISTRIBUTED CSPs : Packaging and Transporting CSPs]	Yes
108. Facility provides a multiple component formal training program to ensure patients and caregivers understand the proper storage, handling, use, and disposal of CSPs. [PATIENT OR CAREGIVER TRAINING]	Yes

POLICY/PROCEDURE

109. Written procedures detail cleaning and disinfecting the sterile compounding areas including cleansers, disinfectants, and non-shedding wipe and mop materials. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
110. A written procedure is in place for cleaning and disinfecting the Direct Compounding Areas. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
111. Facility has written procedures to verify correct identity, quality, amounts, and purities of ingredients used in CSPs. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Identity and Strength Verification of Ingredients]	Yes
112. Policies address packaging to maintain physical integrity, sterility, stability, and purity of CSPs. [MAINTAINING STERILITY, PURITY, AND STABILITY OF DISPENSED AND DISTRIBUTED CSPs : Packaging and Transporting CSPs]	Yes
113. Written standard procedures describe means for patients to ask questions and report concerns and adverse events with CSPs, and for compounding pharmacists to correct and prevent future problems. [PATIENT MONITORING AND ADVERSE EVENTS REPORTING]	Yes

RADIOPHARMACEUTICALS

114. Facility has appropriate primary engineering controls and radioactivity containment and shielding. Location of primary engineering controls permitted in ISO Class 8 controlled environment. [RADIOPHARMACEUTICALS AS CSPs]	
115. Radiopharmaceuticals prepared as low-risk level CSPs with 12-hour or less BUD are prepared in a segregated compounding area. Segregated compounding area is designated with a line of demarcation. [RADIOPHARMACEUTICALS AS CSPs]	
116. Technetium-99m/Molybdenum-99 generators are eluted in ISO Class 8 conditions. [RADIOPHARMACEUTICALS AS CSPs]	

MISCELLANEOUS

INV797-Sterile Compounding

Insp # 166381

OPTUM INFUSION SERVICES 203, INC

File # 21072

117. Facility engaged in office use sterile compounding for human use is registered with FDA as an outsourcing facility. [FAC 64B16-27.700 (3)(g]	N/A
118. Compounding records are properly maintained. [FAC 64B16-28.140(4)]	Yes
119. When compounding activities require the manipulation of a patient's blood-derived or other biological material, the manipulations are clearly separated from routine material-handling procedures and equipment used in CSP preparation activities, and they are controlled by specific standard operating procedures in order to avoid any cross-contamination. [ENVIRONMENTAL QUALITY AND CONTROL : Placement of Primary Engineering Controls Within ISO Class 7 Buffer Areas]	N/A

SPECIAL PARENTERAL ENTERAL & EXTENDED SCOPE

120. Pharmacy technicians properly identified and supervised. [64B16-27.420, F.A.C.]	
121. Medication properly labeled. [465.0255, F.S.] [64B16-28.108, F.A.C.]	
122. Expired medications removed from the shelves. [64B16-28.110, F.A.C.]	
123. CQI Policy and Procedures and quarterly meetings. [766.101, F.S.] [64B16-27.300, F.A.C.]	
124. Prescriptions have the date dispensed and dispensing pharmacists. [893.04(1)(c) 6, F.S.] [64B16-28.140(3)(b), F.A.C.]	
125. Pharmacy maintains patient profile records. [64B16-27.800, F.A.C.]	
126. All controlled substance prescriptions contain information required. [893.04, F.S.]	
127. Prescriptions for controlled substances are on counterfeit-proof prescription pads or blanks purchased from a Department-approved vendor and the quantity and date meet the requirements of [456.42(2), F.S.].	
128. Controlled substance inventory taken on a biennial basis and available for inspection. [893.07(1)(a), F.S.]	
129. DEA 222 order forms properly completed. [893.07, F.S.]	
130. Controlled substance records and Rx information in computer system is retrievable. [21CFR 1306.22] [64B16-28.140, F.A.C.]	
131. Controlled substance records maintained for 4 years. [465.022(12)(b), F.S.]	
132. Certified daily log OR printout maintained. [21CFR 1306.22(b)(3)] [64B16-28.140(3)(b), F.A.C.]	
133. Pharmacy is reporting to the PDMP within 7 days of dispensing controlled substance. [893.055(4), F.S.]	
134. Pharmacy maintains invoices documenting that medicinal drugs were obtained from a Florida licensed distributor. 499.005 (14)	

CORRECTIVE ACTION PLAN

135. A corrective action plan is required to be submitted within 30 days for the non-compliant items listed above.	Yes

Remarks:

Routine SSCP inspection conducted with Mary Jo Giles, PIC and Leslie Nazario, Rph.

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge. I have received a copy of the Licensee Bill of Rights.

Inspector Signature:

Date:1/30/2020

Representative:

Mary Jo Giles

Date:1/30/2020

STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES
INV797-Sterile Compounding

File # 21072
Insp # 159892

NAME	PERMIT NUMBER	DATE OF INSPECTION
BriovaRx Infusion Services 203, Inc.	27913	05/07/2019
DOING BUSINESS AS BRIOVARX INFUSION SERVICES 203, INC.		
STREET ADDRESS 9984 PREMIER PARKWAY	**TELEPHONE #**	**EXT**
CITY MIRAMAR	**COUNTY** BROWARD	**STATE/ZIP** FL/33025

Additional Information

Business Operation Hours

M-T-W-TH-F Y	Weekly Hours 8:30 am to 5:30
Monday N	Tuesday N
Wednesday N	Thursday N
Friday N	Saturday N
Sunday N	

Registered Pharmacist / Intern / Tech

License # PS49270	Licensee Name Shirley Elisbrun Adams
License Type Registered Pharmacists	
License # PS36287	Licensee Name Vincent Ekebu
License Type Registered Pharmacists	
License # PS52096	Licensee Name Jacqueline Rodriguez
License Type Registered Pharmacists	
License # PS21110	Licensee Name Manuela Vega-Rivera
License Type Registered Pharmacists	
License # PS46873	Licensee Name Mary Jo Giles
License Type Registered Pharmacists	
License # PS38581	Licensee Name Leslie Nazario
License Type Registered Pharmacists	
License # RPT35999	Licensee Name Anthony Quinton Ottley
License Type Pharmacy Tech	
License # RPT38111	Licensee Name Gsa Gsa Alexandria Talamas
License Type Registered Pharmacists	

ACS Manager

Optional Information

Basic License Data - PSD

DEA Reg # BA7935490	

License Relations

Pharmacy Affiliate

ADLER, IAN	License #
BRONSON, DAVID	License #
DEBLASI, PAIGE	License #
FRENI, LAWRENCE	License #

KLEINMAN, IRA	License #
KRAMM, EDWARD P	License #
KRAMM, KATHEE M	License #
WILKINS, JOHN	License #
YORK, CHRISTOPHER	License #

RX DPT MGR/COR/POR

GILES, MARY JO B	License # 46873

Special Sterile Compounding

BRIOVARX INFUSION SERVICES 203, INC.	License # 18740

INV797 - Sterile Compounding

LOW RISK

1. Low risk CSP's are properly identified: Aseptic manipulations within an ISO Class 5 environment using three or fewer sterile products and no more than two entries into any container. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Low-Risk Level CSPs]	Yes
2. Low Risk CSP's, in absence of passing sterility test, stored not more than 48 hours at controlled room temperature, 14 days at cold temperature, or 45 days in solid frozen state at -25° to -10° or colder. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Low-Risk Level CSPs]	Yes
3. Low Risk CSP's with 12 hour BUD are properly identified and comply with all four specific criteria. 1. PEC in Segregated Compounding area 2. Away from windows, doors , high traffic areas 3. Hygiene & garbing required, sinks not adjacent to PEC. 4. Cleaning & Disinfecting, Personnel training, Competency evaluation, Garbing, Aseptic work practices, Viable and non-viable environmental sampling apply. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Low-Risk Level CSPs]	N/A

MEDIUM RISK

4. Medium Risk CSP's are properly identified: Aseptic manipulations within an ISO Class 5 environment using prolonged and complex mixing and transfer, more than three sterile products and entries into any container, and pooling ingredients from multiple sterile products to prepare multiple CSPs. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Medium-Risk Level CSPs]	Yes
5. Medium Risk CSP's, In absence of passing sterility test, stored not more than 30 hours at controlled room temperature, 9 days at cold temperature, or 45 days in solid frozen state at -25° to -10° or colder. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Medium-Risk Level CSPs]	Yes

HIGH RISK

6. Presterilization procedures for high-risk level CSPs, such as weighing and mixing, are completed in no worse than an ISO Class 8 environment. [ENVIRONMENTAL QUALITY AND CONTROL : Placement of Primary Engineering Controls Within ISO Class 7 Buffer Areas]	
7. High Risk CSP's are properly identified: Confirmed presence of nonsterile ingredients and devices, or confirmed or suspected exposure of sterile ingredients for more than one hour to air quality inferior to ISO Class 5 before final sterilization. [CSP MICROBIAL CONTAMINATION RISK LEVELS : High-Risk Level CSPs]	
8. High Risk CSP's, in absence of passing sterility test are not stored more than 24 hours at controlled room temperature, 3 days at cold temperature, or 45 days in solid frozen state at -25° to -10° or colder. [CSP MICROBIAL CONTAMINATION RISK LEVELS : High-Risk Level CSPs]	
9. A 0.2-µm certified sterilizing membrane filter is used that is chemically and physically compatible with the CSP. Filtration is completed rapidly without filter replacement. Sterilization method is verified to achieve sterility for the quantity and type of containers. [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Sterilization of High-Risk Level CSPs by Filtration]	
10. Sterilization method used has documentation that acceptable strength and purity of ingredients and integrity of containers is maintained. [CSP MICROBIAL CONTAMINATION RISK LEVELS : High-Risk Level CSPs]	
11. The manufacturer recommended filter integrity (e.g., bubble point) test is performed and documented for all sterilizing filters after filtering CSPs. [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Sterilization of High-Risk Level CSPs by Filtration]	
12. Autoclave cycle has been verified using appropriate biological indicators. Solutions are passed through a 1.2-µm or smaller filter into final containers to remove particulates before sterilization. [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Sterilization of High-Risk Level CSPs by Steam]	
13. Dry heat ovens used for sterilization have filtered forced air. Only those items that will be damaged by steam are sterilized by dry heat. [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Sterilization of High-Risk Level CSPs by Dry Heat]	
14. The description of dry heat sterilization conditions and duration for specific CSPs is included in written documentation in the compounding facility. The effectiveness of dry heat sterilization is verified using appropriate biological indicators and other confirmation. [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Sterilization of High-Risk Level CSPs by Dry Heat]	
15. Dry heat depyrogenation is used to render glassware or containers, such as vials free from pyrogens as well as viable microbes. The description of the dry heat depyrogenation cycle and duration for specific load items is included in written documentation in the compounding facility. The effectiveness of the dry heat depyrogenation cycle is verified using endotoxin challenge vials (ECVs). [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Depyrogenation by Dry Heat]	
16. Sterility testing is completed for all High-risk level CSPs prepared in batches of more than 25 identical containers, or exposed longer than 12 hours at 2° to 8°, and 6 hours at warmer than 8° before being sterilized. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Sterility Testing]	

USP <71> STERILITY TESTING (Outsourced)

17. Outsourced sterility testing results indicate that it is compliant with USP<71>. A method not described in the USP may be used if validation demonstrates that the alternative is at least as effective and reliable. [STERILITY TEST USP<71>]	
18. Outsourced: The number of articles tested are appropriate according to USP<71>. [STERILITY TEST USP<71> : Number of Articles to Be Tested]	
19. Outsourced: The volume/quantity tested is according to USP<71>. [STERILITY TEST USP<71> : Number of Articles to Be Tested]	
20. Outsourced: A USP<71> method suitability test has been done with appropriate inoculum, additives and rinses. [STERILITY TEST USP<71> : Method Suitability Test]	

21. Outsourced: Sterility testing reports are reviewed and appropriate actions taken and documented. [FINISHED PREPARATION RELEASE CHECKS AND TESTS]	

USP <71> STERILITY TESTING

22. On site: Membrane filtration is used if appropriate. (The technique of membrane filtration is used whenever the nature of the product permits; that is, for filterable aqueous preparations, for alcoholic or oily preparations, and for preparations miscible with, or soluble in, aqueous or oily solvents, provided these solvents do not have an antimicrobial effect in the conditions of the test.) Filters are rinsed according to USP<71>. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Sterility Testing]	
23. On site: Direct inoculation is done only when membrane filtration cannot be carried out. Volume to be inoculated does not exceed 10% of the culture media volume. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Sterility Testing]	
24. On site: The number of articles tested are appropriate according to USP<71>. [STERILITY TEST USP<71> : Number of Articles to Be Tested]	
25. On site: The volume/quantity tested is according to USP<71>. [STERILITY TEST USP<71> : Number of Articles to Be Tested]	
26. On site: A growth promotion test has been done on the media with the 5 specified organisms (not more than 100 CFU) according to USP<71>. [STERILITY TEST USP<71> : Growth Promotion Test of Aerobes, Anaerobes, and Fungi]	
27. On site: A USP<71> method suitability test has been done with appropriate inoculum, additives and rinses. [STERILITY TEST USP<71> : Method Suitability Test]	
28. On site: TSB or SCD is incubated at 20-25 C for 14 days (2 incubators present). [STERILITY TEST USP<71> : Culture Media and Incubation Temperatures]	
29. On site: FTM is incubated at 30-35 C for 14 days (2 incubators present). [STERILITY TEST USP<71> : Culture Media and Incubation Temperatures]	
30. On site: Sterility testing is documented including lot numbers and expiration dates of media. [FINISHED PREPARATION RELEASE CHECKS AND TESTS]	
31. On site: Sterility testing reports are reviewed and appropriate actions taken and documented. [FINISHED PREPARATION RELEASE CHECKS AND TESTS]	

ENDOTOXIN TESTING

32. Endotoxin testing is conducted for High-risk level CSP's that are prepared in batches of more than 25 identical containers, or exposed longer than 12 hours at 2° to 8°, and 6 hours at warmer than 8°, before being sterilized or in multidose containers for administration to multiple patients. (excluding those for inhalation and ophthalmic administration) [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Bacterial Endotoxin (Pyrogen) Testing]	
33. Endotoxin testing process indicates that it is compliant with USP<85>. [BACTERIAL ENDOTOXINS TEST USP<85>]	
34. High Risk CSP's are within allowable limits for bacterial endotoxins. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Bacterial Endotoxin (Pyrogen) Testing]	

IMMEDIATE USE COMPOUNDING

35. Immediate-use compounding complies with all six specified criteria. 1. Low-risk sterile nonhazardous products or diagnostic radiopharmaceutical products from the manufacturers' original containers. Anti-neoplastics shall not be prepared as immediate-use CSPs because they are hazardous drugs. 2. Unless required for the preparation, the compounding procedure is a continuous process not to exceed 1 hour. 3. During preparation, aseptic technique is followed and, if not immediately administered, the finished CSP is under continuous supervision to minimize the potential for contact with nonsterile surfaces, introduction of particulate matter or biological fluids, mix-ups with other CSPs, and direct contact of outside surfaces. 4. Administration begins not later than 1 hour following the start of the preparation of the CSP. 5. Unless immediately and completely administered by the person who prepared it or immediate and complete administration is witnessed by the preparer, the CSP shall bear a label listing patient identification information, the names and amounts of all ingredients, the name or initials of the person who prepared the CSP, and the exact 1-hour BUD and time. 6. If administration has not begun within 1 hour following the start of preparing the CSP, the CSP shall be promptly, properly, and safely discarded. [IMMEDIATE-USE CSPs]	N/A

SINGLE/MULTIPLE DOSE CONTAINER BUD

36. Beyond-use date does not exceed 28 days for multiple-dose containers after initial opening or entry, unless specified otherwise by the manufacturer. [SINGLE-DOSE AND MULTIPLE-DOSE CONTAINERS]	Yes
37. Beyond-use time does not exceed 6 hours for closure sealed single-dose containers in ISO Class 5 or cleaner air after initial opening or entry, unless specified otherwise by the manufacturer. [SINGLE-DOSE AND MULTIPLE-DOSE CONTAINERS] *Preservative free Vancomycin 1g/vial stored in refrigerator without discard/entry time; D5W and NaCl preservative free IV bags hanging in PEC's without discard/entry time.*	No
38. Beyond-use time does not exceed 1 hour for closure sealed single-dose containers after being opened or entered in worse than ISO Class 5 air. [SINGLE-DOSE AND MULTIPLE-DOSE CONTAINERS]	N/A
39. Single-dose ampules are discarded immediately after use. [SINGLE-DOSE AND MULTIPLE-DOSE CONTAINERS]	Yes

HAZARDOUS DRUGS

40. A pressure indicator is installed and differential pressures are monitored and documented daily for hazardous buffer room. [HAZARDOUS DRUGS AS CSPs]	Yes
41. Hazardous drug buffer room is at least 0.01 inch water column negative pressure with 30 ACPH of HEPA filtered air. [HAZARDOUS DRUGS AS CSPs]	Yes
42. At least 0.01 inch water column negative pressure and 12 air changes per hour in non-cleanrooms in which CACIs are located. FAC: USP Chapter 797 requires that: "When closed-system vial-transfer devices (CSTDs) (i.e., vial-transfer systems that allow no venting or exposure of hazardous substance to the environment) are used, they shall be used within an ISO Class 5 environment of a BSC or CACI. The use of the CSTD is preferred because of their inherent closed system process. In facilities that prepare a low volume of hazardous drugs, the use of two tiers of containment (e.g., CSTD within a BSC or CACI that is located in a non-negative pressure room) is acceptable." For purpose of said provision, a "low volume of hazardous drugs" is defined as less than 40 doses per month. [HAZARDOUS DRUGS AS CSPs]	N/A
43. Personnel compounding hazardous drugs wear appropriate personal protective equipment. [HAZARDOUS DRUGS AS CSPs]	N/A
44. Hazardous drugs are handled with caution at all times using appropriate chemotherapy gloves during receiving, distribution, stocking, inventorying, preparing for administration, and disposal. Spill kits are available. [HAZARDOUS DRUGS AS CSPs]	N/A
45. Hazardous drugs are prepared in an ISO Class 5 environment (BSC or CACI) with protective engineering controls in place, following aseptic practices specified for the appropriate contamination risk levels. [HAZARDOUS DRUGS AS CSPs]	N/A

46. Hazardous drugs are stored separately from other inventory in a manner to prevent contamination and personnel exposure. [HAZARDOUS DRUGS AS CSPs]	Yes
47. Access to hazardous drug preparation areas is limited to authorized compounding personnel. [HAZARDOUS DRUGS AS CSPs]	Yes
48. Annual documentation of hazardous drug training of personnel regarding storage, handling, containment techniques and disposal of hazardous drugs is available. [HAZARDOUS DRUGS AS CSPs] *HD compounding has not been implented.*	N/A
49. Compounding personnel of reproductive capability have confirmed in writing that they understand the risks of handling hazardous drugs. [HAZARDOUS DRUGS AS CSPs] *HD compounding has not been implented.*	N/A
50. Facility maintains appropriate disposal containers for all hazardous waste. [HAZARDOUS DRUGS AS CSPs]	Yes

FACILITY DESIGN AND CERTIFICATION

51. Certification and testing of primary (LAFWs, BSCs, CAIs and CACIs) and secondary engineering controls (buffer and ante areas) have been performed by a qualified individual no less than every six months and whenever the device or room is relocated, altered, or major service to the facility is performed. Corrective action for deficiencies are documented. Certification procedures such as those outlined in the CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2006) are conducted under dynamic conditions. [ENVIRONMENTAL QUALITY AND CONTROL : Environmental Nonviable Particle Testing Program] *On 4/25/2019, MTA certified ISO 7 anteroom, ISO 7 IV room, ISO 7 HD room, ISO 7 negative pressure storage room. Equipment used in compounding inside PEC's include 3 TPN Pinnacle machines, 4 X repeater pumps, 2 X Tube rollers; all electronic. PEC's: 6 X VLF's (3 of which used for compounding TPN's with Pinnacle machines), 1 X HLF and 1 X BSC all to ISO 5, with only the Pinnacle machines operational.*	No
52. Primary engineering controls provide unidirectional (i.e., laminar) HEPA filtered air. Air pattern analysis via smoke studies are conducted at the critical site to demonstrate unidirectional airflow and sweeping action over and away from the product under dynamic conditions.[ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
53. The primary engineering controls are placed within a buffer area in such a manner as to avoid conditions that could adversely affect their operation. The PEC is placed out of the traffic flow and in a manner to avoid disruption from the HVAC system and room cross drafts. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
54. All HEPA filters are leak tested after installation and every six months thereafter. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes

ISOLATORS

55. CAIs are proven to maintain ISO Class 5 air when particle counts are sampled 6 to 12 inches upstream of critical site exposure areas during performance of normal inward and outward transfer of materials, and compounding manipulations when such CAIs are located in air quality worse than ISO Class 7. [ENVIRONMENTAL QUALITY AND CONTROL : Placement of Primary Engineering Controls Within ISO Class 7 Buffer Areas]	
56. Adequate recovery time for isolators to achieve ISO Class 5 air quality is allowed after material transfer before and during compounding operations. [ENVIRONMENTAL QUALITY AND CONTROL : Placement of Primary Engineering Controls Within ISO Class 7 Buffer Areas]	
57. Personnel garbing requirements are followed for CAIs unless manufacturer provides written documentation based on validated testing that any components of PPE are not required to maintain sterility of CSPs. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	

FACILITY DESIGN AND CERTIFICATION (Secondary Engineering Controls)

58. Facility has pressure gauges or velocity meters to monitor the pressure differential or airflow between the buffer area and ante-area, and the ante-area and the general environment outside the compounding area. The results are reviewed and documented on a log at least daily or by a continuous recording device. The pressures differentials meet or exceed 5 Pa (0.02 inch water column (w.c.)). Alternatively, in facilities where low- and medium-risk level CSPs are prepared, differential airflow is maintained at a minimum velocity of 0.2 meter/second (40 fpm) across a line of demarcation between buffer area and ante-area. [ENVIRONMENTAL QUALITY AND CONTROL : Pressure Differential Monitoring]	Yes
59. Clean rooms for nonhazardous and nonradioactive CSPs are supplied with HEPA filtered air that enters from ceilings with return vents low on walls, and that provides not less than 30 air changes per hour or qualifies for exception in 64B16-27.797(4)(c). [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
60. Activities and tasks carried out within the buffer area are limited to only those necessary when working within a controlled environment. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
61. Only the furniture, equipment, supplies, and other material required for the compounding activities to be performed are brought into the buffer room. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
62. Surfaces and essential furniture in buffer rooms or zones and clean rooms are nonporous, smooth, non-shedding, impermeable, cleanable, and resistant to disinfectants. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
63. The surfaces of ceilings, walls, floors, fixtures, shelving, counters, and cabinets in the buffer area are smooth, impervious, free from cracks and crevices, and non-shedding, thereby promoting cleanability, and minimizing spaces in which microorganisms and other contaminants may accumulate. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
64. Ceiling tiles are caulked around each perimeter and to walls to seal them to the support frame. The exterior lens surface of ceiling lighting fixtures is smooth, mounted flush, and sealed. All other penetrations through the ceiling or walls are sealed. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
65. The buffer area does not contain sources of water (sinks) or floor drains. Work surfaces are constructed of smooth, impervious materials, such as stainless steel or molded plastic, so that they are easily cleaned and disinfected. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
66. Storage shelving, counters, cabinets and carts/casters in the buffer area are smooth, impervious, free from cracks and crevices, non-shedding, non-porous, cleanable, and disinfectable. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
67. When devices (e.g., computers and printers) and objects (e.g., carts and cabinets) are placed in buffer areas, air quality is verified by particle counts on certification. [ENVIRONMENTAL QUALITY AND CONTROL : ISO Class 5 Air Sources, Buffer Areas, and Ante-Areas] *There are 4 X repeater pumps, 3 X Pinnacle machines and 2 Tube rollers that are located in PEC's. Per Rph, only the Pinnacle TPN machines are operational during particle counts.*	No

QUALITY AND CONTROL

68. An appropriate environmental sampling plan has been developed for airborne viable particles based on a risk assessment of compounding activities performed. Volumetric air sampling is conducted every six months and sites include locations within each ISO Class 5 environment and in the ISO Class 7 and 8 areas, and the areas at greatest risk of contamination (e.g., work areas near the ISO Class 5 environment, counters near doors, pass-through boxes). The plan includes sample locations, method of collection, frequency of sampling, volume of air sampled, and time of day as related to activity in the compounding area and action levels. [ENVIRONMENTAL QUALITY AND CONTROL : Environmental Viable Airborne Particle Testing Program—Sampling Plan]	Yes
69. Evaluation of airborne microorganisms using volumetric collection methods in the controlled air environments is performed by properly trained individuals for all compounding risk levels. [ENVIRONMENTAL QUALITY AND CONTROL : Viable Air Sampling] *Per policy 9701 quarterly VAS (using CLIMET impactor) is collected in all ISO classified air.*	Yes
70. Volumetric air sampling using malt extract agar (MEA) or some other media that supports the growth of fungi is used in high-risk level compounding environments. [ENVIRONMENTAL QUALITY AND CONTROL : Growth Media]	N/A
71. For low-risk level CSPs with 12-hour or less BUD, air sampling is performed at locations inside the ISO Class 5 environment and other areas that are in close proximity to the ISO class 5 environment. [ENVIRONMENTAL QUALITY AND CONTROL : Viable Air Sampling]	N/A
72. The number of discrete colonies of microorganisms is counted and reported as colony-forming units (cfu) and documented on an environmental monitoring form. Counts from air monitoring are transformed into cfu/cubic meter of air and evaluated for adverse trends. [ENVIRONMENTAL QUALITY AND CONTROL : Incubation Period] *Trending data is in the process of being implemented by corporate.*	No
73. Surface sampling is accomplished in all ISO classified areas on a periodic basis using TSA contact plates with lecithin and polysorbate 80 and/or swabs and is done at the conclusion of compounding. [ENVIRONMENTAL QUALITY AND CONTROL : Surface Cleaning and Disinfection Sampling and Assessment] *This is done in house monthly, per policy. EM policy 9701 (implemented March 2019) requires two incubation temperatures, 30-35 degrees C X 2 days, then 20-25 degrees C X 5 days. Facility practice is incubation at 30-35 C X 72 hours.*	No
74. Sampling data is collected and reviewed on a periodic basis as a means of evaluating the overall state of control of the compounding environment. [ENVIRONMENTAL QUALITY AND CONTROL : Action Levels, Documentation and Data Evaluation]	Yes
75. Competent microbiology personnel are consulted if an environmental sampling consistently shows elevated levels of microbial growth. If any mold, yeast, coagulase positive staphylococcus, or gram negative rods are detected immediate remediation and investigation into the cause and source was conducted. [ENVIRONMENTAL QUALITY AND CONTROL : Action Levels, Documentation and Data Evaluation]	Yes
76. Surfaces in the LAFWs, BSCs, CAIs, and CACIs are cleaned and disinfected frequently, including at the beginning of each work shift, before each batch preparation is started, every 30 minutes during continuous compounding periods of individual CSPs, when there are spills, and when surface contamination is known or suspected from procedural breaches. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
77. Cleaning and disinfecting occurs before compounding is performed. Items are removed from all areas to be cleaned, and surfaces are cleaned by removing loose material and residue from spills, e.g., water-soluble solid residues are removed with Sterile Water and low-shedding wipes. This shall be followed by wiping with a residue-free disinfecting agent, such as sterile 70% IPA, which is allowed to dry before compounding begins. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
78. Cleaning and disinfecting agents and methods of application are in accordance with written SOPs and followed by custodial and/or compounding personnel. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
79. Cleaning materials, such as wipes, sponges, and mops, are non-shedding, preferably composed of synthetic micro fibers, and dedicated to use in the buffer area, ante-area, and segregated compounding areas and are not removed from these areas except for disposal. If cleaning materials are reused (e.g., mops), there are procedures based on manufacturer recommendations that ensure that the effectiveness of the cleaning device is maintained and repeated use does not add to the bioburden of the area being cleaned. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
80. Supplies and equipment removed from shipping cartons are wiped with a suitable disinfecting agent (e.g., sterile 70% IPA). [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas] *Inspector observed RPT remove sterile drug component from ISO 5 air into ISO 7 air, remove cap and return item to ISO 5 without disinfecting.*	No
81. Disinfectant sprayed or wiped on a surface to be disinfected is allowed to dry, and during this time the item is not be used for compounding purposes. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
82. Sterile 70% IPA pads are used to disinfect the sterile entry points of packages and devices. Wetted gauze pads or other particle-generating material are not appropriate. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas] *Inspector observed RPT spray septum with sIPA without wiping.*	No

QUALITY AND CONTROL (Secondary Engineering Controls)

83. Work surfaces in ISO Class 7 and 8 areas and segregated compounding areas are cleaned at least daily. IPA (70% isopropyl alcohol) remains on surfaces to be disinfected for at least 30 seconds before such surfaces are used to prepare CSPs. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
84. Floors in ISO Class 7 and 8 areas are mopped daily by trained personnel at a time when no aseptic operations are in progress using approved agents and procedures described in written SOP's. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
85. Shelving, walls, and ceilings in ante-areas and buffer areas are cleaned and disinfected at least monthly. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas] *Yes, BUT advise to document day of monthly cleaning to ensure consistency.*	Yes

PERSONNEL CLEANSING, GARBING & COMPETENCY EVALUATION

86. Personnel preparing CSP's are free from rashes, sunburn, weeping sores, conjunctivitis, and active respiratory infections. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	Yes
87. Compounding personnel remove personal outer garments; cosmetics; artificial nails; hand, wrist, and body jewelry that can interfere with the fit of gowns and gloves; and visible body piercing above the neck. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	Yes
88. Facility has adequate supplies to meet PPE requirements of USP<797>. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	Yes
89. Garbing and hand hygiene are accomplished in the ante-area in order of dirtiest to cleanest: shoes or shoe covers, head and facial hair covers, face mask, fingernail cleansing, hand and forearm washing and drying; non-shedding gown. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	Yes
90. Sterile gloves are donned in the buffer room/isolator after hand cleansing with an alcohol-based product with persistent activity and hands are allowed to dry. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	Yes
91. Gloves are routinely disinfected with sterile 70% IPA after contacting nonsterile objects. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	Yes

92. Personnel repeat garbing and hand hygiene after they are exposed to direct contact contamination or worse than ISO Class 8 air. Gowns may be hung in the anteroom and reused during the same workshift. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	Yes
93. Low/Medium Risk media-fill tests that closely simulate the most challenging or stressful conditions encountered during compounding are completed at least annually by compounding personnel. Media-filled vials are appropriately incubated for 14 days. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Medium-Risk Level CSPs]	Yes
94. High Risk Media-fill tests that closely simulate the most challenging or stressful conditions encountered during compounding have been completed at least semiannually by compounding personnel. Media-filled vials are appropriately incubated for 14 days. [CSP MICROBIAL CONTAMINATION RISK LEVELS : High-Risk Level CSPs]	N/A
95. Documentation indicates compounding personnel have successfully completed didactic training, passed written competency assessments, undergone skill assessment using observational audit tools (hand hygiene, garbing, aseptic technique) and media-fill testing annually or semiannually (high risk) and before any compounding personnel begin to prepare CSPs . [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures]	Yes
96. Compounding personnel who fail written tests, observational audits, or whose media-fill test vials have one or more units showing visible microbial contamination, are reinstructed and re-evaluated by expert compounding personnel to ensure correction of all aseptic work practice deficiencies. Corrective action is documented. Compounding personnel pass all evaluations prior to resuming compounding of sterile preparations. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures] *Media fill tests for three compounding RPT's (RS, WG, GT) indicate particles found in media; Employees were not re-validated.*	No
97. Other cleaning personnel performing cleaning and disinfecting procedures (e.g. environmental) are thoroughly trained in proper hand hygiene, and garbing, cleaning, and disinfection procedures by a qualified aseptic compounding expert. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures]	N/A
98. Compounding personnel and other personnel responsible for cleaning routinely undergo performance evaluation of proper hand hygiene, garbing, and all applicable cleaning and disinfecting procedures conducted by a qualified aseptic compounding expert. Visual observation of hand hygiene, garbing and cleaning is documented and maintained to provide a permanent record and long-term assessment of personnel competency. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures] *GT RPT performs monthly cleaning, but has not demonstrated proficency for this task.*	No
99. Immediately after the compounder completes the hand hygiene and garbing procedure, the evaluator collects a gloved fingertip and thumb sample from both hands of the compounder onto appropriate agar plates. The plates are incubated at 30-35° for 2–3 days. All compounding personnel have successfully completed an initial competency evaluation and gloved fingertip/thumb sampling procedure (0 cfu) no less than three times before initially being allowed to compound CSPs for human use. [ENVIRONMENTAL QUALITY AND CONTROL : Gloved Fingertip Sampling] *Employee DB RPH failed one set of GFT on initial test, redone only once. Policy 9705 (1)(j) indicates to repeat for the number of failed GFT's observed, NOT three times.*	No
100. Re-evaluation of glove fingertip testing onto appropriate agar plates (Trypticase soy agar (TSA) with lecithin and polysorbate 80) for all compounding personnel occurs at least annually for low- and medium-risk level CSPs and semiannually for high-risk level CSPs before being allowed to continue compounding CSPs. Gloves shall not be disinfected with sterile 70% IPA prior to testing. The cfu action level is based on the total number of cfu on both gloves and not per hand. [ENVIRONMENTAL QUALITY AND CONTROL : Gloved Fingertip Sampling]	Yes

VERIFICATION

101. Labels of CSPs contain name and address of pharmacy, correct names and amounts or concentrations of ingredients, total volumes, beyond-use dates, storage conditions, and route(s) of administration. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Identity and Strength Verification of Ingredients]	Yes
102. Facility has documentation that procedures have been followed to ensure sterility, purity, correct identities and amounts of ingredients, and stability. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Inspection of Solution Dosage Forms and Review of Compounding Procedures]	Yes
103. CSP's are visually inspected for abnormal particulate matter and color, and intact containers and seals. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Inspection of Solution Dosage Forms and Review of Compounding Procedures] *Yes, BUT company policy 9620 requires use of black/white light box to inspect CSP's for particulates but this isn't being done.*	Yes
104. Beyond Use Dates are assigned using direct stability-indicating assays or authoritative literature that supports the assigned BUD. [STORAGE AND BEYOND-USE DATING : Determining Beyond-Use Dates]	Yes
105. Storage time of assembled bag and vial systems are according to the manufacturer recommendations. (eg Minibag plus, Addvantage, Add-ease) [STORAGE AND BEYOND-USE DATING : Proprietary Bag and Vial Systems]	Yes

DISPENSING/DISTRIBUTION

106. Facility has written procedures for proper packaging, storage, and transportation conditions to maintain sterility, quality, purity, and strength of CSPs. [MAINTAINING STERILITY, PURITY, AND STABILITY OF DISPENSED AND DISTRIBUTED CSPs :]	Yes
107. Modes of transport are used that maintain appropriate temperatures and prevent damage to CSPs. [MAINTAINING STERILITY, PURITY, AND STABILITY OF DISPENSED AND DISTRIBUTED CSPs : Packaging and Transporting CSPs]	Yes
108. Facility provides a multiple component formal training program to ensure patients and caregivers understand the proper storage, handling, use, and disposal of CSPs. [PATIENT OR CAREGIVER TRAINING]	Yes

POLICY/PROCEDURE

109. Written procedures detail cleaning and disinfecting the sterile compounding areas including cleansers, disinfectants, and non-shedding wipe and mop materials. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
110. A written procedure is in place for cleaning and disinfecting the Direct Compounding Areas. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
111. Facility has written procedures to verify correct identity, quality, amounts, and purities of ingredients used in CSPs. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Identity and Strength Verification of Ingredients]	Yes
112. Policies address packaging to maintain physical integrity, sterility, stability, and purity of CSPs. [MAINTAINING STERILITY, PURITY, AND STABILITY OF DISPENSED AND DISTRIBUTED CSPs : Packaging and Transporting CSPs]	Yes
113. Written standard procedures describe means for patients to ask questions and report concerns and adverse events with CSPs, and for compounding pharmacists to correct and prevent future problems. [PATIENT MONITORING AND ADVERSE EVENTS REPORTING]	N/A

RADIOPHARMACEUTICALS

114. Facility has appropriate primary engineering controls and radioactivity containment and shielding. Location of primary engineering controls permitted in ISO Class 8 controlled environment. [RADIOPHARMACEUTICALS AS CSPs]	

115. Radiopharmaceuticals prepared as low-risk level CSPs with 12-hour or less BUD are prepared in a segregated compounding area. Segregated compounding area is designated with a line of demarcation. [RADIOPHARMACEUTICALS AS CSPs]	
116. Technetium-99m/Molybdenum-99 generators are eluted in ISO Class 8 conditions. [RADIOPHARMACEUTICALS AS CSPs]	

MISCELLANEOUS

117. Facility engaged in office use sterile compounding for human use is registered with FDA as an outsourcing facility. [FAC 64B16-27.700 (3)(g]	N/A
118. Compounding records are properly maintained. [FAC 64B16-28.140(4)]	Yes
119. When compounding activities require the manipulation of a patient's blood-derived or other biological material, the manipulations are clearly separated from routine material-handling procedures and equipment used in CSP preparation activities, and they are controlled by specific standard operating procedures in order to avoid any cross-contamination. [ENVIRONMENTAL QUALITY AND CONTROL : Placement of Primary Engineering Controls Within ISO Class 7 Buffer Areas]	N/A

SPECIAL PARENTERAL ENTERAL & EXTENDED SCOPE

120. Pharmacy technicians properly identified and supervised. [64B16-27.420, F.A.C.]	
121. Medication properly labeled. [465.0255, F.S.] [64B16-28.108, F.A.C.]	
122. Expired medications removed from the shelves. [64B16-28.110, F.A.C.]	
123. CQI Policy and Procedures and quarterly meetings. [766.101, F.S.] [64B16-27.300, F.A.C.]	
124. Prescriptions have the date dispensed and dispensing pharmacists. [893.04(1)(c) 6, F.S.] [64B16-28.140(3)(b), F.A.C.]	
125. Pharmacy maintains patient profile records. [64B16-27.800, F.A.C.]	
126. All controlled substance prescriptions contain information required. [893.04, F.S.]	
127. Prescriptions for controlled substances are on counterfeit-proof prescription pads or blanks purchased from a Department-approved vendor and the quantity and date meet the requirements of [456.42(2), F.S.].	
128. Controlled substance inventory taken on a biennial basis and available for inspection. [893.07(1)(a), F.S.]	
129. DEA 222 order forms properly completed. [893.07, F.S.]	
130. Controlled substance records and Rx information in computer system is retrievable. [21CFR 1306.22] [64B16-28.140, F.A.C.]	
131. Controlled substance records maintained for 4 years. [465.022(12)(b), F.S.]	
132. Certified daily log OR printout maintained. [21CFR 1306.22(b)(3)] [64B16-28.140(3)(b), F.A.C.]	
133. Pharmacy is reporting to the PDMP within 7 days of dispensing controlled substance. [893.055(4), F.S.]	
134. Pharmacy maintains invoices documenting that medicinal drugs were obtained from a Florida licensed distributor. 499.005 (14)	

Remarks:

Facility has certified an ISO 7 negtive pressure hazardous cleanroom and negative pressure HD storage room. Hazardous comopounding has not been implemented at this facility at this time.
Routine inspection conducted with Shirley Adams RPH, Leslie Nazario, and Mary Jo Giles (PIC) .
Corrective action requested for all items marked "no" on or before June 7, 2019.

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge. I have received a copy of the Licensee Bill of Rights.

Inspector Signature:

Date:5/7/2019

Representative:

Mary Jo Giles

Date:5/7/2019

STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES
INV797-Sterile Compounding

File # 21072
Insp # 158704

NAME	PERMIT NUMBER	DATE OF INSPECTION
BriovaRx Infusion Services 203, Inc.	27913	06/01/2018
DOING BUSINESS AS BRIOVARX INFUSION SERVICES 203, INC.		
STREET ADDRESS 9984 PREMIER PARKWAY	**TELEPHONE #**	**EXT**
CITY MIRAMAR	**COUNTY** BROWARD	**STATE/ZIP** FL/33025

Additional Information

Business Operation Hours

M-T-W-TH-F Y	Weekly Hours 8:30 am to 5:30
Monday N	Tuesday N
Wednesday N	Thursday N
Friday N	Saturday N
Sunday N	

Registered Pharmacist / Intern / Tech

License # PS49270	Licensee Name Shirley Elisbrun
License Type Registered Pharmacists	
License # PS36287	Licensee Name Vincent Ekebu
License Type Registered Pharmacists	
License # PS52096	Licensee Name Jacqueline Rodriguez
License Type Registered Pharmacists	
License # PS21110	Licensee Name Manuela Vega-Rivera
License Type Registered Pharmacists	
License # 29706	Licensee Name Katrina Phillip
License Type Pharmacy Tech	
License # PS46873	Licensee Name Mary Jo Giles
License Type Registered Pharmacists	

ACS Manager

Optional Information

Basic License Data - PSD

DEA Reg # BA7935490	

License Relations

Pharmacy Affiliate

ADLER, IAN	License #
BRONSON, DAVID	License #
DEBLASI, PAIGE	License #
FRENI, LAWRENCE	License #
KLEINMAN, IRA	License #
KRAMM, EDWARD P	License #
KRAMM, KATHEE M	License #
WILKINS, JOHN	License #

YORK, CHRISTOPHER	License #

RX DPT MGR/COR/POR

ELISBRUN, SHIRLEY	License # 49270

Special Sterile Compounding

BRIOVARX INFUSION SERVICES 203, INC.	License # 18740

INV797 - Sterile Compounding

LOW RISK

1. Low risk CSP's are properly identified: Aseptic manipulations within an ISO Class 5 environment using three or fewer sterile products and no more than two entries into any container. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Low-Risk Level CSPs]	
2. Low Risk CSP's, in absence of passing sterility test, stored not more than 48 hours at controlled room temperature, 14 days at cold temperature, or 45 days in solid frozen state at -25° to -10° or colder. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Low-Risk Level CSPs]	
3. Low Risk CSP's with 12 hour BUD are properly identified and comply with all four specific criteria. 1. PEC in Segregated Compounding area 2. Away from windows, doors , high traffic areas 3. Hygiene & garbing required, sinks not adjacent to PEC. 4. Cleaning & Disinfecting, Personnel training, Competency evaluation, Garbing, Aseptic work practices, Viable and non-viable environmental sampling apply. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Low-Risk Level CSPs]	

MEDIUM RISK

4. Medium Risk CSP's are properly identified: Aseptic manipulations within an ISO Class 5 environment using prolonged and complex mixing and transfer, more than three sterile products and entries into any container, and pooling ingredients from multiple sterile products to prepare multiple CSPs. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Medium-Risk Level CSPs]	
5. Medium Risk CSP's, In absence of passing sterility test, stored not more than 30 hours at controlled room temperature, 9 days at cold temperature, or 45 days in solid frozen state at -25° to -10° or colder. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Medium-Risk Level CSPs]	

HIGH RISK

6. Presterilization procedures for high-risk level CSPs, such as weighing and mixing, are completed in no worse than an ISO Class 8 environment. [ENVIRONMENTAL QUALITY AND CONTROL : Placement of Primary Engineering Controls Within ISO Class 7 Buffer Areas]	
7. High Risk CSP's are properly identified: Confirmed presence of nonsterile ingredients and devices, or confirmed or suspected exposure of sterile ingredients for more than one hour to air quality inferior to ISO Class 5 before final sterilization. [CSP MICROBIAL CONTAMINATION RISK LEVELS : High-Risk Level CSPs]	
8. High Risk CSP's, in absence of passing sterility test are not stored more than 24 hours at controlled room temperature, 3 days at cold temperature, or 45 days in solid frozen state at -25° to -10° or colder. [CSP MICROBIAL CONTAMINATION RISK LEVELS : High-Risk Level CSPs]	
9. A 0.2-µm certified sterilizing membrane filter is used that is chemically and physically compatible with the CSP. Filtration is completed rapidly without filter replacement. Sterilization method is verified to achieve sterility for the quantity and type of containers. [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Sterilization of High-Risk Level CSPs by Filtration]	
10. Sterilization method used has documentation that acceptable strength and purity of ingredients and integrity of containers is maintained. [CSP MICROBIAL CONTAMINATION RISK LEVELS : High-Risk Level CSPs]	
11. The manufacturer recommended filter integrity (e.g., bubble point) test is performed and documented for all sterilizing filters after filtering CSPs. [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Sterilization of High-Risk Level CSPs by Filtration]	
12. Autoclave cycle has been verified using appropriate biological indicators. Solutions are passed through a 1.2-µm or smaller filter into final containers to remove particulates before sterilization. [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Sterilization of High-Risk Level CSPs by Steam]	
13. Dry heat ovens used for sterilization have filtered forced air. Only those items that will be damaged by steam are sterilized by dry heat. [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Sterilization of High-Risk Level CSPs by Dry Heat]	
14. The description of dry heat sterilization conditions and duration for specific CSPs is included in written documentation in the compounding facility. The effectiveness of dry heat sterilization is verified using appropriate biological indicators and other confirmation. [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Sterilization of High-Risk Level CSPs by Dry Heat]	
15. Dry heat depyrogenation is used to render glassware or containers, such as vials free from pyrogens as well as viable microbes. The description of the dry heat depyrogenation cycle and duration for specific load items is included in written documentation in the compounding facility. The effectiveness of the dry heat depyrogenation cycle is verified using endotoxin challenge vials (ECVs). [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Depyrogenation by Dry Heat]	
16. Sterility testing is completed for all High-risk level CSPs prepared in batches of more than 25 identical containers, or exposed longer than 12 hours at 2° to 8°, and 6 hours at warmer than 8° before being sterilized. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Sterility Testing]	

USP <71> STERILITY TESTING (Outsourced)

17. Outsourced sterility testing results indicate that it is compliant with USP<71>. A method not described in the USP may be used if validation demonstrates that the alternative is at least as effective and reliable. [STERILITY TEST USP<71>]	
18. Outsourced: The number of articles tested are appropriate according to USP<71>. [STERILITY TEST USP<71> : Number of Articles to Be Tested]	
19. Outsourced: The volume/quantity tested is according to USP<71>. [STERILITY TEST USP<71> : Number of Articles to Be Tested]	
20. Outsourced: A USP<71> method suitability test has been done with appropriate inoculum, additives and rinses. [STERILITY TEST USP<71> : Method Suitability Test]	
21. Outsourced: Sterility testing reports are reviewed and appropriate actions taken and documented. [FINISHED PREPARATION RELEASE CHECKS AND TESTS]	

USP <71> STERILITY TESTING

22. On site: Membrane filtration is used if appropriate. (The technique of membrane filtration is used whenever the nature of the product permits; that is, for filterable aqueous preparations, for alcoholic or oily preparations, and for preparations miscible with, or soluble in, aqueous or oily solvents, provided these solvents do not have an antimicrobial effect in the conditions of the test.) Filters are rinsed according to USP<71>. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Sterility Testing]	
23. On site: Direct inoculation is done only when membrane filtration cannot be carried out. Volume to be inoculated does not exceed 10% of the culture media volume. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Sterility Testing]	
24. On site: The number of articles tested are appropriate according to USP<71>. [STERILITY TEST USP<71> : Number of Articles to Be Tested]	
25. On site: The volume/quantity tested is according to USP<71>. [STERILITY TEST USP<71> : Number of Articles to Be Tested]	
26. On site: A growth promotion test has been done on the media with the 5 specified organisms (not more than 100 CFU) according to USP<71>. [STERILITY TEST USP<71> : Growth Promotion Test of Aerobes, Anaerobes, and Fungi]	
27. On site: A USP<71> method suitability test has been done with appropriate inoculum, additives and rinses. [STERILITY TEST USP<71> : Method Suitability Test]	
28. On site: TSB or SCD is incubated at 20-25 C for 14 days (2 incubators present). [STERILITY TEST USP<71> : Culture Media and Incubation Temperatures]	
29. On site: FTM is incubated at 30-35 C for 14 days (2 incubators present). [STERILITY TEST USP<71> : Culture Media and Incubation Temperatures]	
30. On site: Sterility testing is documented including lot numbers and expiration dates of media. [FINISHED PREPARATION RELEASE CHECKS AND TESTS]	
31. On site: Sterility testing reports are reviewed and appropriate actions taken and documented. [FINISHED PREPARATION RELEASE CHECKS AND TESTS]	

ENDOTOXIN TESTING

32. Endotoxin testing is conducted for High-risk level CSP's that are prepared in batches of more than 25 identical containers, or exposed longer than 12 hours at 2° to 8°, and 6 hours at warmer than 8°, before being sterilized or in multidose containers for administration to multiple patients. (excluding those for inhalation and ophthalmic administration) [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Bacterial Endotoxin (Pyrogen) Testing]	
33. Endotoxin testing process indicates that it is compliant with USP<85>. [BACTERIAL ENDOTOXINS TEST USP<85>]	
34. High Risk CSP's are within allowable limits for bacterial endotoxins. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Bacterial Endotoxin (Pyrogen) Testing]	

IMMEDIATE USE COMPOUNDING

35. Immediate-use compounding complies with all six specified criteria. 1. Low-risk sterile nonhazardous products or diagnostic radiopharmaceutical products from the manufacturers' original containers. Anti-neoplastics shall not be prepared as immediate-use CSPs because they are hazardous drugs. 2. Unless required for the preparation, the compounding procedure is a continuous process not to exceed 1 hour. 3. During preparation, aseptic technique is followed and, if not immediately administered, the finished CSP is under continuous supervision to minimize the potential for contact with nonsterile surfaces, introduction of particulate matter or biological fluids, mix-ups with other CSPs, and direct contact of outside surfaces. 4. Administration begins not later than 1 hour following the start of the preparation of the CSP. 5. Unless immediately and completely administered by the person who prepared it or immediate and complete administration is witnessed by the preparer, the CSP shall bear a label listing patient identification information, the names and amounts of all ingredients, the name or initials of the person who prepared the CSP, and the exact 1-hour BUD and time. 6. If administration has not begun within 1 hour following the start of preparing the CSP, the CSP shall be promptly, properly, and safely discarded. [IMMEDIATE-USE CSPs]	N/A

SINGLE/MULTIPLE DOSE CONTAINER BUD

36. Beyond-use date does not exceed 28 days for multiple-dose containers after initial opening or entry, unless specified otherwise by the manufacturer. [SINGLE-DOSE AND MULTIPLE-DOSE CONTAINERS]	Yes
37. Beyond-use time does not exceed 6 hours for closure sealed single-dose containers in ISO Class 5 or cleaner air after initial opening or entry, unless specified otherwise by the manufacturer. [SINGLE-DOSE AND MULTIPLE-DOSE CONTAINERS] *Policy 7065 instructs SDV's and Pharmacy Bulk Packages to be discarded after six hours, but does not indicate if opened and remains in ISO 5 PEC*	No
38. Beyond-use time does not exceed 1 hour for closure sealed single-dose containers after being opened or entered in worse than ISO Class 5 air. [SINGLE-DOSE AND MULTIPLE-DOSE CONTAINERS]	N/A
39. Single-dose ampules are discarded immediately after use. [SINGLE-DOSE AND MULTIPLE-DOSE CONTAINERS]	Yes

HAZARDOUS DRUGS

40. A pressure indicator is installed and differential pressures are monitored and documented daily for hazardous buffer room. [HAZARDOUS DRUGS AS CSPs]	N/A
41. Hazardous drug buffer room is at least 0.01 inch water column negative pressure with 30 ACPH of HEPA filtered air. [HAZARDOUS DRUGS AS CSPs]	Yes
42. At least 0.01 inch water column negative pressure and 12 air changes per hour in non-cleanrooms in which CACIs are located. FAC: USP Chapter 797 requires that: "When closed-system vial-transfer devices (CSTDs) (i.e., vial-transfer systems that allow no venting or exposure of hazardous substance to the environment) are used, they shall be used within an ISO Class 5 environment of a BSC or CACI. The use of the CSTD is preferred because of their inherent closed system process. In facilities that prepare a low volume of hazardous drugs, the use of two tiers of containment (e.g., CSTD within a BSC or CACI that is located in a non-negative pressure room) is acceptable." For purpose of said provision, a "low volume of hazardous drugs" is defined as less than 40 doses per month. [HAZARDOUS DRUGS AS CSPs]	N/A
43. Personnel compounding hazardous drugs wear appropriate personal protective equipment. [HAZARDOUS DRUGS AS CSPs]	N/A
44. Hazardous drugs are handled with caution at all times using appropriate chemotherapy gloves during receiving, distribution, stocking, inventorying, preparing for administration, and disposal. Spill kits are available. [HAZARDOUS DRUGS AS CSPs]	Yes
45. Hazardous drugs are prepared in an ISO Class 5 environment (BSC or CACI) with protective engineering controls in place, following aseptic practices specified for the appropriate contamination risk levels. [HAZARDOUS DRUGS AS CSPs]	N/A
46. Hazardous drugs are stored separately from other inventory in a manner to prevent contamination and personnel exposure. [HAZARDOUS DRUGS AS CSPs] *Clean room suite contains a negative pressure storage room; -0.02"w.c. at time of inspection.*	Yes
47. Access to hazardous drug preparation areas is limited to authorized compounding personnel. [HAZARDOUS DRUGS AS CSPs]	N/A

48. Annual documentation of hazardous drug training of personnel regarding storage, handling, containment techniques and disposal of hazardous drugs is available. [HAZARDOUS DRUGS AS CSPs]	N/A
49. Compounding personnel of reproductive capability have confirmed in writing that they understand the risks of handling hazardous drugs. [HAZARDOUS DRUGS AS CSPs]	N/A
50. Facility maintains appropriate disposal containers for all hazardous waste. [HAZARDOUS DRUGS AS CSPs]	N/A

FACILITY DESIGN AND CERTIFICATION

51. Certification and testing of primary (LAFWs, BSCs, CAIs and CACIs) and secondary engineering controls (buffer and ante areas) have been performed by a qualified individual no less than every six months and whenever the device or room is relocated, altered, or major service to the facility is performed. Corrective action for deficiencies are documented. Certification procedures such as those outlined in the CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2006) are conducted under dynamic conditions. [ENVIRONMENTAL QUALITY AND CONTROL : Environmental Nonviable Particle Testing Program] *MTA certified ISO 7 ante, ISO 7 clean room, ISO 7 HD room and a negative pressure hazardous drug storage room. PEC's: 7 X LAFW and 1 BSC Class II A 2 all to ISO 5 under as built conditions.*	Yes
52. Primary engineering controls provide unidirectional (i.e., laminar) HEPA filtered air. Air pattern analysis via smoke studies are conducted at the critical site to demonstrate unidirectional airflow and sweeping action over and away from the product under dynamic conditions.[ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
53. The primary engineering controls are placed within a buffer area in such a manner as to avoid conditions that could adversely affect their operation. The PEC is placed out of the traffic flow and in a manner to avoid disruption from the HVAC system and room cross drafts. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
54. All HEPA filters are leak tested after installation and every six months thereafter. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes

ISOLATORS

55. CAIs are proven to maintain ISO Class 5 air when particle counts are sampled 6 to 12 inches upstream of critical site exposure areas during performance of normal inward and outward transfer of materials, and compounding manipulations when such CAIs are located in air quality worse than ISO Class 7. [ENVIRONMENTAL QUALITY AND CONTROL : Placement of Primary Engineering Controls Within ISO Class 7 Buffer Areas]	
56. Adequate recovery time for isolators to achieve ISO Class 5 air quality is allowed after material transfer before and during compounding operations. [ENVIRONMENTAL QUALITY AND CONTROL : Placement of Primary Engineering Controls Within ISO Class 7 Buffer Areas]	
57. Personnel garbing requirements are followed for CAIs unless manufacturer provides written documentation based on validated testing that any components of PPE are not required to maintain sterility of CSPs. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	

FACILITY DESIGN AND CERTIFICATION (Secondary Engineering Controls)

58. Facility has pressure gauges or velocity meters to monitor the pressure differential or airflow between the buffer area and ante-area, and the ante-area and the general environment outside the compounding area. The results are reviewed and documented on a log at least daily or by a continuous recording device. The pressures differentials meet or exceed 5 Pa (0.02 inch water column (w.c.)). Alternatively, in facilities where low- and medium-risk level CSPs are prepared, differential airflow is maintained at a minimum velocity of 0.2 meter/second (40 fpm) across a line of demarcation between buffer area and ante-area. [ENVIRONMENTAL QUALITY AND CONTROL : Pressure Differential Monitoring]	Yes
59. Clean rooms for nonhazardous and nonradioactive CSPs are supplied with HEPA filtered air that enters from ceilings with return vents low on walls, and that provides not less than 30 air changes per hour or qualifies for exception in 64B16-27.797(4)(c). [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
60. Activities and tasks carried out within the buffer area are limited to only those necessary when working within a controlled environment. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	N/A
61. Only the furniture, equipment, supplies, and other material required for the compounding activities to be performed are brought into the buffer room. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
62. Surfaces and essential furniture in buffer rooms or zones and clean rooms are nonporous, smooth, non-shedding, impermeable, cleanable, and resistant to disinfectants. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
63. The surfaces of ceilings, walls, floors, fixtures, shelving, counters, and cabinets in the buffer area are smooth, impervious, free from cracks and crevices, and non-shedding, thereby promoting cleanability, and minimizing spaces in which microorganisms and other contaminants may accumulate. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
64. Ceiling tiles are caulked around each perimeter and to walls to seal them to the support frame. The exterior lens surface of ceiling lighting fixtures is smooth, mounted flush, and sealed. All other penetrations through the ceiling or walls are sealed. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
65. The buffer area does not contain sources of water (sinks) or floor drains. Work surfaces are constructed of smooth, impervious materials, such as stainless steel or molded plastic, so that they are easily cleaned and disinfected. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
66. Storage shelving, counters, cabinets and carts/casters in the buffer area are smooth, impervious, free from cracks and crevices, non-shedding, non-porous, cleanable, and disinfectable. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
67. When devices (e.g., computers and printers) and objects (e.g., carts and cabinets) are placed in buffer areas, air quality is verified by particle counts on certification. [ENVIRONMENTAL QUALITY AND CONTROL : ISO Class 5 Air Sources, Buffer Areas, and Ante-Areas]	Yes

QUALITY AND CONTROL

68. An appropriate environmental sampling plan has been developed for airborne viable particles based on a risk assessment of compounding activities performed. Volumetric air sampling is conducted every six months and sites include locations within each ISO Class 5 environment and in the ISO Class 7 and 8 areas, and the areas at greatest risk of contamination (e.g., work areas near the ISO Class 5 environment, counters near doors, pass-through boxes). The plan includes sample locations, method of collection, frequency of sampling, volume of air sampled, and time of day as related to activity in the compounding area and action levels. [ENVIRONMENTAL QUALITY AND CONTROL : Environmental Viable Airborne Particle Testing Program—Sampling Plan] *Environmental policy 9701 does not include USP <797> required viable air sampling by impaction, amount of air to be sampled in each ISO class space and sampling locations. Advise to use viable air sampling locations to evaluate CFU trends.*	No
69. Evaluation of airborne microorganisms using volumetric collection methods in the controlled air environments is performed by properly trained individuals for all compounding risk levels. [ENVIRONMENTAL QUALITY AND CONTROL : Viable Air Sampling]	Yes
70. Volumetric air sampling using malt extract agar (MEA) or some other media that supports the growth of fungi is used in high-risk level compounding environments. [ENVIRONMENTAL QUALITY AND CONTROL : Growth Media]	N/A

71. For low-risk level CSPs with 12-hour or less BUD, air sampling is performed at locations inside the ISO Class 5 environment and other areas that are in close proximity to the ISO class 5 environment. [ENVIRONMENTAL QUALITY AND CONTROL : Viable Air Sampling]	N/A
72. The number of discrete colonies of microorganisms is counted and reported as colony-forming units (cfu) and documented on an environmental monitoring form. Counts from air monitoring are transformed into cfu/cubic meter of air and evaluated for adverse trends. [ENVIRONMENTAL QUALITY AND CONTROL : Incubation Period] *N/A*	Yes
73. Surface sampling is accomplished in all ISO classified areas on a periodic basis using TSA contact plates with lecithin and polysorbate 80 and/or swabs and is done at the conclusion of compounding. [ENVIRONMENTAL QUALITY AND CONTROL : Surface Cleaning and Disinfection Sampling and Assessment] *Facility does monthly surface sampling in house.*	Yes
74. Sampling data is collected and reviewed on a periodic basis as a means of evaluating the overall state of control of the compounding environment. [ENVIRONMENTAL QUALITY AND CONTROL : Action Levels, Documentation and Data Evaluation] *N/A*	Yes
75. Competent microbiology personnel are consulted if an environmental sampling consistently shows elevated levels of microbial growth. If any mold, yeast, coagulase positive staphylococcus, or gram negative rods are detected immediate remediation and investigation into the cause and source was conducted. [ENVIRONMENTAL QUALITY AND CONTROL : Action Levels, Documentation and Data Evaluation] *Hazardous drug clean room viable air sampling resulted in fungal growth; investigation and terminal cleaning was completed. Retesting was completed on May 21st, results pending.*	Yes
76. Surfaces in the LAFWs, BSCs, CAIs, and CACIs are cleaned and disinfected frequently, including at the beginning of each work shift, before each batch preparation is started, every 30 minutes during continuous compounding periods of individual CSPs, when there are spills, and when surface contamination is known or suspected from procedural breaches. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas] *N/A*	Yes
77. Cleaning and disinfecting occurs before compounding is performed. Items are removed from all areas to be cleaned, and surfaces are cleaned by removing loose material and residue from spills, e.g., water-soluble solid residues are removed with Sterile Water and low-shedding wipes. This shall be followed by wiping with a residue-free disinfecting agent, such as sterile 70% IPA, which is allowed to dry before compounding begins. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas] *N/A*	Yes
78. Cleaning and disinfecting agents and methods of application are in accordance with written SOPs and followed by custodial and/or compounding personnel. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
79. Cleaning materials, such as wipes, sponges, and mops, are non-shedding, preferably composed of synthetic micro fibers, and dedicated to use in the buffer area, ante-area, and segregated compounding areas and are not removed from these areas except for disposal. If cleaning materials are reused (e.g., mops), there are procedures based on manufacturer recommendations that ensure that the effectiveness of the cleaning device is maintained and repeated use does not add to the bioburden of the area being cleaned. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
80. Supplies and equipment removed from shipping cartons are wiped with a suitable disinfecting agent (e.g., sterile 70% IPA). [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
81. Disinfectant sprayed or wiped on a surface to be disinfected is allowed to dry, and during this time the item is not be used for compounding purposes. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
82. Sterile 70% IPA pads are used to disinfect the sterile entry points of packages and devices. Wetted gauze pads or other particle-generating material are not appropriate. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes

QUALITY AND CONTROL (Secondary Engineering Controls)

83. Work surfaces in ISO Class 7 and 8 areas and segregated compounding areas are cleaned at least daily. IPA (70% isopropyl alcohol) remains on surfaces to be disinfected for at least 30 seconds before such surfaces are used to prepare CSPs. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	N/A
84. Floors in ISO Class 7 and 8 areas are mopped daily by trained personnel at a time when no aseptic operations are in progress using approved agents and procedures described in written SOP's. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	N/A
85. Shelving, walls, and ceilings in ante-areas and buffer areas are cleaned and disinfected at least monthly. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	N/A

PERSONNEL CLEANSING, GARBING & COMPETENCY EVALUATION

86. Personnel preparing CSP's are free from rashes, sunburn, weeping sores, conjunctivitis, and active respiratory infections. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	Yes
87. Compounding personnel remove personal outer garments; cosmetics; artificial nails; hand, wrist, and body jewelry that can interfere with the fit of gowns and gloves; and visible body piercing above the neck. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	Yes
88. Facility has adequate supplies to meet PPE requirements of USP<797>. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	Yes
89. Garbing and hand hygiene are accomplished in the ante-area in order of dirtiest to cleanest: shoes or shoe covers, head and facial hair covers, face mask, fingernail cleansing, hand and forearm washing and drying; non-shedding gown. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	Yes
90. Sterile gloves are donned in the buffer room/isolator after hand cleansing with an alcohol-based product with persistent activity and hands are allowed to dry. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	Yes
91. Gloves are routinely disinfected with sterile 70% IPA after contacting nonsterile objects. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	Yes
92. Personnel repeat garbing and hand hygiene after they are exposed to direct contact contamination or worse than ISO Class 8 air. Gowns may be hung in the anteroom and reused during the same workshift. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	Yes
93. Low/Medium Risk media-fill tests that closely simulate the most challenging or stressful conditions encountered during compounding are completed at least annually by compounding personnel. Media-filled vials are appropriately incubated for 14 days. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Medium-Risk Level CSPs]	Yes
94. High Risk Media-fill tests that closely simulate the most challenging or stressful conditions encountered during compounding have been completed at least semiannually by compounding personnel. Media-filled vials are appropriately incubated for 14 days. [CSP MICROBIAL CONTAMINATION RISK LEVELS : High-Risk Level CSPs]	N/A

95. Documentation indicates compounding personnel have successfully completed didactic training, passed written competency assessments, undergone skill assessment using observational audit tools (hand hygiene, garbing, aseptic technique) and media-fill testing annually or semiannually (high risk) and before any compounding personnel begin to prepare CSPs . [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures]	Yes
96. Compounding personnel who fail written tests, observational audits, or whose media-fill test vials have one or more units showing visible microbial contamination, are reinstructed and re-evaluated by expert compounding personnel to ensure correction of all aseptic work practice deficiencies. Corrective action is documented. Compounding personnel pass all evaluations prior to resuming compounding of sterile preparations. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures]	N/A
97. Other cleaning personnel performing cleaning and disinfecting procedures (e.g. environmental) are thoroughly trained in proper hand hygiene, and garbing, cleaning, and disinfection procedures by a qualified aseptic compounding expert. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures]	N/A
98. Compounding personnel and other personnel responsible for cleaning routinely undergo performance evaluation of proper hand hygiene, garbing, and all applicable cleaning and disinfecting procedures conducted by a qualified aseptic compounding expert. Visual observation of hand hygiene, garbing and cleaning is documented and maintained to provide a permanent record and long-term assessment of personnel competency. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures]	Yes
99. Immediately after the compounder completes the hand hygiene and garbing procedure, the evaluator collects a gloved fingertip and thumb sample from both hands of the compounder onto appropriate agar plates. The plates are incubated at 30-35° for 2–3 days. All compounding personnel have successfully completed an initial competency evaluation and gloved fingertip/thumb sampling procedure (0 cfu) no less than three times before initially being allowed to compound CSPs for human use. [ENVIRONMENTAL QUALITY AND CONTROL : Gloved Fingertip Sampling] *Policy 9705 indicates new employees shall complete hand hygiene three times, but not regarb three times.*	No
100. Re-evaluation of glove fingertip testing onto appropriate agar plates (Trypticase soy agar (TSA) with lecithin and polysorbate 80) for all compounding personnel occurs at least annually for low- and medium-risk level CSPs and semiannually for high-risk level CSPs before being allowed to continue compounding CSPs. Gloves shall not be disinfected with sterile 70% IPA prior to testing. The cfu action level is based on the total number of cfu on both gloves and not per hand. [ENVIRONMENTAL QUALITY AND CONTROL : Gloved Fingertip Sampling]	Yes

VERIFICATION

101. Labels of CSPs contain name and address of pharmacy, correct names and amounts or concentrations of ingredients, total volumes, beyond-use dates, storage conditions, and route(s) of administration. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Identity and Strength Verification of Ingredients] *N/A*	Yes
102. Facility has documentation that procedures have been followed to ensure sterility, purity, correct identities and amounts of ingredients, and stability. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Inspection of Solution Dosage Forms and Review of Compounding Procedures]	Yes
103. CSP's are visually inspected for abnormal particulate matter and color, and intact containers and seals. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Inspection of Solution Dosage Forms and Review of Compounding Procedures]	Yes
104. Beyond Use Dates are assigned using direct stability-indicating assays or authoritative literature that supports the assigned BUD. [STORAGE AND BEYOND-USE DATING : Determining Beyond-Use Dates] *N/A*	Yes
105. Storage time of assembled bag and vial systems are according to the manufacturer recommendations. (eg Minibag plus, Addvantage, Add-ease) [STORAGE AND BEYOND-USE DATING : Proprietary Bag and Vial Systems]	N/A

DISPENSING/DISTRIBUTION

106. Facility has written procedures for proper packaging, storage, and transportation conditions to maintain sterility, quality, purity, and strength of CSPs. [MAINTAINING STERILITY, PURITY, AND STABILITY OF DISPENSED AND DISTRIBUTED CSPs :]	N/A
107. Modes of transport are used that maintain appropriate temperatures and prevent damage to CSPs. [MAINTAINING STERILITY, PURITY, AND STABILITY OF DISPENSED AND DISTRIBUTED CSPs : Packaging and Transporting CSPs]	N/A
108. Facility provides a multiple component formal training program to ensure patients and caregivers understand the proper storage, handling, use, and disposal of CSPs. [PATIENT OR CAREGIVER TRAINING]	N/A

POLICY/PROCEDURE

109. Written procedures detail cleaning and disinfecting the sterile compounding areas including cleansers, disinfectants, and non-shedding wipe and mop materials. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
110. A written procedure is in place for cleaning and disinfecting the Direct Compounding Areas. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
111. Facility has written procedures to verify correct identity, quality, amounts, and purities of ingredients used in CSPs. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Identity and Strength Verification of Ingredients]	Yes
112. Policies address packaging to maintain physical integrity, sterility, stability, and purity of CSPs. [MAINTAINING STERILITY, PURITY, AND STABILITY OF DISPENSED AND DISTRIBUTED CSPs : Packaging and Transporting CSPs]	Yes
113. Written standard procedures describe means for patients to ask questions and report concerns and adverse events with CSPs, and for compounding pharmacists to correct and prevent future problems. [PATIENT MONITORING AND ADVERSE EVENTS REPORTING]	Yes

RADIOPHARMACEUTICALS

114. Facility has appropriate primary engineering controls and radioactivity containment and shielding. Location of primary engineering controls permitted in ISO Class 8 controlled environment. [RADIOPHARMACEUTICALS AS CSPs]	
115. Radiopharmaceuticals prepared as low-risk level CSPs with 12-hour or less BUD are prepared in a segregated compounding area. Segregated compounding area is designated with a line of demarcation. [RADIOPHARMACEUTICALS AS CSPs]	
116. Technetium-99m/Molybdenum-99 generators are eluted in ISO Class 8 conditions. [RADIOPHARMACEUTICALS AS CSPs]	

MISCELLANEOUS

117. Facility engaged in office use sterile compounding for human use is registered with FDA as an outsourcing facility. [FAC 64B16-27.700 (3)(g]	N/A
118. Compounding records are properly maintained. [FAC 64B16-28.140(4)]	N/A

119. When compounding activities require the manipulation of a patient's blood-derived or other biological material, the manipulations are clearly separated from routine material-handling procedures and equipment used in CSP preparation activities, and they are controlled by specific standard operating procedures in order to avoid any cross-contamination. [ENVIRONMENTAL QUALITY AND CONTROL : Placement of Primary Engineering Controls Within ISO Class 7 Buffer Areas]	N/A

SPECIAL PARENTERAL ENTERAL & EXTENDED SCOPE

120. Pharmacy technicians properly identified and supervised. [64B16-27.420, F.A.C.]	
121. Medication properly labeled. [465.0255, F.S.] [64B16-28.108, F.A.C.]	
122. Expired medications removed from the shelves. [64B16-28.110, F.A.C.]	
123. CQI Policy and Procedures and quarterly meetings. [766.101, F.S.] [64B16-27.300, F.A.C.]	
124. Prescriptions have the date dispensed and dispensing pharmacists. [893.04(1)(c) 6, F.S.] [64B16-28.140(3)(b), F.A.C.]	
125. Pharmacy maintains patient profile records. [64B16-27.800, F.A.C.]	
126. All controlled substance prescriptions contain information required. [893.04, F.S.]	
127. Prescriptions for controlled substances are on counterfeit-proof prescription pads or blanks purchased from a Department-approved vendor and the quantity and date meet the requirements of [456.42(2), F.S.].	
128. Controlled substance inventory taken on a biennial basis and available for inspection. [893.07(1)(a), F.S.]	
129. DEA 222 order forms properly completed. [893.07, F.S.]	
130. Controlled substance records and Rx information in computer system is retrievable. [21CFR 1306.22] [64B16-28.140, F.A.C.]	
131. Controlled substance records maintained for 4 years. [465.022(12)(b), F.S.]	
132. Certified daily log OR printout maintained. [21CFR 1306.22(b)(3)] [64B16-28.140(3)(b), F.A.C.]	
133. Pharmacy is reporting to the PDMP within 7 days of dispensing controlled substance. [893.055(4), F.S.]	
134. Pharmacy maintains invoices documenting that medicinal drugs were obtained from a Florida licensed distributor. 499.005 (14)	

Remarks:

This is a change of location inspection; Previously located at 15951 SW 41 St; Davie under the name of Ambient Healthcare of So. Florida, Inc. Many answers are N/A; Firm will not be compounding hazardous CSP's at this time, but has a negative pressure chemical room and a negative pressure clean room. Inspection conducted with Shirley Elisbrun Rph PIC and Mary Jo Giles RXM; Please send inspector a corrective action plan for all deficiencies on or before July 2, 2018.

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge. I have received a copy of the Licensee Bill of Rights.

Inspector Signature:

Date:6/1/2018

Representative:

Shirley Elisbrun

Date:6/1/2018

STATE OF FLORIDA

D PART NT A T

INVESTIGATIVE REPORT

Office: Fort Lauderdale – Area 10	Date of Complaint: 08/29/2017	Case Number: 2017-15122

Subject: AMBIENT HEALTHCARE OF S. FLORIDA, INC 15951 SW 41st Street, Suite 500 Davie, FL 33331	Source: DEPARTMENT OF HEALTH/MQA/ISU/FORT LAUDERDALE
Profession: Pharmacy	License Number and Status: PH27913 CLEAR
Related Case(s): PS 2017-15123	Period of Investigation and Type of Report: 08/29/2017 To 09/20/2017 - FINAL

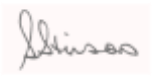
Alleged Violation: S.S. 456.072(1)(k)(dd), 465.016(1)(r), 465.023 (1)(c), F.S. and Rule 64B16-27.797 F.A.C.

Synopsis: This investigation is predicated upon an internally generated complaint (Case Summary and attachments, Exhibit #1), from the DEPARTMENT OF HEALTH/MQA/ISU/FORT LAUDERDALE, notifying of a failed sterile compounding inspection at AMBIENT HEALTHCARE OF S. FLORIDA, INC., located at 15951 SW 41st Street, Suite 500, Davie, Florida. The inspection was conducted on 08/24/2017, by MONICA BOWER, R.Ph., Senior Pharmacist, who identified multiple deficiencies including failure to cease sterile compounding on a hood that failed certification due to HEPA filter leak; failure to maintain clean air inside the buffer room and ante room; failure to use proper plate to identify fungi in clean room; failure to indicate time/day of initial entry of single dose bags inside hood or discard after initial use; failure to discard a vial of sterile drug kept in the refrigerator after initial use with no time stamp of initial entry; failure to disinfect dirty scissors before placing non-sterile item in the hood; failure to train a newly hired employee before allowing person to compound sterile products; failure to validate effectiveness of hand hygiene and garbing of all personnel with the exception of one technician; failure to validate that any employee is competent to compound sterile products; and failure to validate compounding personnel through mimicking the most challenging batch;

☒ Yes ☐ No Subject Notification Completed?
☒ Yes ☐ No Subject Responded?
☐ Yes ☒ No Patient Notification Completed?
☒ Yes ☐ No Above referenced licensure checked in database/LEIDS?
☐ Yes ☒ No Board certified? Name of Board: Date:
Specialty:

Law Enforcement
☐ Notified Date:
☐ Involved Agency:

☐ Yes ☒ No Subject represented by an attorney?
Attorney information:

Investigator/Date:  Sylma C. Stinson, Medical Quality Assurance Investigator Li-99 09/20/2017	Approved By/Date: Patricia A. Callahan, C.F.E., Investigations Manager Li-96

Distribution: HQ/ISU

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Interview of DAN HAYES, RVP (Witness) 5

Interview of ENRIQUE HERNANDEZ, RPh, Pharmacy Manager (Witness/Exhibit #14)..... 5-6

IV. EXHIBITS

* 1. Case Summary and Attachments 7-22

2. Copy of Subject Notification letter, dated 08/29/2017, served via email and US Mail to AMBIENT HEALTHCARE OF S. FLORIDA INC. 23-24

3. Copies of Inspection reports dated 08/24/2017, 8/01/2016, 8/07/2017, & 8/05/2014. .. 25-46

4. Copy of AMBIENT HEALTHCARE OF S. FLORIDA'S Certification Report showing failed hood certification on 7/14/2017, received via email from BOWER 47-61

5. Copy of AMBIENT HEALTHCARE OF S. FLORIDA's Cleaning Logs for the period April 2017 to August 2017, received via email from BOWER 62-66

6. One (1) CD with Twenty (20) pictures taken during pharmacy inspection on 08/24/2017, received via email from BOWER..... 67-68

7. Copies of AMBIENT HEALTHCARE OF S. FLORIDA's Policies and Procedures received via email from the Pharmacy Manager 69-86

8. USP 797 Pharmacy Clean Room Compliancy Inspection report #3699-1 dated 07/14/2017, and attachments received via email from the Pharmacy Manager 87-112

9. Copies of Conflikt ® Detergent/Disinfectant Technical Data; product information on Sporicidal Disinfectant and Cleaner; and Efficacy Reports, received via email from the Pharmacy Manager..... 113-124

10. Documentation re ValiteQ's Aseptic Technique Validation System, received from the Pharmacy Manager..... 125-126

11. Copy of Quotation #QT35528, dated 8/30/2017, to Axelcare Davie Re sample TSA surface on IV Room Cart, received from Pharmacy Manager 127

12. One CD with Nine (9) post inspection pictures taken as proof of corrective actions taken at AMBIENT HEALTHCARE OF S. FLORIDA..... 128-129

13. Copies of Initial Training documents for technician, MICHELLE FLEISCHER, (RPT16028), received from the Pharmacy Manager 130-134

14. Response detailing corrective actions taken at AMBIENT HEALTHCARE OF S. FLORIDA, received from the Pharmacy Manager 135-144

T CDs N TS # AND # R ARD D N A S PARAT PAC AG T PS A D PR SS

* Exhibits contain information which identifies patient(s) by name and are sealed pursuant to section 456.057(9)(a) Florida Statute.

INVESTIGATIVE DETAILS

INTERVIEW OF MONICA BOWER, R.Ph (Source)
Employment:
Senior Pharmacist
Florida Department of Health MQA/ISU
1400 W. Commercial Boulevard, Suite 130
Fort Lauderdale, FL 33309
(954) 267-4530

On 08/30/2017, MONICA BOWER, who was interviewed via phone, stated she found many deficiencies during her inspection of AMBIENT HEALTHCARE OF SOUTH FORIDA, INC., on 08/24/2017. BOWER stated the pharmacy is a home infusion care provider, and a main concern was that no evaluation was done on a newly hired pharmacy technician, GSA-GSA TALAMAS (RPT38111), regarding garbing and to see if she could perform glove fingerprint testing without contaminating her hands. BOWER saw TALAMAS in the buffer room wearing jewelry – necklace and earrings; she was wearing nail polish, makeup and wore false eye lashes. TALAMAS was compounding sterile products and being trained by another technician – RANGELO SARIANO (RPT13639), who did not have his beard covered.

BOWER stated staff was not trained in keeping microorganisms out of compounded sterile products. The HEPA filter failed certification due to leaks inside the filter, and sterile compounding was being done in the hood during the period of failure. No compounding should have been done; the integrity of the HEPA filter was compromised, so there is a possibility that the products could have been contaminated with microorganisms.

BOWER stated there were non-sterile items and she witnessed a dirty pair of scissors placed inside the hood that should have been disinfected. There were dirty chairs in the clean room which was cluttered and messy with bins and trays (Exhibit #6). BOWER stated whenever the swing door that leads to the ante room from the pharmacy is open, the buffer room door also opens; it is not secured, and lets in dirty air each time someone leaves or enters the clean room. The door inside the clean room is also dirty and needs to be repaired. BOWER also stated a radio was stored under the hood and it was playing loudly.

BOWER found a single-dose vial in the refrigerator with sterile Vancomycin which had no time or date of initial use, and should have been discarded (Exhibit #6). While in the clean room she also saw bags with sterile water for injection hanging, and she was told it was only used that morning. BOWER stated the technicians should have put dates and times on the bags.

On 09/06/2017, BOWER stated in an interview at the Fort Lauderdale field office, with AMBIENT HEALTHCARE's Pharmacy Manager, ENRIQUE HERNANDEZ, KATRINA PHILLIP (RPT29706), DAN HAYES, and MICHAEL GERACI, a newly employed General Manager, also presented. BOWER referred to the pharmacy inspection done on 08/01/2016 (Exhibit #3), and stated she spoke with HERNANDEZ about the deficiencies. However, only some of the deficiencies were corrected; the other issues came up again during the repeat inspection on 08/24/2017 (Exhibit #3).

BOWER advised of "dirty air" inside the buffer, and ante rooms, which is compromising patients' health. She observed employees leaving the ante room door open. She also noted the buffer room door kept swinging. HAYES stated attempts were made to contact contractors to repair or replace the air handler in the buffer room, but had not identified anyone who was willing to "take on the work."

BOWER disputed item #61 in HERNANDEZ's response (Exhibit #14), and stated when she walked in the clean room, she found it "very cluttered;" HERNANDEZ, in his statement, said they only keep essential equipment and supplies for each day's compounding activity. While BOWER stated she understands employees need the right atmosphere to work, she could hardly hear anybody speaking over the radio. BOWER stated no one was refilling the stock. BOWER understands the clean room is inspected and certified every six (6) months; however, the inspection/certification process is not related to the concern she has regarding employees bringing in items to the clean room.

Reference item #80 (Exhibit #14), BOWER stated she saw a technician handing the compounding employee a pair of scissors that were not disinfected with alcohol; the scissors were dirty. BOWER stated the pharmacy has monthly cleaning records, however there was no record of cleaning of walls and ceilings in the month of April. She made recommendations to do same week cleaning each month to prevent a lag in the process.

BOWER stated when HERNANDEZ accompanied her to the ante room, he walked away, and left the door open. She looked in the see-through panel in the buffer room and saw the new employee compounding (Exhibit #6), contrary to what HERNANDEZ stated in his response (Exhibit #14).

BOWER stated this was the second inspection where aseptic techniques and garbing were not being practiced.

<u>INTERVIEW OF DAN HAYES (Witness)</u>
Employment:
Regional Vice President, Branch Operations FL/GA
Ambient Healthcare of S. Florida Inc.
Office: (727) 786-1964(O); (727-313-1057 (C)

HAYES presented to the Fort Lauderdale field office on 09/06/2017, stated the deficiencies identified at the 2016 inspection would have been dealt with, but the corporation had plans to move the pharmacy to Miramar. HAYES stated corporate had concerns with the city of Miramar regarding issuance of a permit to operate, which is still not done to date.

HAYES stated upon receipt of the complaint (Exhibit #2), the decision was made to immediately comply with the Department; efforts are in place to make the changes and correct the issues at hand. HAYES stated the pharmacy got a quote (Exhibit #11), and they are working on rectifying the problems with the clean room; corrective action plans are in place (Exhibit #14), and work is in process to expedite the matter. HAYES stated a new facility is still planned for Miramar Parkway.

<u>INTERVIEW OF ENRIQUE HERNANDEZ, R.Ph</u>
Employment:
Pharmacy Manager
Ambient Healthcare of S. Florida Inc.
15951 SW 41st Street, Suite 500
Davie, FL 33331
(954) 389-1126/991-3627

On 08/29/2017, HERNANDEZ stated via phone that the owners of AMBIENT HEALTHCARE OF S. FLORIDA, INC., are located in the city of Lenexa in Kansas; however, Regional Vice President, DAN HAYES was visiting the Florida pharmacy.

HERNANDEZ stated it appeared to him that BOWER might have misinterpreted some of what she was told during her inspection, and it was his intention to treat each line item listed on the complaint, and show what has been done or remains to be re-done. HERNANDEZ stated he would provide an initial response and evidence of corrective actions (Exhibit #14) taken with immediate effect.

On 09/05/2017, HERNANDEZ stated several things are in place, such as door repairs, and attempts being made to obtain a quote for additional repairs.

On 09/06/2017, HERNANDEZ presented to the Fort Lauderdale field office with KATRINA PHILLIP (RPT29706). HERNANDEZ stated attempts were made to explain to BOWER that equipment and supplies were kept in the clean room only for daily compounding activities. And at the time of her arrival, that was the day when the refilling of stock was performed, hence the reason for so many supply bins in the clean room. HERNANDEZ stated the clean room is recertified every six (6) months and they've not been advised about obstruction or turbulences interrupting ISO conditions. HERNANDEZ stated the radio was taken from the clean room.

HERNANDEZ stated all items in the clean room are cleaned on a daily basis. The chairs have been replaced (Exhibit #12). HERNANDEZ stated the doors in the clean room have been re-surfaced and painted (Exhibit #12). HERNANDEZ stated the corporate office has made changes to the policy, per recommendation made by BOWER, and staff will be trained on the updated policies and procedures (Exhibit #7).

HERNANDEZ stated a door in the clean room has a hinge that is not functional, and a vendor has been contacted about replacing the doors with a metal framed single door that will close automatically. A latch has been installed on the swing doors to prevent them from swinging (Exhibit #12).

HERNANDEZ stated TALAMAS - the new pharmacy technician who BOWER saw in the clean room with make-up and jewelry on, was only "observing" procedures; she was not performing any compounding. HERNANDEZ stated he did not recall SORIANO wearing a beard, but beard covers are provided to the staff. HERNANDEZ stated both technicians were addressed about BOWER's observation, and they denied TALAMAS was performing any form of compounding activity. HERNANDEZ stated all compounding technicians were educated on garbing and aseptic techniques.

CASE SUMMARY

CONFIDENTIAL

Case No: 201715122
Please use this number in all correspondence with the Department concerning this matter.

RESPONDENT INFORMATION

License: 27913 Profession: 2205 Pharmacy
Name: AMBIENT HEALTHCARE OF S. FLORIDA, INC
Address: 15951 SW 41ST STREET
SUITE 500
DAVIE, FL 33331
Home Phone:

SOURCE OF INFORMATION

Name: Department Of Health/MQA/ISU/Ft. Lauderdale
Address:

Home Phone:

REPORTED INFORMATION

Receive Date: 08/29/2017 Source Code: 5 Form Code: 2
Responsible Party: ha73 Status Code: 10
Classification Code: Incident Date: 08/24/2017

Patient Name:

Possible Code(s): 18, 15

Summary:
Possible Violation of s.s. 456.072(1)(k)(dd) 465.016(1)(r) 465.023(1)(c), F.S. Rule 64B16-27.797 F.A.C. failure to perform legal/statutory obligation; violating statute/rule; failed Sterile Compounding inspection

Received internally generated complaint from Ft. Lauderdale Investigative Services Unit notifying a failed inspection for Ambient Healthcare of South Florida, Inc. located at 15951 SW 41st Street, Suite 500 in Davie. Inspection was conducted on August 24, 2017 with multiple deficiencies noted including failure to cease sterile compounding on a hood that failed certification due to HEPA filter leak; failure to maintain clean air inside the buffer room and ante room; failure to use proper plate to identify fungi in clean room; failure to indicate time/day of initial entry of single dose bags inside hood or discard after initial use; failure to discard a vial of sterile drug kept in the refrigerator after initial use with no time stamp of initial entry; failure to wipe down dirty scissors before placing non sterile item in the hood; failure to train newly hired employee before allowing person to compound sterile products; failure to validate effectiveness of hand hygiene and garbing of all personnel with the exception of one technician; failure to validate that any employee is competent to compound sterile products; failure to validate compounding personnel through mimicking most challenging batch; failure to remove makeup and jewelry before compounding sterile products ; failure to wear beard cover while compounding sterile products; failure to assure compounding personnel are adequately compounding sterile products without the introduction of bacteria and fungus into the final product; failure to ensure employees are

capable of cleaning and disinfecting hoods and rooms keeping microorganisms out of sterile products; failure to consistently clean ante and buffer rooms monthly; failure to clean areas within buffer room; failure to keep essential items in the buffer area clean; failure to keep buffer room uncluttered and failure to ensure all employees know facilities procedure on how to properly clean and disinfect the direct area where compounding takes place.
Analyzed by: Shondra A. Watson

Shondra A. Watson
August 29, 2017

201715122-73

Health Care Provider Complaint Form

This infomation MUST be completed to investigate your complaint, as we correspond via U.S. mail. Incomplete forms CANNOT be processed.

Florida Statutes 456.073, Disciplinary proceeding: (1) The department, for the boards under its jurisdiction, shall cause to be investigated any complaint that is filed before it if the complaint is in writing, signed by the complainant, and legally sufficient. *If an investigation of any subject is undertaken, the Department will furnish to the subject or the subject's attorney a copy of the complaint or document that resulted in the initiation of the investigation.*

Health Care Provider Information:

Name: Ambient Healthcare of S Fl,Inc (Last) Pharmacy (First) PH27913 (M.I. / Profession / License Number)

Address: 15951 SW 41st St; Suite 500 (Number & Street) Davie (City) FL (State) 33331 (Zip)

Phone number(s): 954-389-1126 Website: _____

Complainant Information:

Your Name: Florida Dept of Health/Ft. Lauderdale/MQA/ISU (Last / First / M.I.)

Address: 1400 West Commercial Blvd (Number & Street) Ft. Lauderdale (City) FL (State) 33309 (Zip)

Home Phone: 954-267-4530 Work Phone: _____ Best Time to Call: _____

Patient Information:

Name: _____ (Last / First / M.I.)

Address: _____ (Number & Street / City / State / Zip)

Phone Number: : _____ Date of birth: _____

Your relationship to the patient:

☐ Parent ☐ Son/Daughter ☐ Spouse ☐ Brother/Sister ☐ Friend ☐ Legal Guardian ☒ Other

Please provide documentation indicating your appointment as the Legal Authority/Guardianship or Personal Representative

The department does not investigate complaints regarding the amount charged for a procedure, broken or missed appointments, customer service, bedside manner, rudeness, professionalism or personality conflicts.

What is the reason for your complaint? Please check all that apply.

☐ Quality of care	☐ Unlicensed	☐ Misfilled prescription	☐ Patient abandonment/neglect
☐ Misdiagnosis	☐ Abuse	☐ Impaired provider	☐ Failure to release patient records
☐ Substance abuse	☐ Sexual contact	☐ Inappropriate prescribing	☒ Other Failed SSCP Inspecti
☐ Advertising	☐ Insurance fraud	☐ Excessive test/treatment	

Date of Incident: 8/24/2017

If the incident involved criminal conduct contact local law enforcement; have you contacted local law enforcement?
Yes No

If yes, name of contact: _____, date: _____, case number: _____

Agency Name: _____

Providers Who Treated You After the Incident (Use a separate sheet if necessary)

Name: _____
Last First M.I.

Address: _____
Number & Street City State Zip

Name: _____
Last First M.I.

Address: _____
Number & Street City State Zip

Provide a complete description of the complaint/report.
Include facts, details, dates, locations, etc. (Who, what, when and where)

Attach copies of medical records, correspondence, contracts and any other documents that will help support your complaint. Failure to attach records will delay the investigation. (Attach additional sheets if necessary).

See Attached.

Florida Statutes 837.06, False Official Statements: Whoever knowingly makes a false statement in writing with the intent to mislead a public servant in the performance of his or her official duty shall be guilty of a misdemeanor of the second degree.

Signature: _____ Date: 8/28/2017
(Required to file complaint)

AUTHORIZATION FOR RELEASE OF PATIENT INFORMATION

To: Any and All Treating Health Care Practitioners or Facilities:
This authorization meets the requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA Privacy Law) found at 45 CFR, Part 164.

This document authorizes any and all licensed health care practitioners, including but not limited to: physicians, nurses, therapists, social workers, counselors, dentists, chiropractors, podiatrists, optometrists, hospitals, clinics, laboratories, medical attendants and other persons who have participated in providing any health care or service to me, to discuss any communication, whether confidential or privileged, and to provide full and complete patient reports and records justifying the course of treatment including but not limited to: patient histories, x-rays, examination and test results, HIV, mental health, drug abuse treatment, psychiatric and psychological records, reports or information prepared by other persons that may be in your possession and all financial records, to the Department of Health (or any official representative of the Department) pursuant to Section 456.057, Florida Statutes.
This document provides full authorization to the Department of Health (or any official representative of the Department) to use any of the aforementioned reports and information for reproduction, investigation or other use for licensure or disciplinary actions and civil, criminal or administrative proceedings, as needed by the Department and may be subject to re-disclosure by the recipient and may no longer be protected by the federal privacy laws and regulation.
By signing below, the patient understands, acknowledges and authorizes the Department to release their identity and medical records to law enforcement and other regulatory agencies in appropriate circumstances at the Department's discretion.

A photocopy of this document is as sufficient as the original.

I understand that this authorization may be revoked upon my written request except to the extent that action has already been taken on this authorization.

Patient Name (Print): _____ Signature: _____

D.O.B.: _____ SSN: _____ Date: _____

Name of Authorized Person Other than Patient (Print): _____

Signature of Authorized Person Other than Patient: _____

Witness Name (Print): _____ Witness Signature: _____

DOH USE ONLY
Reference Number

_____-_____

Unlicensed Practice

Please fill out this form with information regarding individuals engaging in unlicensed activity.

What is your relationship to the subject? _____

How did you become aware of the alleged unlicensed practice? _____

When did you become aware of the alleged unlicensed practice? _____

Location of alleged unlicensed practice: _____

Time and date of treatment or incident: _____

If payment was made, how was subject paid? _____

Does the subject or subject's business accept Medicaid? _____

Does the subject or subject's business accept Medicare? _____

Physical description of subject:

Race: _____ Sex: _____ Height: _____ Weight: _____ Eye Color: _____

Description of Vehicle:

Year: _____ Make: _____ Model: _____ Tag No: _____ Color: _____

_____

_____

Names and addresses of patients/victims/witnesses aware of your complaint:

Name: _____ Address: _____

Name: _____ Address: _____

Names of other subjects/licensees at the same location or business: _____

_____

Please return completed complaint form to:

Consumer Services Unit
4052 Bald Cypress Way, Bin C-75
Tallahassee, FL 32399-3275

Email: mqa.consumerservices@flhealth.gov

Fax: (850) 488-0796

STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES
INV797-Sterile Compounding

File # 21072
Insp # 147189

NAME	PERMIT NUMBER	DATE OF INSPECTION
AMBIENT HEALTHCARE OF S. FLORIDA, INC	27913	08/24/2017
DOING BUSINESS AS AMBIENT HEALTHCARE OF S. FLORIDA, INC		
STREET ADDRESS 15951 SW 41ST ST SUITE 500	**TELEPHONE #** 954-389-1126	**EXT**
CITY DAVIE	**COUNTY** BROWARD	**STATE/ZIP** FL/33331

Additional Information

Business Operation Hours

M-T-W-TH-F Y	Weekly Hours 8:30 am to 5:30
Monday N	Tuesday N
Wednesday N	Thursday N
Friday N	Saturday N
Sunday N	

Registered Pharmacist / Intern / Tech

License # PS49270	Licensee Name Shirley Elisbrun
License Type Registered Pharmacists	
License # PS36287	Licensee Name Vincent Ekebu
License Type Registered Pharmacists	
License # PS52096	Licensee Name Jacqueline Rodriguez
License Type Registered Pharmacists	
License # PS21110	Licensee Name Manuela Vega-Rivera
License Type Registered Pharmacists	
License # PS28016	Licensee Name Enrique Hernandez
License Type Registered Pharmacists	
License # 29706	Licensee Name Katrina Phillip
License Type Pharmacy Tech	

ACS Manager

Optional Information

Basic License Data - PSD

DEA Reg # BA7935490	

License Relations

Pharmacy Affiliate

ADLER, IAN	License #
BRONSON, DAVID	License #
DEBLASI, PAIGE	License #
FRENI, LAWRENCE	License #
KLEINMAN, IRA	License #
KRAMM, EDWARD P	License #
KRAMM, KATHEE M	License #
WILKINS, JOHN	License #

YORK, CHRISTOPHER	License #

RX DPT MGR/COR/POR

HERNANDEZ, ENRIQUE JAVIER	License # 28016

Special Sterile Compounding

AMBIENT HEALTHCARE OF S. FLORIDA, INC	License # 18740

INV797 - Sterile Compounding

LOW RISK

1. Low risk CSP's are properly identified: Aseptic manipulations within an ISO Class 5 environment using three or fewer sterile products and no more than two entries into any container. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Low-Risk Level CSPs]	Yes
2. Low Risk CSP's, in absence of passing sterility test, stored not more than 48 hours at controlled room temperature, 14 days at cold temperature, or 45 days in solid frozen state at -25° to -10° or colder. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Low-Risk Level CSPs]	Yes
3. Low Risk CSP's with 12 hour BUD are properly identified and comply with all four specific criteria. 1. PEC in Segregated Compounding area 2. Away from windows, doors , high traffic areas 3. Hygiene & garbing required, sinks not adjacent to PEC. 4. Cleaning & Disinfecting, Personnel training, Competency evaluation, Garbing, Aseptic work practices, Viable and non-viable environmental sampling apply. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Low-Risk Level CSPs]	N/A

MEDIUM RISK

4. Medium Risk CSP's are properly identified: Aseptic manipulations within an ISO Class 5 environment using prolonged and complex mixing and transfer, more than three sterile products and entries into any container, and pooling ingredients from multiple sterile products to prepare multiple CSPs. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Medium-Risk Level CSPs]	Yes
5. Medium Risk CSP's, In absence of passing sterility test, stored not more than 30 hours at controlled room temperature, 9 days at cold temperature, or 45 days in solid frozen state at -25° to -10° or colder. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Medium-Risk Level CSPs]	Yes

HIGH RISK

6. Presterilization procedures for high-risk level CSPs, such as weighing and mixing, are completed in no worse than an ISO Class 8 environment. [ENVIRONMENTAL QUALITY AND CONTROL : Placement of Primary Engineering Controls Within ISO Class 7 Buffer Areas]	
7. High Risk CSP's are properly identified: Confirmed presence of nonsterile ingredients and devices, or confirmed or suspected exposure of sterile ingredients for more than one hour to air quality inferior to ISO Class 5 before final sterilization. [CSP MICROBIAL CONTAMINATION RISK LEVELS : High-Risk Level CSPs]	
8. High Risk CSP's, in absence of passing sterility test are not stored more than 24 hours at controlled room temperature, 3 days at cold temperature, or 45 days in solid frozen state at -25° to -10° or colder. [CSP MICROBIAL CONTAMINATION RISK LEVELS : High-Risk Level CSPs]	
9. A 0.2-µm certified sterilizing membrane filter is used that is chemically and physically compatible with the CSP. Filtration is completed rapidly without filter replacement. Sterilization method is verified to achieve sterility for the quantity and type of containers. [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Sterilization of High-Risk Level CSPs by Filtration]	
10. Sterilization method used has documentation that acceptable strength and purity of ingredients and integrity of containers is maintained. [CSP MICROBIAL CONTAMINATION RISK LEVELS : High-Risk Level CSPs]	
11. The manufacturer recommended filter integrity (e.g., bubble point) test is performed and documented for all sterilizing filters after filtering CSPs. [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Sterilization of High-Risk Level CSPs by Filtration]	
12. Autoclave cycle has been verified using appropriate biological indicators. Solutions are passed through a 1.2-µm or smaller filter into final containers to remove particulates before sterilization. [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Sterilization of High-Risk Level CSPs by Steam]	
13. Dry heat ovens used for sterilization have filtered forced air. Only those items that will be damaged by steam are sterilized by dry heat. [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Sterilization of High-Risk Level CSPs by Dry Heat]	
14. The description of dry heat sterilization conditions and duration for specific CSPs is included in written documentation in the compounding facility. The effectiveness of dry heat sterilization is verified using appropriate biological indicators and other confirmation. [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Sterilization of High-Risk Level CSPs by Dry Heat]	
15. Dry heat depyrogenation is used to render glassware or containers, such as vials free from pyrogens as well as viable microbes. The description of the dry heat depyrogenation cycle and duration for specific load items is included in written documentation in the compounding facility. The effectiveness of the dry heat depyrogenation cycle is verified using endotoxin challenge vials (ECVs). [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Depyrogenation by Dry Heat]	
16. Sterility testing is completed for all High-risk level CSPs prepared in batches of more than 25 identical containers, or exposed longer than 12 hours at 2° to 8°, and 6 hours at warmer than 8° before being sterilized. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Sterility Testing]	

USP <71> STERILITY TESTING (Outsourced)

17. Outsourced sterility testing results indicate that it is compliant with USP<71>. A method not described in the USP may be used if validation demonstrates that the alternative is at least as effective and reliable. [STERILITY TEST USP<71>]	
18. Outsourced: The number of articles tested are appropriate according to USP<71>. [STERILITY TEST USP<71> : Number of Articles to Be Tested]	
19. Outsourced: The volume/quantity tested is according to USP<71>. [STERILITY TEST USP<71> : Number of Articles to Be Tested]	
20. Outsourced: A USP<71> method suitability test has been done with appropriate inoculum, additives and rinses. [STERILITY TEST USP<71> : Method Suitability Test]	
21. Outsourced: Sterility testing reports are reviewed and appropriate actions taken and documented. [FINISHED PREPARATION RELEASE CHECKS AND TESTS]	

USP <71> STERILITY TESTING

22. On site: Membrane filtration is used if appropriate. (The technique of membrane filtration is used whenever the nature of the product permits; that is, for filterable aqueous preparations, for alcoholic or oily preparations, and for preparations miscible with, or soluble in, aqueous or oily solvents, provided these solvents do not have an antimicrobial effect in the conditions of the test.) Filters are rinsed according to USP<71>. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Sterility Testing]	
23. On site: Direct inoculation is done only when membrane filtration cannot be carried out. Volume to be inoculated does not exceed 10% of the culture media volume. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Sterility Testing]	
24. On site: The number of articles tested are appropriate according to USP<71>. [STERILITY TEST USP<71> : Number of Articles to Be Tested]	
25. On site: The volume/quantity tested is according to USP<71>. [STERILITY TEST USP<71> : Number of Articles to Be Tested]	
26. On site: A growth promotion test has been done on the media with the 5 specified organisms (not more than 100 CFU) according to USP<71>. [STERILITY TEST USP<71> : Growth Promotion Test of Aerobes, Anaerobes, and Fungi]	
27. On site: A USP<71> method suitability test has been done with appropriate inoculum, additives and rinses. [STERILITY TEST USP<71> : Method Suitability Test]	
28. On site: TSB or SCD is incubated at 20-25 C for 14 days (2 incubators present). [STERILITY TEST USP<71> : Culture Media and Incubation Temperatures]	
29. On site: FTM is incubated at 30-35 C for 14 days (2 incubators present). [STERILITY TEST USP<71> : Culture Media and Incubation Temperatures]	
30. On site: Sterility testing is documented including lot numbers and expiration dates of media. [FINISHED PREPARATION RELEASE CHECKS AND TESTS]	
31. On site: Sterility testing reports are reviewed and appropriate actions taken and documented. [FINISHED PREPARATION RELEASE CHECKS AND TESTS]	

ENDOTOXIN TESTING

32. Endotoxin testing is conducted for High-risk level CSP's that are prepared in batches of more than 25 identical containers, or exposed longer than 12 hours at 2° to 8°, and 6 hours at warmer than 8°, before being sterilized or in multidose containers for administration to multiple patients. (excluding those for inhalation and ophthalmic administration) [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Bacterial Endotoxin (Pyrogen) Testing]	
33. Endotoxin testing process indicates that it is compliant with USP<85>. [BACTERIAL ENDOTOXINS TEST USP<85>]	
34. High Risk CSP's are within allowable limits for bacterial endotoxins. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Bacterial Endotoxin (Pyrogen) Testing]	

IMMEDIATE USE COMPOUNDING

35. Immediate-use compounding complies with all six specified criteria. 1. Low-risk sterile nonhazardous products or diagnostic radiopharmaceutical products from the manufacturers' original containers. Anti-neoplastics shall not be prepared as immediate-use CSPs because they are hazardous drugs. 2. Unless required for the preparation, the compounding procedure is a continuous process not to exceed 1 hour. 3. During preparation, aseptic technique is followed and, if not immediately administered, the finished CSP is under continuous supervision to minimize the potential for contact with nonsterile surfaces, introduction of particulate matter or biological fluids, mix-ups with other CSPs, and direct contact of outside surfaces. 4. Administration begins not later than 1 hour following the start of the preparation of the CSP. 5. Unless immediately and completely administered by the person who prepared it or immediate and complete administration is witnessed by the preparer, the CSP shall bear a label listing patient identification information, the names and amounts of all ingredients, the name or initials of the person who prepared the CSP, and the exact 1-hour BUD and time. 6. If administration has not begun within 1 hour following the start of preparing the CSP, the CSP shall be promptly, properly, and safely discarded. [IMMEDIATE-USE CSPs]	N/A

SINGLE/MULTIPLE DOSE CONTAINER BUD

36. Beyond-use date does not exceed 28 days for multiple-dose containers after initial opening or entry, unless specified otherwise by the manufacturer. [SINGLE-DOSE AND MULTIPLE-DOSE CONTAINERS]	Yes
37. Beyond-use time does not exceed 6 hours for closure sealed single-dose containers in ISO Class 5 or cleaner air after initial opening or entry, unless specified otherwise by the manufacturer. [SINGLE-DOSE AND MULTIPLE-DOSE CONTAINERS] *Multiple single use SWI were in the PEC's with no puncture date or time.*	No
38. Beyond-use time does not exceed 1 hour for closure sealed single-dose containers after being opened or entered in worse than ISO Class 5 air. [SINGLE-DOSE AND MULTIPLE-DOSE CONTAINERS] *Entered pharmacy bulk package of vancoymycin Lot # 772953A in refrigerator with no time or date of puncture.*	No
39. Single-dose ampules are discarded immediately after use. [SINGLE-DOSE AND MULTIPLE-DOSE CONTAINERS]	Yes

HAZARDOUS DRUGS

40. A pressure indicator is installed and differential pressures are monitored and documented daily for hazardous buffer room. [HAZARDOUS DRUGS AS CSPs]	
41. Hazardous drug buffer room is at least 0.01 inch water column negative pressure with 30 ACPH of HEPA filtered air. [HAZARDOUS DRUGS AS CSPs]	
42. At least 0.01 inch water column negative pressure and 12 air changes per hour in non-cleanrooms in which CACIs are located. FAC: USP Chapter 797 requires that: "When closed-system vial-transfer devices (CSTDs) (i.e., vial-transfer systems that allow no venting or exposure of hazardous substance to the environment) are used, they shall be used within an ISO Class 5 environment of a BSC or CACI. The use of the CSTD is preferred because of their inherent closed system process. In facilities that prepare a low volume of hazardous drugs, the use of two tiers of containment (e.g., CSTD within a BSC or CACI that is located in a non-negative pressure room) is acceptable." For purpose of said provision, a "low volume of hazardous drugs" is defined as less than 40 doses per month. [HAZARDOUS DRUGS AS CSPs]	
43. Personnel compounding hazardous drugs wear appropriate personal protective equipment. [HAZARDOUS DRUGS AS CSPs]	
44. Hazardous drugs are handled with caution at all times using appropriate chemotherapy gloves during receiving, distribution, stocking, inventorying, preparing for administration, and disposal. Spill kits are available. [HAZARDOUS DRUGS AS CSPs]	
45. Hazardous drugs are prepared in an ISO Class 5 environment (BSC or CACI) with protective engineering controls in place, following aseptic practices specified for the appropriate contamination risk levels. [HAZARDOUS DRUGS AS CSPs]	
46. Hazardous drugs are stored separately from other inventory in a manner to prevent contamination and personnel exposure. [HAZARDOUS DRUGS AS CSPs]	
47. Access to hazardous drug preparation areas is limited to authorized compounding personnel. [HAZARDOUS DRUGS AS CSPs]	

48. Annual documentation of hazardous drug training of personnel regarding storage, handling, containment techniques and disposal of hazardous drugs is available. [HAZARDOUS DRUGS AS CSPs]	
49. Compounding personnel of reproductive capability have confirmed in writing that they understand the risks of handling hazardous drugs. [HAZARDOUS DRUGS AS CSPs]	
50. Facility maintains appropriate disposal containers for all hazardous waste. [HAZARDOUS DRUGS AS CSPs]	

FACILITY DESIGN AND CERTIFICATION

51. Certification and testing of primary (LAFWs, BSCs, CAIs and CACIs) and secondary engineering controls (buffer and ante areas) have been performed by a qualified individual no less than every six months and whenever the device or room is relocated, altered, or major service to the facility is performed. Corrective action for deficiencies are documented. Certification procedures such as those outlined in the CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2006) are conducted under dynamic conditions. [ENVIRONMENTAL QUALITY AND CONTROL : Environmental Nonviable Particle Testing Program] *MTA 7-14-17 tested PECs and SECs ; ante room did not pass with the required 20 ACPH - room had 15 THIS IS YOUR SECOND ADVISORY ; there are 4 X ISO 5 HLF hoods ; Hood # 2298 HEPA filter failed on this date with multiple leaks; a new HEPA filter was shipped on 7-27 and replaced on 8-7-17 and the PEC was recertified on this date. Per PDM HH, facility continued to compound in the PEC after filter failure and before new filter was replaced (7-14 thru 8-7).*	No
52. Primary engineering controls provide unidirectional (i.e., laminar) HEPA filtered air. Air pattern analysis via smoke studies are conducted at the critical site to demonstrate unidirectional airflow and sweeping action over and away from the product under dynamic conditions.[ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
53. The primary engineering controls are placed within a buffer area in such a manner as to avoid conditions that could adversely affect their operation. The PEC is placed out of the traffic flow and in a manner to avoid disruption from the HVAC system and room cross drafts. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls] *The door from the IV room to ante room is a double swing door . When the ante room door opens, the clean room swing doors open; During inspection, employees were exiting and entering clean room into the ante room while the ante room door was left open, letting dirty air enter through the main pharmacy into the ante room and IV room.*	No
54. All HEPA filters are leak tested after installation and every six months thereafter. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes

ISOLATORS

55. CAIs are proven to maintain ISO Class 5 air when particle counts are sampled 6 to 12 inches upstream of critical site exposure areas during performance of normal inward and outward transfer of materials, and compounding manipulations when such CAIs are located in air quality worse than ISO Class 7. [ENVIRONMENTAL QUALITY AND CONTROL : Placement of Primary Engineering Controls Within ISO Class 7 Buffer Areas]	
56. Adequate recovery time for isolators to achieve ISO Class 5 air quality is allowed after material transfer before and during compounding operations. [ENVIRONMENTAL QUALITY AND CONTROL : Placement of Primary Engineering Controls Within ISO Class 7 Buffer Areas]	
57. Personnel garbing requirements are followed for CAIs unless manufacturer provides written documentation based on validated testing that any components of PPE are not required to maintain sterility of CSPs. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	

FACILITY DESIGN AND CERTIFICATION (Secondary Engineering Controls)

58. Facility has pressure gauges or velocity meters to monitor the pressure differential or airflow between the buffer area and ante-area, and the ante-area and the general environment outside the compounding area. The results are reviewed and documented on a log at least daily or by a continuous recording device. The pressures differentials meet or exceed 5 Pa (0.02 inch water column (w.c.)). Alternatively, in facilities where low- and medium-risk level CSPs are prepared, differential airflow is maintained at a minimum velocity of 0.2 meter/second (40 fpm) across a line of demarcation between buffer area and ante-area. [ENVIRONMENTAL QUALITY AND CONTROL : Pressure Differential Monitoring]	Yes
59. Clean rooms for nonhazardous and nonradioactive CSPs are supplied with HEPA filtered air that enters from ceilings with return vents low on walls, and that provides not less than 30 air changes per hour or qualifies for exception in 64B16-27.797(4)(c). [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
60. Activities and tasks carried out within the buffer area are limited to only those necessary when working within a controlled environment. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
61. Only the furniture, equipment, supplies, and other material required for the compounding activities to be performed are brought into the buffer room. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls] *Clean room is cluttered with multiple half empty bins, storage containers and an empty plastic tray stored under cart; a radio is stored under a hood*	No
62. Surfaces and essential furniture in buffer rooms or zones and clean rooms are nonporous, smooth, non-shedding, impermeable, cleanable, and resistant to disinfectants. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls] *There are three chairs in the clean room that are dirty; the door on the inside of the clean room is filthy.*	No
63. The surfaces of ceilings, walls, floors, fixtures, shelving, counters, and cabinets in the buffer area are smooth, impervious, free from cracks and crevices, and non-shedding, thereby promoting cleanability, and minimizing spaces in which microorganisms and other contaminants may accumulate. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls] *The inside door of the clean room has remnants of sticky material stuck onto glass window;*	No
64. Ceiling tiles are caulked around each perimeter and to walls to seal them to the support frame. The exterior lens surface of ceiling lighting fixtures is smooth, mounted flush, and sealed. All other penetrations through the ceiling or walls are sealed. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
65. The buffer area does not contain sources of water (sinks) or floor drains. Work surfaces are constructed of smooth, impervious materials, such as stainless steel or molded plastic, so that they are easily cleaned and disinfected. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls] *The wheel attachments on PEC is showing signs of rust.*	No
66. Storage shelving, counters, cabinets and carts/casters in the buffer area are smooth, impervious, free from cracks and crevices, non-shedding, non-porous, cleanable, and disinfectable. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls] *Bins containing sterile drug vials are dirty and have sticky material on the outside;*	No
67. When devices (e.g., computers and printers) and objects (e.g., carts and cabinets) are placed in buffer areas, air quality is verified by particle counts on certification. [ENVIRONMENTAL QUALITY AND CONTROL : ISO Class 5 Air Sources, Buffer Areas, and Ante-Areas]	Yes

QUALITY AND CONTROL

68. An appropriate environmental sampling plan has been developed for airborne viable particles based on a risk assessment of compounding activities performed. Volumetric air sampling is conducted every six months and sites include locations within each ISO Class 5 environment and in the ISO Class 7 and 8 areas, and the areas at greatest risk of contamination (e.g., work areas near the ISO Class 5 environment, counters near doors, pass-through boxes). The plan includes sample locations, method of collection, frequency of sampling, volume of air sampled, and time of day as related to activity in the compounding area and action levels. [ENVIRONMENTAL QUALITY AND CONTROL : Environmental Viable Airborne Particle Testing Program—Sampling Plan] *Your viable sampling plan states that PASSIVE air sampling must be conducted monthly and does not mention USP<797> requirements of VOLUMETRIC air sampling and the volume of air to be sampled in each ISO classified area; Surface sampling policy does not state that ss shall be conducted at the conclusion of compounding, rather at the end of cleaning - also, plates must contain polysorbate 80 and lechitin to deactivate disinfectants and cleaning agents - include this in your policy*	No
69. Evaluation of airborne microorganisms using volumetric collection methods in the controlled air environments is performed by properly trained individuals for all compounding risk levels. [ENVIRONMENTAL QUALITY AND CONTROL : Viable Air Sampling]	Yes
70. Volumetric air sampling using malt extract agar (MEA) or some other media that supports the growth of fungi is used in high-risk level compounding environments. [ENVIRONMENTAL QUALITY AND CONTROL : Growth Media]	N/A
71. For low-risk level CSPs with 12-hour or less BUD, air sampling is performed at locations inside the ISO Class 5 environment and other areas that are in close proximity to the ISO class 5 environment. [ENVIRONMENTAL QUALITY AND CONTROL : Viable Air Sampling]	N/A
72. The number of discrete colonies of microorganisms is counted and reported as colony-forming units (cfu) and documented on an environmental monitoring form. Counts from air monitoring are transformed into cfu/cubic meter of air and evaluated for adverse trends. [ENVIRONMENTAL QUALITY AND CONTROL : Incubation Period]	No
73. Surface sampling is accomplished in all ISO classified areas on a periodic basis using TSA contact plates with lecithin and polysorbate 80 and/or swabs and is done at the conclusion of compounding. [ENVIRONMENTAL QUALITY AND CONTROL : Surface Cleaning and Disinfection Sampling and Assessment] *Facility conducts monthly surface sampling in addition to semi annually through certification company; Company policy is to conduct surface sampling after cleaning and does not mention that it shall be done at the conclusion of compounding.*	No
74. Sampling data is collected and reviewed on a periodic basis as a means of evaluating the overall state of control of the compounding environment. [ENVIRONMENTAL QUALITY AND CONTROL : Action Levels, Documentation and Data Evaluation]	Yes
75. Competent microbiology personnel are consulted if an environmental sampling consistently shows elevated levels of microbial growth. If any mold, yeast, coagulase positive staphylococcus, or gram negative rods are detected immediate remediation and investigation into the cause and source was conducted. [ENVIRONMENTAL QUALITY AND CONTROL : Action Levels, Documentation and Data Evaluation] *MTA surface sampling on 7-14 in the clean room revealed chrysosporium sp. which is a fungus. The resampling was done on a TSA plate that is not fungal specific.*	No
76. Surfaces in the LAFWs, BSCs, CAIs, and CACIs are cleaned and disinfected frequently, including at the beginning of each work shift, before each batch preparation is started, every 30 minutes during continuous compounding periods of individual CSPs, when there are spills, and when surface contamination is known or suspected from procedural breaches. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
77. Cleaning and disinfecting occurs before compounding is performed. Items are removed from all areas to be cleaned, and surfaces are cleaned by removing loose material and residue from spills, e.g., water-soluble solid residues are removed with Sterile Water and low-shedding wipes. This shall be followed by wiping with a residue-free disinfecting agent, such as sterile 70% IPA, which is allowed to dry before compounding begins. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
78. Cleaning and disinfecting agents and methods of application are in accordance with written SOPs and followed by custodial and/or compounding personnel. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas] *Your policy states you should be using RTU agents however MF RPT informed inspector that a capful of Lph se is mixed with a bucket of water.*	No
79. Cleaning materials, such as wipes, sponges, and mops, are non-shedding, preferably composed of synthetic micro fibers, and dedicated to use in the buffer area, ante-area, and segregated compounding areas and are not removed from these areas except for disposal. If cleaning materials are reused (e.g., mops), there are procedures based on manufacturer recommendations that ensure that the effectiveness of the cleaning device is maintained and repeated use does not add to the bioburden of the area being cleaned. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas] *dedicated mops are stored in ante room with mop head in direct contact with floor and are not mounted.*	No
80. Supplies and equipment removed from shipping cartons are wiped with a suitable disinfecting agent (e.g., sterile 70% IPA). [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas] *Technician placed a dirty pair of scissors on direct compounding area without wiping down with sterile alcohol.*	No
81. Disinfectant sprayed or wiped on a surface to be disinfected is allowed to dry, and during this time the item is not be used for compounding purposes. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
82. Sterile 70% IPA pads are used to disinfect the sterile entry points of packages and devices. Wetted gauze pads or other particle-generating material are not appropriate. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes

QUALITY AND CONTROL (Secondary Engineering Controls)

83. Work surfaces in ISO Class 7 and 8 areas and segregated compounding areas are cleaned at least daily. IPA (70% isopropyl alcohol) remains on surfaces to be disinfected for at least 30 seconds before such surfaces are used to prepare CSPs. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	N/A
84. Floors in ISO Class 7 and 8 areas are mopped daily by trained personnel at a time when no aseptic operations are in progress using approved agents and procedures described in written SOP's. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	N/A
85. Shelving, walls, and ceilings in ante-areas and buffer areas are cleaned and disinfected at least monthly. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas] *Monthly cleaning records show walls , ceilings and outside of hoods were not cleaned; ceilings were not cleaned in may ; April records show there was no monthly cleaning*	No

PERSONNEL CLEANSING, GARBING & COMPETENCY EVALUATION

86. Personnel preparing CSP's are free from rashes, sunburn, weeping sores, conjunctivitis, and active respiratory infections. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	Yes
87. Compounding personnel remove personal outer garments; cosmetics; artificial nails; hand, wrist, and body jewelry that can interfere with the fit of gowns and gloves; and visible body piercing above the neck. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing] *Technician GT was observed wearing a large necklace , earrings, make up and false eyelashes. Technician FS has a heavy beard and was compounding sterile products without donning a beard cover.*	No
88. Facility has adequate supplies to meet PPE requirements of USP<797>. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing] *Male technician RS has a beard and was compounding without beard covered; No beard covers available at facility*	No

89. Garbing and hand hygiene are accomplished in the ante-area in order of dirtiest to cleanest: shoes or shoe covers, head and facial hair covers, face mask, fingernail cleansing, hand and forearm washing and drying; non-shedding gown. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	Yes
90. Sterile gloves are donned in the buffer room/isolator after hand cleansing with an alcohol-based product with persistent activity and hands are allowed to dry. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	Yes
91. Gloves are routinely disinfected with sterile 70% IPA after contacting nonsterile objects. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	Yes
92. Personnel repeat garbing and hand hygiene after they are exposed to direct contact contamination or worse than ISO Class 8 air. Gowns may be hung in the anteroom and reused during the same workshift. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	Yes
93. Low/Medium Risk media-fill tests that closely simulate the most challenging or stressful conditions encountered during compounding are completed at least annually by compounding personnel. Media-filled vials are appropriately incubated for 14 days. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Medium-Risk Level CSPs] *compoudning records show morphine sulfate / NS 4mg/4ml RX #280177040 requires 64 entries into a IV bag however media fill conducted by facility uses only 6 manipulations.*	No
94. High Risk Media-fill tests that closely simulate the most challenging or stressful conditions encountered during compounding have been completed at least semiannually by compounding personnel. Media-filled vials are appropriately incubated for 14 days. [CSP MICROBIAL CONTAMINATION RISK LEVELS : High-Risk Level CSPs]	N/A
95. Documentation indicates compounding personnel have successfully completed didactic training, passed written competency assessments, undergone skill assessment using observational audit tools (hand hygiene, garbing, aseptic technique) and media-fill testing annually or semiannually (high risk) and before any compounding personnel begin to prepare CSPs . [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures] *THIS IS YOUR SECOND ADVISORY. See #98*	No
96. Compounding personnel who fail written tests, observational audits, or whose media-fill test vials have one or more units showing visible microbial contamination, are reinstructed and re-evaluated by expert compounding personnel to ensure correction of all aseptic work practice deficiencies. Corrective action is documented. Compounding personnel pass all evaluations prior to resuming compounding of sterile preparations. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures]	N/A
97. Other cleaning personnel performing cleaning and disinfecting procedures (e.g. environmental) are thoroughly trained in proper hand hygiene, and garbing, cleaning, and disinfection procedures by a qualified aseptic compounding expert. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures]	N/A
98. Compounding personnel and other personnel responsible for cleaning routinely undergo performance evaluation of proper hand hygiene, garbing, and all applicable cleaning and disinfecting procedures conducted by a qualified aseptic compounding expert. Visual observation of hand hygiene, garbing and cleaning is documented and maintained to provide a permanent record and long-term assessment of personnel competency. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures] *All compounding technicians are overdue on all observational assessments ; employee folders have blank checklists dated for 2016 that have not been completed. Last observational assessments for aseptic technique, cleaning and disinfecting and hand hygiene and garbing were completed in 2015*	No
99. Immediately after the compounder completes the hand hygiene and garbing procedure, the evaluator collects a gloved fingertip and thumb sample from both hands of the compounder onto appropriate agar plates. The plates are incubated at 30-35° for 2–3 days. All compounding personnel have successfully completed an initial competency evaluation and gloved fingertip/thumb sampling procedure (0 cfu) no less than three times before initially being allowed to compound CSPs for human use. [ENVIRONMENTAL QUALITY AND CONTROL : Gloved Fingertip Sampling] *GT Rpt informed inspector she did not complete any GFT and yet she was observed compounding in the IV room during the time of this inspection. MF RPT was hired in 4-2017 and documentation shows only 1 GFT was completed.*	No
100. Re-evaluation of glove fingertip testing onto appropriate agar plates (Trypticase soy agar (TSA) with lecithin and polysorbate 80) for all compounding personnel occurs at least annually for low- and medium-risk level CSPs and semiannually for high-risk level CSPs before being allowed to continue compounding CSPs. Gloves shall not be disinfected with sterile 70% IPA prior to testing. The cfu action level is based on the total number of cfu on both gloves and not per hand. [ENVIRONMENTAL QUALITY AND CONTROL : Gloved Fingertip Sampling] *Per PDM HH, all Rphs are validated for Sterile compounding however their documentation was not available at the time of this inspection; All technicians are overdue for their GFT with the exception of KP Rpt.*	No

VERIFICATION

101. Labels of CSPs contain name and address of pharmacy, correct names and amounts or concentrations of ingredients, total volumes, beyond-use dates, storage conditions, and route(s) of administration. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Identity and Strength Verification of Ingredients]	Yes
102. Facility has documentation that procedures have been followed to ensure sterility, purity, correct identities and amounts of ingredients, and stability. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Inspection of Solution Dosage Forms and Review of Compounding Procedures]	Yes
103. CSP's are visually inspected for abnormal particulate matter and color, and intact containers and seals. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Inspection of Solution Dosage Forms and Review of Compounding Procedures]	Yes
104. Beyond Use Dates are assigned using direct stability-indicating assays or authoritative literature that supports the assigned BUD. [STORAGE AND BEYOND-USE DATING : Determining Beyond-Use Dates]	Yes
105. Storage time of assembled bag and vial systems are according to the manufacturer recommendations. (eg Minibag plus, Addvantage, Add-ease) [STORAGE AND BEYOND-USE DATING : Proprietary Bag and Vial Systems]	Yes

DISPENSING/DISTRIBUTION

106. Facility has written procedures for proper packaging, storage, and transportation conditions to maintain sterility, quality, purity, and strength of CSPs. [MAINTAINING STERILITY, PURITY, AND STABILITY OF DISPENSED AND DISTRIBUTED CSPs :]	Yes
107. Modes of transport are used that maintain appropriate temperatures and prevent damage to CSPs. [MAINTAINING STERILITY, PURITY, AND STABILITY OF DISPENSED AND DISTRIBUTED CSPs : Packaging and Transporting CSPs]	Yes
108. Facility provides a multiple component formal training program to ensure patients and caregivers understand the proper storage, handling, use, and disposal of CSPs. [PATIENT OR CAREGIVER TRAINING]	Yes

POLICY/PROCEDURE

109. Written procedures detail cleaning and disinfecting the sterile compounding areas including cleansers, disinfectants, and non-shedding wipe and mop materials. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas] *Cleaning policy is vague and does not detail method of cleaning buffer room or PEC's; In addition, your policy references USP <797> for cleaning agents rather than including specific agents in your policy. Include agents, method of application, dwell time and mixing procedures in your cleaning policy so that anyone reading this policy will be able to clean all areas without question.*	No

110. A written procedure is in place for cleaning and disinfecting the Direct Compounding Areas. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas] *Policy should be easily understood so anyone that reads policy would understand.*	No
111. Facility has written procedures to verify correct identity, quality, amounts, and purities of ingredients used in CSPs. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Identity and Strength Verification of Ingredients]	Yes
112. Policies address packaging to maintain physical integrity, sterility, stability, and purity of CSPs. [MAINTAINING STERILITY, PURITY, AND STABILITY OF DISPENSED AND DISTRIBUTED CSPs : Packaging and Transporting CSPs]	Yes
113. Written standard procedures describe means for patients to ask questions and report concerns and adverse events with CSPs, and for compounding pharmacists to correct and prevent future problems. [PATIENT MONITORING AND ADVERSE EVENTS REPORTING]	Yes

RADIOPHARMACEUTICALS

114. Facility has appropriate primary engineering controls and radioactivity containment and shielding. Location of primary engineering controls permitted in ISO Class 8 controlled environment. [RADIOPHARMACEUTICALS AS CSPs]	
115. Radiopharmaceuticals prepared as low-risk level CSPs with 12-hour or less BUD are prepared in a segregated compounding area. Segregated compounding area is designated with a line of demarcation. [RADIOPHARMACEUTICALS AS CSPs]	
116. Technetium-99m/Molybdenum-99 generators are eluted in ISO Class 8 conditions. [RADIOPHARMACEUTICALS AS CSPs]	

MISCELLANEOUS

117. Facility engaged in office use sterile compounding for human use is registered with FDA as an outsourcing facility. [FAC 64B16-27.700 (3)(g]	N/A
118. Compounding records are properly maintained. [FAC 64B16-28.140(4)]	Yes
119. When compounding activities require the manipulation of a patient's blood-derived or other biological material, the manipulations are clearly separated from routine material-handling procedures and equipment used in CSP preparation activities, and they are controlled by specific standard operating procedures in order to avoid any cross-contamination. [ENVIRONMENTAL QUALITY AND CONTROL : Placement of Primary Engineering Controls Within ISO Class 7 Buffer Areas]	N/A

SPECIAL PARENTERAL ENTERAL & EXTENDED SCOPE

120. Pharmacy technicians properly identified and supervised. [64B16-27.420, F.A.C.]	
121. Medication properly labeled. [465.0255, F.S.] [64B16-28.108, F.A.C.]	
122. Expired medications removed from the shelves. [64B16-28.110, F.A.C.]	
123. CQI Policy and Procedures and quarterly meetings. [766.101, F.S.] [64B16-27.300, F.A.C.]	
124. Prescriptions have the date dispensed and dispensing pharmacists. [893.04(1)(c) 6, F.S.] [64B16-28.140(3)(b), F.A.C.]	
125. Pharmacy maintains patient profile records. [64B16-27.800, F.A.C.]	
126. All controlled substance prescriptions contain information required. [893.04, F.S.]	
127. Prescriptions for controlled substances are on counterfeit-proof prescription pads or blanks purchased from a Department-approved vendor and the quantity and date meet the requirements of [456.42(2), F.S.].	
128. Controlled substance inventory taken on a biennial basis and available for inspection. [893.07(1)(a), F.S.]	
129. DEA 222 order forms properly completed. [893.07, F.S.]	
130. Controlled substance records and Rx information in computer system is retrievable. [21CFR 1306.22] [64B16-28.140, F.A.C.]	
131. Controlled substance records maintained for 4 years. [465.022(12)(b), F.S.]	
132. Certified daily log OR printout maintained. [21CFR 1306.22(b)(3)] [64B16-28.140(3)(b), F.A.C.]	
133. Pharmacy is reporting to the PDMP within 7 days of dispensing controlled substance. [893.055(4), F.S.]	
134. Pharmacy maintains invoices documenting that medicinal drugs were obtained from a Florida licensed distributor. 499.005 (14)	

Remarks:

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge. I have received a copy of the Licensee Bill of Rights.

Inspector Signature:

BOWER, MONICA

Date:8/24/2017

Representative:

Henry Hernandez

Date:8/24/2017

On August 24, 2017, Sr Pharmacist Monica Bower conducted a routine SSCP inspection at Ambient Healthcare of S. Florida, Inc. (PH27913) located at 15951 SW 41st St; St 500; Davie, FL 33331. The inspection was conducted with Enrique Hernandez Rph and PDM (PS28016). The following observations were made:

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51) CERTIFICATION OF PEC'S (HOODS) AND SEC'S (ROOMS) HAVE BEEN PERFORMED EVERY SIX MONTHS ... AND CORRECTIVE ACTIONS OF DEFICIENCIES HAVE BEEN DOCUMENTED.
*Failure to cease sterile compounding on a hood that failed certification due to HEPA filter leak. Facility continued to mix sterile compounds and release product from 7-14-17 thru 8-7-17 in a hood that FAILED certification, thus leaving the possibility of products being contaminated with microorganisms.

53) THE PRIMARY ENGINEERING CONTROLS (PEC'S) ARE PLACED IN THE BUFFER AREA (ROOM) IN ... A MANNER .. TO AVOID CONDITIONS THAT COULD ADVERSELY AFFECT THEIR OPERATION
*Failure to maintain clean air inside the buffer room and ante room.
Buffer room (where compounding takes place and hoods are located) door is a double swing door that is not secured. Positive pressure from buffer room to ante room ensures the cleaner air inside the buffer room stays inside, however; during and throughout the inspection, inspector observed ante room door remain OPEN therefore pulling unsecured buffer room doors OPEN allowing dirty air from the unclassified pharmacy into the ante room AND buffer room.

75) COMPETENT MICROBIOLOGY PERSONNEL ARE CONSULTED IF ..SAMPLING .. SHOWS ELEVATED LEVELS OF MICROBIAL GROWTH. IF ANY MOLD, YEAST, ... ARE DETECTED, IMMEDIATE REMEDIATION AND INVESTIGATION INTO THE CAUSE AND SOURCE WAS CONDUCTED.
*Failure to use proper plates to identify fungi in clean room.
On 7-14-17, Surface sampling revealed chrysosporium sp , a fungus. Resampling was conducted on a TSA plate that is specific to bacteria and may not be effective in detecting fungus.

37) BEYOND USE TIME DOES NOT EXCEED 6 HOURS FOR SINGLE DOES CONTAINERS IN ISO CLASS 5 (HOOD) .. AFTER INITIAL OPENING OR ENTRY.
*Failure to indicate time / day of initial entry of single dose bags inside hood or to discard after initial use.

38) BEYOND USE TIME DOES NOT EXCEED 1 HOUR FOR CLOSURE SELAED SINGLE – DOSE CONTAINERS AFTER BEING OPENED OR ENTERED IN WORSE THAN ISO CLASS 5 AIR.
*Failure to discard a vial of sterile drug kept in the refrigerator after initial use with no time stamp of initial entry.

80) SUPPLIES AND EQUIPMENT.. ARE WIPED WITH SUITABLE DISINFECTING AGENT.
*Failure to wipe down dirty scissors before placing non sterile item in the hood .

99) IMMEDIATELY AFTER THE COMPOUNDER COMPLETES THE HAND HYGIENE AND GARBING PROCEDURE, ... ALL COMPOUNDING EMPLOYEES HAVE SUCCESSFULLY COMPLETED AN INITIAL COMPETENCY EVAULATION AND GLOVED FINGERTIP/THUMB SAMPLING PROCEDURE (0 cfu)NO LESS THAN THREE TIMES BEFORE INITIALLY BEING ALLOWED TO COMPOUND CSPS FOR HUMAN USE.
*Failure to train newly hired employee before allowing person to compound sterile products. Inspector observed a newly hired technician physically compounding sterile products with the direction of another technician, without passing ANY GFT (gloved fingerprint test). This does not ensure

technician is effective in hand hygiene and garbing without introducing microorganisms into the final product.

100) RE-EVALUATION OF GFT ... FOR ALL COMPOUNDING PERSONNEL OCCURS AT LEAST... ANNUALLY BEFORE BEING ALLOWED TO CONTINUE COMPOUNDING CSP'S (COMPOUNDED STERILE PRODUCTS)
*Failure to validate the effectiveness of hand hygiene and garbing of all personnel with the exception of one technician.

95) DOCUMENTATION INDICATES COMPOUNDING PERSONNEL HAVE SUCCESSFULLY UNGERGONE SKILL ASSESSMENT USING OBSERVATIONAL TOOLS (HAND HYGIENE, GARBING, ASEPTIC TECHNIQUE) AND MEDIA FILL
*Failure to validate that any employee is competent to compound sterile products. All employees have not been observed to prove they are able to compound without introducing bacteria and fungus into the room (proper hand hygiene and garbing technique) AND into the finished product (aseptic technique).

93) LOW/MEDIUM RISK MEDIA FILL TESTS THAT CLOSELY SIMULATE THE MOST CHALLENGING OR STRESSFUL CONDITIONS ENCOUNTERED DURING COMPOUNDING ARE COMPLETED BY ALL COMPOUNDING PERSONNEL.
*Failure to validate compounding personnel through mimicking most challenging batch. Compounding records show a batch of 64 syringes of a CSP were dispensed , however media fill procedure calls for only 6 manipulations.

87) COMPOUNDING PERSONNEL REMOVE PERONAL OUTER GARMENTS; COSMETICS, ... HAND, WRIST AND BODY JEWELRY ... AND VISIBLE BODY PIERCING ABOVE THE NECK.
*Failure to remove make up and jewelry before compounding sterile products. New technician was observed in the buffer room compounding sterile products wearing false eyelashes, makeup, a large necklace and earrings.

88) FACILITY HAS ADEQUATE SUPPLIES TO MEET PPE REQUIREMENTS OF USP<797>
*Failure to wear appropriate beard cover while compounding sterile products.

73) SURFACE SAMPLING IS ACCOMPLISHED IN ALL ISO CLASSIFIED AREAS (HOODS AND ROOMS) ... AT THE CONCLUSION OF COMPOUNDING.
*Failure to assure compounding personnel are adequately compounding sterile products without the introduction of bacteria and fungus into the final product. Company policy states surface sampling shall be completed at the conclusion of cleaning.

98) COMPOUNDING PERSONNEL ... RESPONSIBLE FOR CLEANING ROUTINELY UNDERGO PERFORMANCE EVALUATION OF... ALL APPLICABLE CLEANING AND DISINFECTING PROCEDURES.. VISUAL OBSERVATION OF .. CLEANING IS DOCUMENTED ..TO PROVIDE A PERMANENT RECORD AND LONG TERM ASSESSMENT OF .. COMPETENCY.
*Failure to ensure employees are capable to cleaning and disinfecting hoods and rooms keeping microorganisms out of sterile products.

85) SHELVING, WALLS AND CEILINGS IN ANTE AREAS AND BUFFER AREAS ARE CLEANED AND DISINFECTED AT LEAST MONTHLY.
*Failure to consistently clean ante and buffer rooms monthly.

62) SURFACES AND ESSENTIAL FURNITURE IN THE BUFFER ROOMS... ARE CLEANABLE AND RESISTANT TO DISINFECTANTS.
*Failure to clean areas within buffer room. Inspector observed three dirty chairs inside the buffer room. Also, the inside door of the buffer room was filthy.

66) STORAGE SHELVING, COUNTERS, CABINETS AND CARTS ... ARE CLEANABLE.
*Failure to keep essential items in the buffer area clean. Bins containing sterile vials are dirty.

63) ONLY THE FURNITURE, EQUIPMENT, SUPPLIES AND OTHER MATERIAL REQUIRED FOR COMPOUNDING ... ARE BROUGHT INTO THE BUFFER ROOM.
*Failure to keep buffer room uncluttered.

110) A WRITTEN PROCEDURE IS IN PLACE FOR CLEANING AND DISINFECTING THE DIRECT COMPOUNDING AREAS.
*Failure to ensure all employees know facilities procedure on how to properly clean and disinfect the direct area where compounding takes place.

August 29, 2017

CONFIDENTIAL TO:
Ambient Healthcare of S. Florida, Inc.
15951 SW 41st Street, Suite 500
DAVIE, FL 33331

Case Number: PS 2017-15122

Dear Ambient Healthcare of S. Florida:

We are currently investigating the enclosed document received by the Department of Health. This investigation was initiated after it was determined that you may have violated the Pharmacy Practice Act.

Within **20 days** of receiving this letter, you may:
- submit a **written response** to the address below; **or**
- call our office to schedule an **interview**.

Please provide a copy of your **curriculum vitae** and identify your **specialty** even if you choose not to submit a response. Include the above-referenced case number in any correspondence that you send.

Florida law requires that this case and all investigative information remain confidential until 10 days after the Probable Cause Panel has determined that a violation occurred or you give up the right to confidentiality. Therefore, the contents of the investigation cannot be disclosed to you or the general public. You may make a written request for a copy of the investigative file and it will be sent to you when the investigation is complete.

You are not required to answer any questions or give any statement, and you have the right to be represented by an attorney. It is not possible to estimate how long it will take to complete this investigation because the circumstances of each investigation differ.

The mission of the Department of Health is to protect, promote & improve the health of all people in Florida through intregrated state, county and community efforts. If you have any questions, please call us at (954) 267-4511.

Sincerely,

Sylma C. Stinson
Medical Quality Assurance Investigator
/ss

Encl. Case Summary and Attachment

Stinson, Sylma

From: Hayes, Dan B <dhayes@briovarxinfusion.com>
Sent: Tuesday, August 29, 2017 3:34 PM
To: Stinson, Sylma
Subject: Read: Notification Letter
Attachments: ATT00001; ATT00002.txt; ATT00003.htm

Your message

To: Hayes, Dan B
Subject: Notification Letter
Sent: Tuesday, August 29, 2017 3:27:52 PM (UTC-05:00) Eastern Time (US & Canada)

was read on Tuesday, August 29, 2017 3:33:52 PM (UTC-05:00) Eastern Time (US & Canada).

STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES
INV797-Sterile Compounding

File # 21072
Insp # 147189

NAME	PERMIT NUMBER	DATE OF INSPECTION
AMBIENT HEALTHCARE OF S. FLORIDA, INC	27913	08/24/2017
DOING BUSINESS AS AMBIENT HEALTHCARE OF S. FLORIDA, INC		
STREET ADDRESS 15951 SW 41ST ST SUITE 500	**TELEPHONE #** 954-389-1126	**EXT**
CITY DAVIE	**COUNTY** BROWARD	**STATE/ZIP** FL/33331

Additional Information

Business Operation Hours

M-T-W-TH-F Y	Weekly Hours 8:30 am to 5:30
Monday N	Tuesday N
Wednesday N	Thursday N
Friday N	Saturday N
Sunday N	

Registered Pharmacist / Intern / Tech

License # PS49270	Licensee Name Shirley Elisbrun
License Type Registered Pharmacists	
License # PS36287	Licensee Name Vincent Ekebu
License Type Registered Pharmacists	
License # PS52096	Licensee Name Jacqueline Rodriguez
License Type Registered Pharmacists	
License # PS21110	Licensee Name Manuela Vega-Rivera
License Type Registered Pharmacists	
License # PS28016	Licensee Name Enrique Hernandez
License Type Registered Pharmacists	
License # 29706	Licensee Name Katrina Phillip
License Type Pharmacy Tech	

ACS Manager

Optional Information

Basic License Data - PSD

DEA Reg # BA7935490	

License Relations

Pharmacy Affiliate

ADLER, IAN	License #
BRONSON, DAVID	License #
DEBLASI, PAIGE	License #
FRENI, LAWRENCE	License #
KLEINMAN, IRA	License #
KRAMM, EDWARD P	License #
KRAMM, KATHEE M	License #
WILKINS, JOHN	License #

EXHIBIT #3

YORK, CHRISTOPHER	License #

RX DPT MGR/COR/POR

HERNANDEZ, ENRIQUE JAVIER	License # 28016

Special Sterile Compounding

AMBIENT HEALTHCARE OF S. FLORIDA, INC	License # 18740

INV797 - Sterile Compounding

LOW RISK

1. Low risk CSP's are properly identified: Aseptic manipulations within an ISO Class 5 environment using three or fewer sterile products and no more than two entries into any container. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Low-Risk Level CSPs]	Yes
2. Low Risk CSP's, in absence of passing sterility test, stored not more than 48 hours at controlled room temperature, 14 days at cold temperature, or 45 days in solid frozen state at -25° to -10° or colder. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Low-Risk Level CSPs]	Yes
3. Low Risk CSP's with 12 hour BUD are properly identified and comply with all four specific criteria. 1. PEC in Segregated Compounding area 2. Away from windows, doors , high traffic areas 3. Hygiene & garbing required, sinks not adjacent to PEC. 4. Cleaning & Disinfecting, Personnel training, Competency evaluation, Garbing, Aseptic work practices, Viable and non-viable environmental sampling apply. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Low-Risk Level CSPs]	N/A

MEDIUM RISK

4. Medium Risk CSP's are properly identified: Aseptic manipulations within an ISO Class 5 environment using prolonged and complex mixing and transfer, more than three sterile products and entries into any container, and pooling ingredients from multiple sterile products to prepare multiple CSPs. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Medium-Risk Level CSPs]	Yes
5. Medium Risk CSP's, In absence of passing sterility test, stored not more than 30 hours at controlled room temperature, 9 days at cold temperature, or 45 days in solid frozen state at -25° to -10° or colder. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Medium-Risk Level CSPs]	Yes

HIGH RISK

6. Presterilization procedures for high-risk level CSPs, such as weighing and mixing, are completed in no worse than an ISO Class 8 environment. [ENVIRONMENTAL QUALITY AND CONTROL : Placement of Primary Engineering Controls Within ISO Class 7 Buffer Areas]	
7. High Risk CSP's are properly identified: Confirmed presence of nonsterile ingredients and devices, or confirmed or suspected exposure of sterile ingredients for more than one hour to air quality inferior to ISO Class 5 before final sterilization. [CSP MICROBIAL CONTAMINATION RISK LEVELS : High-Risk Level CSPs]	
8. High Risk CSP's, in absence of passing sterility test are not stored more than 24 hours at controlled room temperature, 3 days at cold temperature, or 45 days in solid frozen state at -25° to -10° or colder. [CSP MICROBIAL CONTAMINATION RISK LEVELS : High-Risk Level CSPs]	
9. A 0.2-µm certified sterilizing membrane filter is used that is chemically and physically compatible with the CSP. Filtration is completed rapidly without filter replacement. Sterilization method is verified to achieve sterility for the quantity and type of containers. [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Sterilization of High-Risk Level CSPs by Filtration]	
10. Sterilization method used has documentation that acceptable strength and purity of ingredients and integrity of containers is maintained. [CSP MICROBIAL CONTAMINATION RISK LEVELS : High-Risk Level CSPs]	
11. The manufacturer recommended filter integrity (e.g., bubble point) test is performed and documented for all sterilizing filters after filtering CSPs. [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Sterilization of High-Risk Level CSPs by Filtration]	
12. Autoclave cycle has been verified using appropriate biological indicators. Solutions are passed through a 1.2-µm or smaller filter into final containers to remove particulates before sterilization. [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Sterilization of High-Risk Level CSPs by Steam]	
13. Dry heat ovens used for sterilization have filtered forced air. Only those items that will be damaged by steam are sterilized by dry heat. [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Sterilization of High-Risk Level CSPs by Dry Heat]	
14. The description of dry heat sterilization conditions and duration for specific CSPs is included in written documentation in the compounding facility. The effectiveness of dry heat sterilization is verified using appropriate biological indicators and other confirmation. [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Sterilization of High-Risk Level CSPs by Dry Heat]	
15. Dry heat depyrogenation is used to render glassware or containers, such as vials free from pyrogens as well as viable microbes. The description of the dry heat depyrogenation cycle and duration for specific load items is included in written documentation in the compounding facility. The effectiveness of the dry heat depyrogenation cycle is verified using endotoxin challenge vials (ECVs). [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Depyrogenation by Dry Heat]	
16. Sterility testing is completed for all High-risk level CSPs prepared in batches of more than 25 identical containers, or exposed longer than 12 hours at 2° to 8°, and 6 hours at warmer than 8° before being sterilized. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Sterility Testing]	

USP <71> STERILITY TESTING (Outsourced)

17. Outsourced sterility testing results indicate that it is compliant with USP<71>. A method not described in the USP may be used if validation demonstrates that the alternative is at least as effective and reliable. [STERILITY TEST USP<71>]	
18. Outsourced: The number of articles tested are appropriate according to USP<71>. [STERILITY TEST USP<71> : Number of Articles to Be Tested]	
19. Outsourced: The volume/quantity tested is according to USP<71>. [STERILITY TEST USP<71> : Number of Articles to Be Tested]	
20. Outsourced: A USP<71> method suitability test has been done with appropriate inoculum, additives and rinses. [STERILITY TEST USP<71> : Method Suitability Test]	
21. Outsourced: Sterility testing reports are reviewed and appropriate actions taken and documented. [FINISHED PREPARATION RELEASE CHECKS AND TESTS]	

USP <71> STERILITY TESTING

22. On site: Membrane filtration is used if appropriate. (The technique of membrane filtration is used whenever the nature of the product permits; that is, for filterable aqueous preparations, for alcoholic or oily preparations, and for preparations miscible with, or soluble in, aqueous or oily solvents, provided these solvents do not have an antimicrobial effect in the conditions of the test.) Filters are rinsed according to USP<71>. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Sterility Testing]	
23. On site: Direct inoculation is done only when membrane filtration cannot be carried out. Volume to be inoculated does not exceed 10% of the culture media volume. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Sterility Testing]	
24. On site: The number of articles tested are appropriate according to USP<71>. [STERILITY TEST USP<71> : Number of Articles to Be Tested]	
25. On site: The volume/quantity tested is according to USP<71>. [STERILITY TEST USP<71> : Number of Articles to Be Tested]	
26. On site: A growth promotion test has been done on the media with the 5 specified organisms (not more than 100 CFU) according to USP<71>. [STERILITY TEST USP<71> : Growth Promotion Test of Aerobes, Anaerobes, and Fungi]	
27. On site: A USP<71> method suitability test has been done with appropriate inoculum, additives and rinses. [STERILITY TEST USP<71> : Method Suitability Test]	
28. On site: TSB or SCD is incubated at 20-25 C for 14 days (2 incubators present). [STERILITY TEST USP<71> : Culture Media and Incubation Temperatures]	
29. On site: FTM is incubated at 30-35 C for 14 days (2 incubators present). [STERILITY TEST USP<71> : Culture Media and Incubation Temperatures]	
30. On site: Sterility testing is documented including lot numbers and expiration dates of media. [FINISHED PREPARATION RELEASE CHECKS AND TESTS]	
31. On site: Sterility testing reports are reviewed and appropriate actions taken and documented. [FINISHED PREPARATION RELEASE CHECKS AND TESTS]	

ENDOTOXIN TESTING

32. Endotoxin testing is conducted for High-risk level CSP's that are prepared in batches of more than 25 identical containers, or exposed longer than 12 hours at 2° to 8°, and 6 hours at warmer than 8°, before being sterilized or in multidose containers for administration to multiple patients. (excluding those for inhalation and ophthalmic administration) [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Bacterial Endotoxin (Pyrogen) Testing]	
33. Endotoxin testing process indicates that it is compliant with USP<85>. [BACTERIAL ENDOTOXINS TEST USP<85>]	
34. High Risk CSP's are within allowable limits for bacterial endotoxins. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Bacterial Endotoxin (Pyrogen) Testing]	

IMMEDIATE USE COMPOUNDING

35. Immediate-use compounding complies with all six specified criteria. 1. Low-risk sterile nonhazardous products or diagnostic radiopharmaceutical products from the manufacturers' original containers. Anti-neoplastics shall not be prepared as immediate-use CSPs because they are hazardous drugs. 2. Unless required for the preparation, the compounding procedure is a continuous process not to exceed 1 hour. 3. During preparation, aseptic technique is followed and, if not immediately administered, the finished CSP is under continuous supervision to minimize the potential for contact with nonsterile surfaces, introduction of particulate matter or biological fluids, mix-ups with other CSPs, and direct contact of outside surfaces. 4. Administration begins not later than 1 hour following the start of the preparation of the CSP. 5. Unless immediately and completely administered by the person who prepared it or immediate and complete administration is witnessed by the preparer, the CSP shall bear a label listing patient identification information, the names and amounts of all ingredients, the name or initials of the person who prepared the CSP, and the exact 1-hour BUD and time. 6. If administration has not begun within 1 hour following the start of preparing the CSP, the CSP shall be promptly, properly, and safely discarded. [IMMEDIATE-USE CSPs]	N/A

SINGLE/MULTIPLE DOSE CONTAINER BUD

36. Beyond-use date does not exceed 28 days for multiple-dose containers after initial opening or entry, unless specified otherwise by the manufacturer. [SINGLE-DOSE AND MULTIPLE-DOSE CONTAINERS]	Yes
37. Beyond-use time does not exceed 6 hours for closure sealed single-dose containers in ISO Class 5 or cleaner air after initial opening or entry, unless specified otherwise by the manufacturer. [SINGLE-DOSE AND MULTIPLE-DOSE CONTAINERS] *Multiple single use SWI were in the PEC's with no puncture date or time.*	No
38. Beyond-use time does not exceed 1 hour for closure sealed single-dose containers after being opened or entered in worse than ISO Class 5 air. [SINGLE-DOSE AND MULTIPLE-DOSE CONTAINERS] *Entered pharmacy bulk package of vancoymycin Lot # 772953A in refrigerator with no time or date of puncture.*	No
39. Single-dose ampules are discarded immediately after use. [SINGLE-DOSE AND MULTIPLE-DOSE CONTAINERS]	Yes

HAZARDOUS DRUGS

40. A pressure indicator is installed and differential pressures are monitored and documented daily for hazardous buffer room. [HAZARDOUS DRUGS AS CSPs]	
41. Hazardous drug buffer room is at least 0.01 inch water column negative pressure with 30 ACPH of HEPA filtered air. [HAZARDOUS DRUGS AS CSPs]	
42. At least 0.01 inch water column negative pressure and 12 air changes per hour in non-cleanrooms in which CACIs are located. FAC: USP Chapter 797 requires that: "When closed-system vial-transfer devices (CSTDs) (i.e., vial-transfer systems that allow no venting or exposure of hazardous substance to the environment) are used, they shall be used within an ISO Class 5 environment of a BSC or CACI. The use of the CSTD is preferred because of their inherent closed system process. In facilities that prepare a low volume of hazardous drugs, the use of two tiers of containment (e.g., CSTD within a BSC or CACI that is located in a non-negative pressure room) is acceptable." For purpose of said provision, a "low volume of hazardous drugs" is defined as less than 40 doses per month. [HAZARDOUS DRUGS AS CSPs]	
43. Personnel compounding hazardous drugs wear appropriate personal protective equipment. [HAZARDOUS DRUGS AS CSPs]	
44. Hazardous drugs are handled with caution at all times using appropriate chemotherapy gloves during receiving, distribution, stocking, inventorying, preparing for administration, and disposal. Spill kits are available. [HAZARDOUS DRUGS AS CSPs]	
45. Hazardous drugs are prepared in an ISO Class 5 environment (BSC or CACI) with protective engineering controls in place, following aseptic practices specified for the appropriate contamination risk levels. [HAZARDOUS DRUGS AS CSPs]	
46. Hazardous drugs are stored separately from other inventory in a manner to prevent contamination and personnel exposure. [HAZARDOUS DRUGS AS CSPs]	
47. Access to hazardous drug preparation areas is limited to authorized compounding personnel. [HAZARDOUS DRUGS AS CSPs]	

48. Annual documentation of hazardous drug training of personnel regarding storage, handling, containment techniques and disposal of hazardous drugs is available. [HAZARDOUS DRUGS AS CSPs]	
49. Compounding personnel of reproductive capability have confirmed in writing that they understand the risks of handling hazardous drugs. [HAZARDOUS DRUGS AS CSPs]	
50. Facility maintains appropriate disposal containers for all hazardous waste. [HAZARDOUS DRUGS AS CSPs]	

FACILITY DESIGN AND CERTIFICATION

51. Certification and testing of primary (LAFWs, BSCs, CAIs and CACIs) and secondary engineering controls (buffer and ante areas) have been performed by a qualified individual no less than every six months and whenever the device or room is relocated, altered, or major service to the facility is performed. Corrective action for deficiencies are documented. Certification procedures such as those outlined in the CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2006) are conducted under dynamic conditions. [ENVIRONMENTAL QUALITY AND CONTROL : Environmental Nonviable Particle Testing Program] *MTA 7-14-17 tested PECs and SECs ; ante room did not pass with the required 20 ACPH - room had 15 THIS IS YOUR SECOND ADVISORY ; there are 4 X ISO 5 HLF hoods ; Hood # 2298 HEPA filter failed on this date with multiple leaks; a new HEPA filter was shipped on 7-27 and replaced on 8-7-17 and the PEC was recertified on this date. Per PDM HH, facility continued to compound in the PEC after filter failure and before new filter was replaced (7-14 thru 8-7).*	No
52. Primary engineering controls provide unidirectional (i.e., laminar) HEPA filtered air. Air pattern analysis via smoke studies are conducted at the critical site to demonstrate unidirectional airflow and sweeping action over and away from the product under dynamic conditions.[ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
53. The primary engineering controls are placed within a buffer area in such a manner as to avoid conditions that could adversely affect their operation. The PEC is placed out of the traffic flow and in a manner to avoid disruption from the HVAC system and room cross drafts. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls] *The door from the IV room to ante room is a double swing door . When the ante room door opens, the clean room swing doors open; During inspection, employees were exiting and entering clean room into the ante room while the ante room door was left open, letting dirty air enter through the main pharmacy into the ante room and IV room.*	No
54. All HEPA filters are leak tested after installation and every six months thereafter. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes

ISOLATORS

55. CAIs are proven to maintain ISO Class 5 air when particle counts are sampled 6 to 12 inches upstream of critical site exposure areas during performance of normal inward and outward transfer of materials, and compounding manipulations when such CAIs are located in air quality worse than ISO Class 7. [ENVIRONMENTAL QUALITY AND CONTROL : Placement of Primary Engineering Controls Within ISO Class 7 Buffer Areas]	
56. Adequate recovery time for isolators to achieve ISO Class 5 air quality is allowed after material transfer before and during compounding operations. [ENVIRONMENTAL QUALITY AND CONTROL : Placement of Primary Engineering Controls Within ISO Class 7 Buffer Areas]	
57. Personnel garbing requirements are followed for CAIs unless manufacturer provides written documentation based on validated testing that any components of PPE are not required to maintain sterility of CSPs. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	

FACILITY DESIGN AND CERTIFICATION (Secondary Engineering Controls)

58. Facility has pressure gauges or velocity meters to monitor the pressure differential or airflow between the buffer area and ante-area, and the ante-area and the general environment outside the compounding area. The results are reviewed and documented on a log at least daily or by a continuous recording device. The pressures differentials meet or exceed 5 Pa (0.02 inch water column (w.c.)). Alternatively, in facilities where low- and medium-risk level CSPs are prepared, differential airflow is maintained at a minimum velocity of 0.2 meter/second (40 fpm) across a line of demarcation between buffer area and ante-area. [ENVIRONMENTAL QUALITY AND CONTROL : Pressure Differential Monitoring]	Yes
59. Clean rooms for nonhazardous and nonradioactive CSPs are supplied with HEPA filtered air that enters from ceilings with return vents low on walls, and that provides not less than 30 air changes per hour or qualifies for exception in 64B16-27.797(4)(c). [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
60. Activities and tasks carried out within the buffer area are limited to only those necessary when working within a controlled environment. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
61. Only the furniture, equipment, supplies, and other material required for the compounding activities to be performed are brought into the buffer room. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls] *Clean room is cluttered with multiple half empty bins, storage containers and an empty plastic tray stored under cart; a radio is stored under a hood*	No
62. Surfaces and essential furniture in buffer rooms or zones and clean rooms are nonporous, smooth, non-shedding, impermeable, cleanable, and resistant to disinfectants. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls] *There are three chairs in the clean room that are dirty; the door on the inside of the clean room is filthy.*	No
63. The surfaces of ceilings, walls, floors, fixtures, shelving, counters, and cabinets in the buffer area are smooth, impervious, free from cracks and crevices, and non-shedding, thereby promoting cleanability, and minimizing spaces in which microorganisms and other contaminants may accumulate. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls] *The inside door of the clean room has remnants of sticky material stuck onto glass window;*	No
64. Ceiling tiles are caulked around each perimeter and to walls to seal them to the support frame. The exterior lens surface of ceiling lighting fixtures is smooth, mounted flush, and sealed. All other penetrations through the ceiling or walls are sealed. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
65. The buffer area does not contain sources of water (sinks) or floor drains. Work surfaces are constructed of smooth, impervious materials, such as stainless steel or molded plastic, so that they are easily cleaned and disinfected. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls] *The wheel attachments on PEC is showing signs of rust.*	No
66. Storage shelving, counters, cabinets and carts/casters in the buffer area are smooth, impervious, free from cracks and crevices, non-shedding, non-porous, cleanable, and disinfectable. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls] *Bins containing sterile drug vials are dirty and have sticky material on the outside;*	No
67. When devices (e.g., computers and printers) and objects (e.g., carts and cabinets) are placed in buffer areas, air quality is verified by particle counts on certification. [ENVIRONMENTAL QUALITY AND CONTROL : ISO Class 5 Air Sources, Buffer Areas, and Ante-Areas]	Yes

QUALITY AND CONTROL

68. An appropriate environmental sampling plan has been developed for airborne viable particles based on a risk assessment of compounding activities performed. Volumetric air sampling is conducted every six months and sites include locations within each ISO Class 5 environment and in the ISO Class 7 and 8 areas, and the areas at greatest risk of contamination (e.g., work areas near the ISO Class 5 environment, counters near doors, pass-through boxes). The plan includes sample locations, method of collection, frequency of sampling, volume of air sampled, and time of day as related to activity in the compounding area and action levels. [ENVIRONMENTAL QUALITY AND CONTROL : Environmental Viable Airborne Particle Testing Program—Sampling Plan] *Your viable sampling plan states that PASSIVE air sampling must be conducted monthly and does not mention USP<797> requirements of VOLUMETRIC air sampling and the volume of air to be sampled in each ISO classified area; Surface sampling policy does not state that ss shall be conducted at the conclusion of compounding, rather at the end of cleaning - also, plates must contain polysorbate 80 and lechitin to deactivate disinfectants and cleaning agents - include this in your policy*	No
69. Evaluation of airborne microorganisms using volumetric collection methods in the controlled air environments is performed by properly trained individuals for all compounding risk levels. [ENVIRONMENTAL QUALITY AND CONTROL : Viable Air Sampling]	Yes
70. Volumetric air sampling using malt extract agar (MEA) or some other media that supports the growth of fungi is used in high-risk level compounding environments. [ENVIRONMENTAL QUALITY AND CONTROL : Growth Media]	N/A
71. For low-risk level CSPs with 12-hour or less BUD, air sampling is performed at locations inside the ISO Class 5 environment and other areas that are in close proximity to the ISO class 5 environment. [ENVIRONMENTAL QUALITY AND CONTROL : Viable Air Sampling]	N/A
72. The number of discrete colonies of microorganisms is counted and reported as colony-forming units (cfu) and documented on an environmental monitoring form. Counts from air monitoring are transformed into cfu/cubic meter of air and evaluated for adverse trends. [ENVIRONMENTAL QUALITY AND CONTROL : Incubation Period]	No
73. Surface sampling is accomplished in all ISO classified areas on a periodic basis using TSA contact plates with lecithin and polysorbate 80 and/or swabs and is done at the conclusion of compounding. [ENVIRONMENTAL QUALITY AND CONTROL : Surface Cleaning and Disinfection Sampling and Assessment] *Facility conducts monthly surface sampling in addition to semi annually through certification company; Company policy is to conduct surface sampling after cleaning and does not mention that it shall be done at the conclusion of compounding.*	No
74. Sampling data is collected and reviewed on a periodic basis as a means of evaluating the overall state of control of the compounding environment. [ENVIRONMENTAL QUALITY AND CONTROL : Action Levels, Documentation and Data Evaluation]	Yes
75. Competent microbiology personnel are consulted if an environmental sampling consistently shows elevated levels of microbial growth. If any mold, yeast, coagulase positive staphylococcus, or gram negative rods are detected immediate remediation and investigation into the cause and source was conducted. [ENVIRONMENTAL QUALITY AND CONTROL : Action Levels, Documentation and Data Evaluation] *MTA surface sampling on 7-14 in the clean room revealed chrysosporium sp. which is a fungus. The resampling was done on a TSA plate that is not fungal specific.*	No
76. Surfaces in the LAFWs, BSCs, CAIs, and CACIs are cleaned and disinfected frequently, including at the beginning of each work shift, before each batch preparation is started, every 30 minutes during continuous compounding periods of individual CSPs, when there are spills, and when surface contamination is known or suspected from procedural breaches. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
77. Cleaning and disinfecting occurs before compounding is performed. Items are removed from all areas to be cleaned, and surfaces are cleaned by removing loose material and residue from spills, e.g., water-soluble solid residues are removed with Sterile Water and low-shedding wipes. This shall be followed by wiping with a residue-free disinfecting agent, such as sterile 70% IPA, which is allowed to dry before compounding begins. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
78. Cleaning and disinfecting agents and methods of application are in accordance with written SOPs and followed by custodial and/or compounding personnel. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas] *Your policy states you should be using RTU agents however MF RPT informed inspector that a capful of Lph se is mixed with a bucket of water.*	No
79. Cleaning materials, such as wipes, sponges, and mops, are non-shedding, preferably composed of synthetic micro fibers, and dedicated to use in the buffer area, ante-area, and segregated compounding areas and are not removed from these areas except for disposal. If cleaning materials are reused (e.g., mops), there are procedures based on manufacturer recommendations that ensure that the effectiveness of the cleaning device is maintained and repeated use does not add to the bioburden of the area being cleaned. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas] *dedicated mops are stored in ante room with mop head in direct contact with floor and are not mounted.*	No
80. Supplies and equipment removed from shipping cartons are wiped with a suitable disinfecting agent (e.g., sterile 70% IPA). [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas] *Technician placed a dirty pair of scissors on direct compounding area without wiping down with sterile alcohol.*	No
81. Disinfectant sprayed or wiped on a surface to be disinfected is allowed to dry, and during this time the item is not be used for compounding purposes. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
82. Sterile 70% IPA pads are used to disinfect the sterile entry points of packages and devices. Wetted gauze pads or other particle-generating material are not appropriate. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes

QUALITY AND CONTROL (Secondary Engineering Controls)

83. Work surfaces in ISO Class 7 and 8 areas and segregated compounding areas are cleaned at least daily. IPA (70% isopropyl alcohol) remains on surfaces to be disinfected for at least 30 seconds before such surfaces are used to prepare CSPs. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	N/A
84. Floors in ISO Class 7 and 8 areas are mopped daily by trained personnel at a time when no aseptic operations are in progress using approved agents and procedures described in written SOP's. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	N/A
85. Shelving, walls, and ceilings in ante-areas and buffer areas are cleaned and disinfected at least monthly. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas] *Monthly cleaning records show walls , ceilings and outside of hoods were not cleaned; ceilings were not cleaned in may ; April records show there was no monthly cleaning*	No

PERSONNEL CLEANSING, GARBING & COMPETENCY EVALUATION

86. Personnel preparing CSP's are free from rashes, sunburn, weeping sores, conjunctivitis, and active respiratory infections. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	Yes
87. Compounding personnel remove personal outer garments; cosmetics; artificial nails; hand, wrist, and body jewelry that can interfere with the fit of gowns and gloves; and visible body piercing above the neck. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing] *Technician GT was observed wearing a large necklace , earrings, make up and false eyelashes. Technician FS has a heavy beard and was compounding sterile products without donning a beard cover.*	No
88. Facility has adequate supplies to meet PPE requirements of USP<797>. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing] *Male technician RS has a beard and was compounding without beard covered; No beard covers available at facility*	No

89. Garbing and hand hygiene are accomplished in the ante-area in order of dirtiest to cleanest: shoes or shoe covers, head and facial hair covers, face mask, fingernail cleansing, hand and forearm washing and drying; non-shedding gown. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	Yes
90. Sterile gloves are donned in the buffer room/isolator after hand cleansing with an alcohol-based product with persistent activity and hands are allowed to dry. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	Yes
91. Gloves are routinely disinfected with sterile 70% IPA after contacting nonsterile objects. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	Yes
92. Personnel repeat garbing and hand hygiene after they are exposed to direct contact contamination or worse than ISO Class 8 air. Gowns may be hung in the anteroom and reused during the same workshift. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	Yes
93. Low/Medium Risk media-fill tests that closely simulate the most challenging or stressful conditions encountered during compounding are completed at least annually by compounding personnel. Media-filled vials are appropriately incubated for 14 days. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Medium-Risk Level CSPs] *compoudning records show morphine sulfate / NS 4mg/4ml RX #280177040 requires 64 entries into a IV bag however media fill conducted by facility uses only 6 manipulations.*	No
94. High Risk Media-fill tests that closely simulate the most challenging or stressful conditions encountered during compounding have been completed at least semiannually by compounding personnel. Media-filled vials are appropriately incubated for 14 days. [CSP MICROBIAL CONTAMINATION RISK LEVELS : High-Risk Level CSPs]	N/A
95. Documentation indicates compounding personnel have successfully completed didactic training, passed written competency assessments, undergone skill assessment using observational audit tools (hand hygiene, garbing, aseptic technique) and media-fill testing annually or semiannually (high risk) and before any compounding personnel begin to prepare CSPs . [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures] *THIS IS YOUR SECOND ADVISORY. See #98*	No
96. Compounding personnel who fail written tests, observational audits, or whose media-fill test vials have one or more units showing visible microbial contamination, are reinstructed and re-evaluated by expert compounding personnel to ensure correction of all aseptic work practice deficiencies. Corrective action is documented. Compounding personnel pass all evaluations prior to resuming compounding of sterile preparations. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures]	N/A
97. Other cleaning personnel performing cleaning and disinfecting procedures (e.g. environmental) are thoroughly trained in proper hand hygiene, and garbing, cleaning, and disinfection procedures by a qualified aseptic compounding expert. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures]	N/A
98. Compounding personnel and other personnel responsible for cleaning routinely undergo performance evaluation of proper hand hygiene, garbing, and all applicable cleaning and disinfecting procedures conducted by a qualified aseptic compounding expert. Visual observation of hand hygiene, garbing and cleaning is documented and maintained to provide a permanent record and long-term assessment of personnel competency. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures] *All compounding technicians are overdue on all observational assessments ; employee folders have blank checklists dated for 2016 that have not been completed. Last observational assessments for aseptic technique, cleaning and disinfecting and hand hygiene and garbing were completed in 2015*	No
99. Immediately after the compounder completes the hand hygiene and garbing procedure, the evaluator collects a gloved fingertip and thumb sample from both hands of the compounder onto appropriate agar plates. The plates are incubated at 30-35° for 2–3 days. All compounding personnel have successfully completed an initial competency evaluation and gloved fingertip/thumb sampling procedure (0 cfu) no less than three times before initially being allowed to compound CSPs for human use. [ENVIRONMENTAL QUALITY AND CONTROL : Gloved Fingertip Sampling] *GT Rpt informed inspector she did not complete any GFT and yet she was observed compounding in the IV room during the time of this inspection. MF RPT was hired in 4-2017 and documentation shows only 1 GFT was completed.*	No
100. Re-evaluation of glove fingertip testing onto appropriate agar plates (Trypticase soy agar (TSA) with lecithin and polysorbate 80) for all compounding personnel occurs at least annually for low- and medium-risk level CSPs and semiannually for high-risk level CSPs before being allowed to continue compounding CSPs. Gloves shall not be disinfected with sterile 70% IPA prior to testing. The cfu action level is based on the total number of cfu on both gloves and not per hand. [ENVIRONMENTAL QUALITY AND CONTROL : Gloved Fingertip Sampling] *Per PDM HH, all Rphs are validated for Sterile compounding however their documentation was not available at the time of this inspection; All technicians are overdue for their GFT with the exception of KP Rpt.*	No

VERIFICATION

101. Labels of CSPs contain name and address of pharmacy, correct names and amounts or concentrations of ingredients, total volumes, beyond-use dates, storage conditions, and route(s) of administration. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Identity and Strength Verification of Ingredients]	Yes
102. Facility has documentation that procedures have been followed to ensure sterility, purity, correct identities and amounts of ingredients, and stability. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Inspection of Solution Dosage Forms and Review of Compounding Procedures]	Yes
103. CSP's are visually inspected for abnormal particulate matter and color, and intact containers and seals. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Inspection of Solution Dosage Forms and Review of Compounding Procedures]	Yes
104. Beyond Use Dates are assigned using direct stability-indicating assays or authoritative literature that supports the assigned BUD. [STORAGE AND BEYOND-USE DATING : Determining Beyond-Use Dates]	Yes
105. Storage time of assembled bag and vial systems are according to the manufacturer recommendations. (eg Minibag plus, Addvantage, Add-ease) [STORAGE AND BEYOND-USE DATING : Proprietary Bag and Vial Systems]	Yes

DISPENSING/DISTRIBUTION

106. Facility has written procedures for proper packaging, storage, and transportation conditions to maintain sterility, quality, purity, and strength of CSPs. [MAINTAINING STERILITY, PURITY, AND STABILITY OF DISPENSED AND DISTRIBUTED CSPs :]	Yes
107. Modes of transport are used that maintain appropriate temperatures and prevent damage to CSPs. [MAINTAINING STERILITY, PURITY, AND STABILITY OF DISPENSED AND DISTRIBUTED CSPs : Packaging and Transporting CSPs]	Yes
108. Facility provides a multiple component formal training program to ensure patients and caregivers understand the proper storage, handling, use, and disposal of CSPs. [PATIENT OR CAREGIVER TRAINING]	Yes

POLICY/PROCEDURE

109. Written procedures detail cleaning and disinfecting the sterile compounding areas including cleansers, disinfectants, and non-shedding wipe and mop materials. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas] *Cleaning policy is vague and does not detail method of cleaning buffer room or PEC's; In addition, your policy references USP <797> for cleaning agents rather than including specific agents in your policy. Include agents, method of application, dwell time and mixing procedures in your cleaning policy so that anyone reading this policy will be able to clean all areas without question.*	No

110. A written procedure is in place for cleaning and disinfecting the Direct Compounding Areas. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas] *Policy should be easily understood so anyone that reads policy would understand.*	No
111. Facility has written procedures to verify correct identity, quality, amounts, and purities of ingredients used in CSPs. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Identity and Strength Verification of Ingredients]	Yes
112. Policies address packaging to maintain physical integrity, sterility, stability, and purity of CSPs. [MAINTAINING STERILITY, PURITY, AND STABILITY OF DISPENSED AND DISTRIBUTED CSPs : Packaging and Transporting CSPs]	Yes
113. Written standard procedures describe means for patients to ask questions and report concerns and adverse events with CSPs, and for compounding pharmacists to correct and prevent future problems. [PATIENT MONITORING AND ADVERSE EVENTS REPORTING]	Yes

RADIOPHARMACEUTICALS

114. Facility has appropriate primary engineering controls and radioactivity containment and shielding. Location of primary engineering controls permitted in ISO Class 8 controlled environment. [RADIOPHARMACEUTICALS AS CSPs]	
115. Radiopharmaceuticals prepared as low-risk level CSPs with 12-hour or less BUD are prepared in a segregated compounding area. Segregated compounding area is designated with a line of demarcation. [RADIOPHARMACEUTICALS AS CSPs]	
116. Technetium-99m/Molybdenum-99 generators are eluted in ISO Class 8 conditions. [RADIOPHARMACEUTICALS AS CSPs]	

MISCELLANEOUS

117. Facility engaged in office use sterile compounding for human use is registered with FDA as an outsourcing facility. [FAC 64B16-27.700 (3)(g]	N/A
118. Compounding records are properly maintained. [FAC 64B16-28.140(4)]	Yes
119. When compounding activities require the manipulation of a patient's blood-derived or other biological material, the manipulations are clearly separated from routine material-handling procedures and equipment used in CSP preparation activities, and they are controlled by specific standard operating procedures in order to avoid any cross-contamination. [ENVIRONMENTAL QUALITY AND CONTROL : Placement of Primary Engineering Controls Within ISO Class 7 Buffer Areas]	N/A

SPECIAL PARENTERAL ENTERAL & EXTENDED SCOPE

120. Pharmacy technicians properly identified and supervised. [64B16-27.420, F.A.C.]	
121. Medication properly labeled. [465.0255, F.S.] [64B16-28.108, F.A.C.]	
122. Expired medications removed from the shelves. [64B16-28.110, F.A.C.]	
123. CQI Policy and Procedures and quarterly meetings. [766.101, F.S.] [64B16-27.300, F.A.C.]	
124. Prescriptions have the date dispensed and dispensing pharmacists. [893.04(1)(c) 6, F.S.] [64B16-28.140(3)(b), F.A.C.]	
125. Pharmacy maintains patient profile records. [64B16-27.800, F.A.C.]	
126. All controlled substance prescriptions contain information required. [893.04, F.S.]	
127. Prescriptions for controlled substances are on counterfeit-proof prescription pads or blanks purchased from a Department-approved vendor and the quantity and date meet the requirements of [456.42(2), F.S.].	
128. Controlled substance inventory taken on a biennial basis and available for inspection. [893.07(1)(a), F.S.]	
129. DEA 222 order forms properly completed. [893.07, F.S.]	
130. Controlled substance records and Rx information in computer system is retrievable. [21CFR 1306.22] [64B16-28.140, F.A.C.]	
131. Controlled substance records maintained for 4 years. [465.022(12)(b), F.S.]	
132. Certified daily log OR printout maintained. [21CFR 1306.22(b)(3)] [64B16-28.140(3)(b), F.A.C.]	
133. Pharmacy is reporting to the PDMP within 7 days of dispensing controlled substance. [893.055(4), F.S.]	
134. Pharmacy maintains invoices documenting that medicinal drugs were obtained from a Florida licensed distributor. 499.005 (14)	

Remarks:

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge. I have received a copy of the Licensee Bill of Rights.

Inspector Signature:

BOWER, MONICA

Date:8/24/2017

Representative:

Henry Hernandez

Date:8/24/2017

STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES
INV797-Sterile Compounding

File # 21072
Insp # 140164

NAME	PERMIT NUMBER	DATE OF INSPECTION
AMBIENT HEALTHCARE OF S. FLORIDA, INC	27913	08/01/2016
DOING BUSINESS AS		
AMBIENT HEALTHCARE OF S. FLORIDA, INC		
STREET ADDRESS	**TELEPHONE #**	**EXT**
15951 SW 41ST ST SUITE 500	954-389-1126	
CITY	**COUNTY**	**STATE/ZIP**
DAVIE	BROWARD	FL/33331

Additional Information

Business Operation Hours

M-T-W-TH-F Y	Weekly Hours 8:30 am to 5:30
Monday N	Tuesday N
Wednesday N	Thursday N
Friday N	Saturday N
Sunday N	

Registered Pharmacist / Intern / Tech

License # PS24556	Licensee Name Karen Hitchen
License Type Registered Pharmacists	
License # PS28016	Licensee Name Enrique Hernandez
License Type Registered Pharmacists	
License # 29706	Licensee Name Katrina Phillip
License Type Pharmacy Tech	

ACS Manager

Optional Information

Basic License Data - PSD

DEA Reg # BA7935490	

License Relations

Pharmacy Affiliate

ADLER, IAN	License #
BRONSON, DAVID	License #
DEBLASI, PAIGE	License #
FRENI, LAWRENCE	License #
KLEINMAN, IRA	License #
KRAMM, EDWARD P	License #
KRAMM, KATHEE M	License #
WILKINS, JOHN	License #
YORK, CHRISTOPHER	License #

RX DPT MGR/COR/POR

HITCHEN, KAREN M	License # 24556

Special Sterile Compounding

AMBIENT HEALTHCARE OF S. FLORIDA, INC	License # 18740

INV797 - Sterile Compounding

LOW RISK

1. Low risk CSP's are properly identified: Aseptic manipulations within an ISO Class 5 environment using three or fewer sterile products and no more than two entries into any container. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Low-Risk Level CSPs]	Yes
2. Low Risk CSP's, in absence of passing sterility test, stored not more than 48 hours at controlled room temperature, 14 days at cold temperature, or 45 days in solid frozen state at -25° to -10° or colder. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Low-Risk Level CSPs]	Yes
3. Low Risk CSP's with 12 hour BUD are properly identified and comply with all four specific criteria. 1. PEC in Segregated Compounding area 2. Away from windows, doors , high traffic areas 3. Hygiene & garbing required, sinks not adjacent to PEC. 4. Cleaning & Disinfecting, Personnel training, Competency evaluation, Garbing, Aseptic work practices, Viable and non-viable environmental sampling apply. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Low-Risk Level CSPs]	N/A

MEDIUM RISK

4. Medium Risk CSP's are properly identified: Aseptic manipulations within an ISO Class 5 environment using prolonged and complex mixing and transfer, more than three sterile products and entries into any container, and pooling ingredients from multiple sterile products to prepare multiple CSPs. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Medium-Risk Level CSPs]	Yes
5. Medium Risk CSP's, In absence of passing sterility test, stored not more than 30 hours at controlled room temperature, 9 days at cold temperature, or 45 days in solid frozen state at -25° to -10° or colder. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Medium-Risk Level CSPs]	Yes

HIGH RISK

6. Presterilization procedures for high-risk level CSPs, such as weighing and mixing, are completed in no worse than an ISO Class 8 environment. [ENVIRONMENTAL QUALITY AND CONTROL : Placement of Primary Engineering Controls Within ISO Class 7 Buffer Areas]	
7. High Risk CSP's are properly identified: Confirmed presence of nonsterile ingredients and devices, or confirmed or suspected exposure of sterile ingredients for more than one hour to air quality inferior to ISO Class 5 before final sterilization. [CSP MICROBIAL CONTAMINATION RISK LEVELS : High-Risk Level CSPs]	
8. High Risk CSP's, in absence of passing sterility test are not stored more than 24 hours at controlled room temperature, 3 days at cold temperature, or 45 days in solid frozen state at -25° to -10° or colder. [CSP MICROBIAL CONTAMINATION RISK LEVELS : High-Risk Level CSPs]	
9. A 0.2-µm certified sterilizing membrane filter is used that is chemically and physically compatible with the CSP. Filtration is completed rapidly without filter replacement. Sterilization method is verified to achieve sterility for the quantity and type of containers. [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Sterilization of High-Risk Level CSPs by Filtration]	
10. Sterilization method used has documentation that acceptable strength and purity of ingredients and integrity of containers is maintained. [CSP MICROBIAL CONTAMINATION RISK LEVELS : High-Risk Level CSPs]	
11. The manufacturer recommended filter integrity (e.g., bubble point) test is performed and documented for all sterilizing filters after filtering CSPs. [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Sterilization of High-Risk Level CSPs by Filtration]	
12. Autoclave cycle has been verified using appropriate biological indicators. Solutions are passed through a 1.2-µm or smaller filter into final containers to remove particulates before sterilization. [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Sterilization of High-Risk Level CSPs by Steam]	
13. Dry heat ovens used for sterilization have filtered forced air. Only those items that will be damaged by steam are sterilized by dry heat. [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Sterilization of High-Risk Level CSPs by Dry Heat]	
14. The description of dry heat sterilization conditions and duration for specific CSPs is included in written documentation in the compounding facility. The effectiveness of dry heat sterilization is verified using appropriate biological indicators and other confirmation. [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Sterilization of High-Risk Level CSPs by Dry Heat]	
15. Dry heat depyrogenation is used to render glassware or containers, such as vials free from pyrogens as well as viable microbes. The description of the dry heat depyrogenation cycle and duration for specific load items is included in written documentation in the compounding facility. The effectiveness of the dry heat depyrogenation cycle is verified using endotoxin challenge vials (ECVs). [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Depyrogenation by Dry Heat]	
16. Sterility testing is completed for all High-risk level CSPs prepared in batches of more than 25 identical containers, or exposed longer than 12 hours at 2° to 8°, and 6 hours at warmer than 8° before being sterilized. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Sterility Testing]	

USP <71> STERILITY TESTING (Outsourced)

17. Outsourced sterility testing results indicate that it is compliant with USP<71>. A method not described in the USP may be used if validation demonstrates that the alternative is at least as effective and reliable. [STERILITY TEST USP<71>]	
18. Outsourced: The number of articles tested are appropriate according to USP<71>. [STERILITY TEST USP<71> : Number of Articles to Be Tested]	
19. Outsourced: The volume/quantity tested is according to USP<71>. [STERILITY TEST USP<71> : Number of Articles to Be Tested]	
20. Outsourced: A USP<71> method suitability test has been done with appropriate inoculum, additives and rinses. [STERILITY TEST USP<71> : Method Suitability Test]	
21. Outsourced: Sterility testing reports are reviewed and appropriate actions taken and documented. [FINISHED PREPARATION RELEASE CHECKS AND TESTS]	

USP <71> STERILITY TESTING

22. On site: Membrane filtration is used if appropriate. (The technique of membrane filtration is used whenever the nature of the product permits; that is, for filterable aqueous preparations, for alcoholic or oily preparations, and for preparations miscible with, or soluble in, aqueous or oily solvents, provided these solvents do not have an antimicrobial effect in the conditions of the test.) Filters are rinsed according to USP<71>. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Sterility Testing]	
23. On site: Direct inoculation is done only when membrane filtration cannot be carried out. Volume to be inoculated does not exceed 10% of the culture media volume. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Sterility Testing]	
24. On site: The number of articles tested are appropriate according to USP<71>. [STERILITY TEST USP<71> : Number of Articles to Be Tested]	
25. On site: The volume/quantity tested is according to USP<71>. [STERILITY TEST USP<71> : Number of Articles to Be Tested]	

26. On site: A growth promotion test has been done on the media with the 5 specified organisms (not more than 100 CFU) according to USP<71>. [STERILITY TEST USP<71> : Growth Promotion Test of Aerobes, Anaerobes, and Fungi]	
27. On site: A USP<71> method suitability test has been done with appropriate inoculum, additives and rinses. [STERILITY TEST USP<71> : Method Suitability Test]	
28. On site: TSB or SCD is incubated at 20-25 C for 14 days (2 incubators present). [STERILITY TEST USP<71> : Culture Media and Incubation Temperatures]	
29. On site: FTM is incubated at 30-35 C for 14 days (2 incubators present). [STERILITY TEST USP<71> : Culture Media and Incubation Temperatures]	
30. On site: Sterility testing is documented including lot numbers and expiration dates of media. [FINISHED PREPARATION RELEASE CHECKS AND TESTS]	
31. On site: Sterility testing reports are reviewed and appropriate actions taken and documented. [FINISHED PREPARATION RELEASE CHECKS AND TESTS]	

ENDOTOXIN TESTING

32. Endotoxin testing is conducted for High-risk level CSP's that are prepared in batches of more than 25 identical containers, or exposed longer than 12 hours at 2° to 8°, and 6 hours at warmer than 8°, before being sterilized or in multidose containers for administration to multiple patients. (excluding those for inhalation and ophthalmic administration) [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Bacterial Endotoxin (Pyrogen) Testing]	
33. Endotoxin testing process indicates that it is compliant with USP<85>. [BACTERIAL ENDOTOXINS TEST USP<85>]	
34. High Risk CSP's are within allowable limits for bacterial endotoxins. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Bacterial Endotoxin (Pyrogen) Testing]	

IMMEDIATE USE COMPOUNDING

35. Immediate-use compounding complies with all six specified criteria. 1. Low-risk sterile nonhazardous products or diagnostic radiopharmaceutical products from the manufacturers' original containers. Anti-neoplastics shall not be prepared as immediate-use CSPs because they are hazardous drugs. 2. Unless required for the preparation, the compounding procedure is a continuous process not to exceed 1 hour. 3. During preparation, aseptic technique is followed and, if not immediately administered, the finished CSP is under continuous supervision to minimize the potential for contact with nonsterile surfaces, introduction of particulate matter or biological fluids, mix-ups with other CSPs, and direct contact of outside surfaces. 4. Administration begins not later than 1 hour following the start of the preparation of the CSP. 5. Unless immediately and completely administered by the person who prepared it or immediate and complete administration is witnessed by the preparer, the CSP shall bear a label listing patient identification information, the names and amounts of all ingredients, the name or initials of the person who prepared the CSP, and the exact 1-hour BUD and time. 6. If administration has not begun within 1 hour following the start of preparing the CSP, the CSP shall be promptly, properly, and safely discarded. [IMMEDIATE-USE CSPs]	N/A

SINGLE/MULTIPLE DOSE CONTAINER BUD

36. Beyond-use date does not exceed 28 days for multiple-dose containers after initial opening or entry, unless specified otherwise by the manufacturer. [SINGLE-DOSE AND MULTIPLE-DOSE CONTAINERS]	Yes
37. Beyond-use time does not exceed 6 hours for closure sealed single-dose containers in ISO Class 5 or cleaner air after initial opening or entry, unless specified otherwise by the manufacturer. [SINGLE-DOSE AND MULTIPLE-DOSE CONTAINERS]	Yes
38. Beyond-use time does not exceed 1 hour for closure sealed single-dose containers after being opened or entered in worse than ISO Class 5 air. [SINGLE-DOSE AND MULTIPLE-DOSE CONTAINERS]	Yes
39. Single-dose ampules are discarded immediately after use. [SINGLE-DOSE AND MULTIPLE-DOSE CONTAINERS]	N/A

HAZARDOUS DRUGS

40. A pressure indicator is installed and differential pressures are monitored and documented daily for hazardous buffer room. [HAZARDOUS DRUGS AS CSPs]	
41. Hazardous drug buffer room is at least 0.01 inch water column negative pressure with 30 ACPH of HEPA filtered air. [HAZARDOUS DRUGS AS CSPs]	
42. At least 0.01 inch water column negative pressure and 12 air changes per hour in non-cleanrooms in which CACIs are located. FAC: USP Chapter 797 requires that: "When closed-system vial-transfer devices (CSTDs) (i.e., vial-transfer systems that allow no venting or exposure of hazardous substance to the environment) are used, they shall be used within an ISO Class 5 environment of a BSC or CACI. The use of the CSTD is preferred because of their inherent closed system process. In facilities that prepare a low volume of hazardous drugs, the use of two tiers of containment (e.g., CSTD within a BSC or CACI that is located in a non-negative pressure room) is acceptable." For purpose of said provision, a "low volume of hazardous drugs" is defined as less than 40 doses per month. [HAZARDOUS DRUGS AS CSPs]	
43. Personnel compounding hazardous drugs wear appropriate personal protective equipment. [HAZARDOUS DRUGS AS CSPs]	
44. Hazardous drugs are handled with caution at all times using appropriate chemotherapy gloves during receiving, distribution, stocking, inventorying, preparing for administration, and disposal. Spill kits are available. [HAZARDOUS DRUGS AS CSPs]	
45. Hazardous drugs are prepared in an ISO Class 5 environment (BSC or CACI) with protective engineering controls in place, following aseptic practices specified for the appropriate contamination risk levels. [HAZARDOUS DRUGS AS CSPs]	
46. Hazardous drugs are stored separately from other inventory in a manner to prevent contamination and personnel exposure. [HAZARDOUS DRUGS AS CSPs]	
47. Access to hazardous drug preparation areas is limited to authorized compounding personnel. [HAZARDOUS DRUGS AS CSPs]	
48. Annual documentation of hazardous drug training of personnel regarding storage, handling, containment techniques and disposal of hazardous drugs is available. [HAZARDOUS DRUGS AS CSPs]	
49. Compounding personnel of reproductive capability have confirmed in writing that they understand the risks of handling hazardous drugs. [HAZARDOUS DRUGS AS CSPs]	
50. Facility maintains appropriate disposal containers for all hazardous waste. [HAZARDOUS DRUGS AS CSPs]	

FACILITY DESIGN AND CERTIFICATION

51. Certification and testing of primary (LAFWs, BSCs, CAIs and CACIs) and secondary engineering controls (buffer and ante areas) have been performed by a qualified individual no less than every six months and whenever the device or room is relocated, altered, or major service to the facility is performed. Corrective action for deficiencies are documented. Certification procedures such as those outlined in the CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2006) are conducted under dynamic conditions. [ENVIRONMENTAL QUALITY AND CONTROL : Environmental Nonviable Particle Testing Program] *Medical Technology Associates 6.29.16. Your ante room failed CETA guidelines and USP 797 requirements for ACPH which was tested as 12.*	Yes
52. Primary engineering controls provide unidirectional (i.e., laminar) HEPA filtered air. Air pattern analysis via smoke studies are conducted at the critical site to demonstrate unidirectional airflow and sweeping action over and away from the product under dynamic conditions.[ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls] *Medical Technology Associates 6.29.16*	Yes
53. The primary engineering controls are placed within a buffer area in such a manner as to avoid conditions that could adversely affect their operation. The PEC is placed out of the traffic flow and in a manner to avoid disruption from the HVAC system and room cross drafts. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
54. All HEPA filters are leak tested after installation and every six months thereafter. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes

ISOLATORS

55. CAIs are proven to maintain ISO Class 5 air when particle counts are sampled 6 to 12 inches upstream of critical site exposure areas during performance of normal inward and outward transfer of materials, and compounding manipulations when such CAIs are located in air quality worse than ISO Class 7. [ENVIRONMENTAL QUALITY AND CONTROL : Placement of Primary Engineering Controls Within ISO Class 7 Buffer Areas]	
56. Adequate recovery time for isolators to achieve ISO Class 5 air quality is allowed after material transfer before and during compounding operations. [ENVIRONMENTAL QUALITY AND CONTROL : Placement of Primary Engineering Controls Within ISO Class 7 Buffer Areas]	
57. Personnel garbing requirements are followed for CAIs unless manufacturer provides written documentation based on validated testing that any components of PPE are not required to maintain sterility of CSPs. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	

FACILITY DESIGN AND CERTIFICATION (Secondary Engineering Controls)

58. Facility has pressure gauges or velocity meters to monitor the pressure differential or airflow between the buffer area and ante-area, and the ante-area and the general environment outside the compounding area. The results are reviewed and documented on a log at least daily or by a continuous recording device. The pressures differentials meet or exceed 5 Pa (0.02 inch water column (w.c.)). Alternatively, in facilities where low- and medium-risk level CSPs are prepared, differential airflow is maintained at a minimum velocity of 0.2 meter/second (40 fpm) across a line of demarcation between buffer area and ante-area. [ENVIRONMENTAL QUALITY AND CONTROL : Pressure Differential Monitoring] *The area between the ante room and buffer room is below acceptable level and reads 0.005. Your differential logs show consistent acceptable levels but one of your swing doors between the two rooms is broken. This needs to be fixed ASAP.*	No
59. Clean rooms for nonhazardous and nonradioactive CSPs are supplied with HEPA filtered air that enters from ceilings with return vents low on walls, and that provides not less than 30 air changes per hour or qualifies for exception in 64B16-27.797(4)(c). [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
60. Activities and tasks carried out within the buffer area are limited to only those necessary when working within a controlled environment. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
61. Only the furniture, equipment, supplies, and other material required for the compounding activities to be performed are brought into the buffer room. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
62. Surfaces and essential furniture in buffer rooms or zones and clean rooms are nonporous, smooth, non-shedding, impermeable, cleanable, and resistant to disinfectants. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
63. The surfaces of ceilings, walls, floors, fixtures, shelving, counters, and cabinets in the buffer area are smooth, impervious, free from cracks and crevices, and non-shedding, thereby promoting cleanability, and minimizing spaces in which microorganisms and other contaminants may accumulate. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
64. Ceiling tiles are caulked around each perimeter and to walls to seal them to the support frame. The exterior lens surface of ceiling lighting fixtures is smooth, mounted flush, and sealed. All other penetrations through the ceiling or walls are sealed. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
65. The buffer area does not contain sources of water (sinks) or floor drains. Work surfaces are constructed of smooth, impervious materials, such as stainless steel or molded plastic, so that they are easily cleaned and disinfected. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
66. Storage shelving, counters, cabinets and carts/casters in the buffer area are smooth, impervious, free from cracks and crevices, non-shedding, non-porous, cleanable, and disinfectable. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
67. When devices (e.g., computers and printers) and objects (e.g., carts and cabinets) are placed in buffer areas, air quality is verified by particle counts on certification. [ENVIRONMENTAL QUALITY AND CONTROL : ISO Class 5 Air Sources, Buffer Areas, and Ante-Areas]	N/A

QUALITY AND CONTROL

68. An appropriate environmental sampling plan has been developed for airborne viable particles based on a risk assessment of compounding activities performed. Volumetric air sampling is conducted every six months and sites include locations within each ISO Class 5 environment and in the ISO Class 7 and 8 areas, and the areas at greatest risk of contamination (e.g., work areas near the ISO Class 5 environment, counters near doors, pass-through boxes). The plan includes sample locations, method of collection, frequency of sampling, volume of air sampled, and time of day as related to activity in the compounding area and action levels. [ENVIRONMENTAL QUALITY AND CONTROL : Environmental Viable Airborne Particle Testing Program—Sampling Plan] *You do not have a ESP that includes air or surface sampling. Your plan needs to include method of air sampling (impaction), frequency of sampling, locations and time of day, This was a deficiency on your last inspection. A Corrective action plan shall be submitted within 30 days.*	No
69. Evaluation of airborne microorganisms using volumetric collection methods in the controlled air environments is performed by properly trained individuals for all compounding risk levels. [ENVIRONMENTAL QUALITY AND CONTROL : Viable Air Sampling]	Yes
70. Volumetric air sampling using malt extract agar (MEA) or some other media that supports the growth of fungi is used in high-risk level compounding environments. [ENVIRONMENTAL QUALITY AND CONTROL : Growth Media]	N/A
71. For low-risk level CSPs with 12-hour or less BUD, air sampling is performed at locations inside the ISO Class 5 environment and other areas that are in close proximity to the ISO class 5 environment. [ENVIRONMENTAL QUALITY AND CONTROL : Viable Air Sampling]	N/A
72. The number of discrete colonies of microorganisms is counted and reported as colony-forming units (cfu) and documented on an environmental monitoring form. Counts from air monitoring are transformed into cfu/cubic meter of air and evaluated for adverse trends. [ENVIRONMENTAL QUALITY AND CONTROL : Incubation Period] *yes but, this is documented by MTA*	Yes

73. Surface sampling is accomplished in all ISO classified areas on a periodic basis using TSA contact plates with lecithin and polysorbate 80 and/or swabs and is done at the conclusion of compounding. [ENVIRONMENTAL QUALITY AND CONTROL : Surface Cleaning and Disinfection Sampling and Assessment] *Yes but this needs to be added to you ESP.*	Yes
74. Sampling data is collected and reviewed on a periodic basis as a means of evaluating the overall state of control of the compounding environment. [ENVIRONMENTAL QUALITY AND CONTROL : Action Levels, Documentation and Data Evaluation]	Yes
75. Competent microbiology personnel are consulted if an environmental sampling consistently shows elevated levels of microbial growth. If any mold, yeast, coagulase positive staphylococcus, or gram negative rods are detected immediate remediation and investigation into the cause and source was conducted. [ENVIRONMENTAL QUALITY AND CONTROL : Action Levels, Documentation and Data Evaluation]	N/A
76. Surfaces in the LAFWs, BSCs, CAIs, and CACIs are cleaned and disinfected frequently, including at the beginning of each work shift, before each batch preparation is started, every 30 minutes during continuous compounding periods of individual CSPs, when there are spills, and when surface contamination is known or suspected from procedural breaches. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas] *Inspector observed AG begin preparation of a TPN without spraying and wiping DCA.*	No
77. Cleaning and disinfecting occurs before compounding is performed. Items are removed from all areas to be cleaned, and surfaces are cleaned by removing loose material and residue from spills, e.g., water-soluble solid residues are removed with Sterile Water and low-shedding wipes. This shall be followed by wiping with a residue-free disinfecting agent, such as sterile 70% IPA, which is allowed to dry before compounding begins. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas] *Inspector observed technician AG fail to wipe DCA with sIPA before working in hood. KP explained to inspector how to clean and disinfect PEC"s and did not explain cleaning and disinfecting the backs of the 3 hoods.*	No
78. Cleaning and disinfecting agents and methods of application are in accordance with written SOPs and followed by custodial and/or compounding personnel. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas] *You state you rotate your cleaning products biweekly but it is not stated in your Policies and procedures*	No
79. Cleaning materials, such as wipes, sponges, and mops, are non-shedding, preferably composed of synthetic micro fibers, and dedicated to use in the buffer area, ante-area, and segregated compounding areas and are not removed from these areas except for disposal. If cleaning materials are reused (e.g., mops), there are procedures based on manufacturer recommendations that ensure that the effectiveness of the cleaning device is maintained and repeated use does not add to the bioburden of the area being cleaned. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
80. Supplies and equipment removed from shipping cartons are wiped with a suitable disinfecting agent (e.g., sterile 70% IPA). [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas] *Inspector observed technician KP receive item in anteroom from rx area, spray with sIPA and then transfer item to buffer room without wiping with lint free cloth or sIPA pads.*	No
81. Disinfectant sprayed or wiped on a surface to be disinfected is allowed to dry, and during this time the item is not be used for compounding purposes. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas] *Inspector observed technician KP fail to spray DCA with sIPA before assembling TPN.*	No
82. Sterile 70% IPA pads are used to disinfect the sterile entry points of packages and devices. Wetted gauze pads or other particle-generating material are not appropriate. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes

QUALITY AND CONTROL (Secondary Engineering Controls)

83. Work surfaces in ISO Class 7 and 8 areas and segregated compounding areas are cleaned at least daily. IPA (70% isopropyl alcohol) remains on surfaces to be disinfected for at least 30 seconds before such surfaces are used to prepare CSPs. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
84. Floors in ISO Class 7 and 8 areas are mopped daily by trained personnel at a time when no aseptic operations are in progress using approved agents and procedures described in written SOP's. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
85. Shelving, walls, and ceilings in ante-areas and buffer areas are cleaned and disinfected at least monthly. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas] *Your cleaning logs show there was no monthly cleaning documented for the months of may and June*	No

PERSONNEL CLEANSING, GARBING & COMPETENCY EVALUATION

86. Personnel preparing CSP's are free from rashes, sunburn, weeping sores, conjunctivitis, and active respiratory infections. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	Yes
87. Compounding personnel remove personal outer garments; cosmetics; artificial nails; hand, wrist, and body jewelry that can interfere with the fit of gowns and gloves; and visible body piercing above the neck. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	Yes
88. Facility has adequate supplies to meet PPE requirements of USP<797>. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing] *you need to have persistent activity alcohol in your buffer room..*	No
89. Garbing and hand hygiene are accomplished in the ante-area in order of dirtiest to cleanest: shoes or shoe covers, head and facial hair covers, face mask, fingernail cleansing, hand and forearm washing and drying; non-shedding gown. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	Yes
90. Sterile gloves are donned in the buffer room/isolator after hand cleansing with an alcohol-based product with persistent activity and hands are allowed to dry. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing] *You need to be using persistent activity alcohol in your buffer room.*	No
91. Gloves are routinely disinfected with sterile 70% IPA after contacting nonsterile objects. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	Yes
92. Personnel repeat garbing and hand hygiene after they are exposed to direct contact contamination or worse than ISO Class 8 air. Gowns may be hung in the anteroom and reused during the same workshift. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	Yes
93. Low/Medium Risk media-fill tests that closely simulate the most challenging or stressful conditions encountered during compounding are completed at least annually by compounding personnel. Media-filled vials are appropriately incubated for 14 days. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Medium-Risk Level CSPs]	Yes
94. High Risk Media-fill tests that closely simulate the most challenging or stressful conditions encountered during compounding have been completed at least semiannually by compounding personnel. Media-filled vials are appropriately incubated for 14 days. [CSP MICROBIAL CONTAMINATION RISK LEVELS : High-Risk Level CSPs]	N/A

95. Documentation indicates compounding personnel have successfully completed didactic training, passed written competency assessments, undergone skill assessment using observational audit tools (hand hygiene, garbing, aseptic technique) and media-fill testing annually or semiannually (high risk) and before any compounding personnel begin to prepare CSPs . [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures] *Technician AG has signed all of her observational assessments has not been completed . WG is almost two years late on HH and garbing and Cleaning and disinfecting technique observations. WG has none of his observational skills completed.*	No
96. Compounding personnel who fail written tests, observational audits, or whose media-fill test vials have one or more units showing visible microbial contamination, are reinstructed and re-evaluated by expert compounding personnel to ensure correction of all aseptic work practice deficiencies. Corrective action is documented. Compounding personnel pass all evaluations prior to resuming compounding of sterile preparations. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures]	Yes
97. Other cleaning personnel performing cleaning and disinfecting procedures (e.g. environmental) are thoroughly trained in proper hand hygiene, and garbing, cleaning, and disinfection procedures by a qualified aseptic compounding expert. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures]	N/A
98. Compounding personnel and other personnel responsible for cleaning routinely undergo performance evaluation of proper hand hygiene, garbing, and all applicable cleaning and disinfecting procedures conducted by a qualified aseptic compounding expert. Visual observation of hand hygiene, garbing and cleaning is documented and maintained to provide a permanent record and long-term assessment of personnel competency. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures] *See #95*	No
99. Immediately after the compounder completes the hand hygiene and garbing procedure, the evaluator collects a gloved fingertip and thumb sample from both hands of the compounder onto appropriate agar plates. The plates are incubated at 30-35° for 2–3 days. All compounding personnel have successfully completed an initial competency evaluation and gloved fingertip/thumb sampling procedure (0 cfu) no less than three times before initially being allowed to compound CSPs for human use. [ENVIRONMENTAL QUALITY AND CONTROL : Gloved Fingertip Sampling] *Your evaluation forms do not include the dates for observations and your GFS forms need to include which hands are being sampled.*	No
100. Re-evaluation of glove fingertip testing onto appropriate agar plates (Trypticase soy agar (TSA) with lecithin and polysorbate 80) for all compounding personnel occurs at least annually for low- and medium-risk level CSPs and semiannually for high-risk level CSPs before being allowed to continue compounding CSPs. Gloves shall not be disinfected with sterile 70% IPA prior to testing. The cfu action level is based on the total number of cfu on both gloves and not per hand. [ENVIRONMENTAL QUALITY AND CONTROL : Gloved Fingertip Sampling]	Yes

VERIFICATION

101. Labels of CSPs contain name and address of pharmacy, correct names and amounts or concentrations of ingredients, total volumes, beyond-use dates, storage conditions, and route(s) of administration. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Identity and Strength Verification of Ingredients]	Yes
102. Facility has documentation that procedures have been followed to ensure sterility, purity, correct identities and amounts of ingredients, and stability. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Inspection of Solution Dosage Forms and Review of Compounding Procedures]	Yes
103. CSP's are visually inspected for abnormal particulate matter and color, and intact containers and seals. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Inspection of Solution Dosage Forms and Review of Compounding Procedures]	Yes
104. Beyond Use Dates are assigned using direct stability-indicating assays or authoritative literature that supports the assigned BUD. [STORAGE AND BEYOND-USE DATING : Determining Beyond-Use Dates]	Yes
105. Storage time of assembled bag and vial systems are according to the manufacturer recommendations. (eg Minibag plus, Addvantage, Add-ease) [STORAGE AND BEYOND-USE DATING : Proprietary Bag and Vial Systems]	Yes

DISPENSING/DISTRIBUTION

106. Facility has written procedures for proper packaging, storage, and transportation conditions to maintain sterility, quality, purity, and strength of CSPs. [MAINTAINING STERILITY, PURITY, AND STABILITY OF DISPENSED AND DISTRIBUTED CSPs :]	N/A
107. Modes of transport are used that maintain appropriate temperatures and prevent damage to CSPs. [MAINTAINING STERILITY, PURITY, AND STABILITY OF DISPENSED AND DISTRIBUTED CSPs : Packaging and Transporting CSPs]	N/A
108. Facility provides a multiple component formal training program to ensure patients and caregivers understand the proper storage, handling, use, and disposal of CSPs. [PATIENT OR CAREGIVER TRAINING]	Yes

POLICY/PROCEDURE

109. Written procedures detail cleaning and disinfecting the sterile compounding areas including cleansers, disinfectants, and non-shedding wipe and mop materials. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas] *Yes but your SOP needs to include the cleaning products you use, how often you rotate your cleaning agents , and how much you mix.*	Yes
110. A written procedure is in place for cleaning and disinfecting the Direct Compounding Areas. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
111. Facility has written procedures to verify correct identity, quality, amounts, and purities of ingredients used in CSPs. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Identity and Strength Verification of Ingredients]	Yes
112. Policies address packaging to maintain physical integrity, sterility, stability, and purity of CSPs. [MAINTAINING STERILITY, PURITY, AND STABILITY OF DISPENSED AND DISTRIBUTED CSPs : Packaging and Transporting CSPs]	Yes
113. Written standard procedures describe means for patients to ask questions and report concerns and adverse events with CSPs, and for compounding pharmacists to correct and prevent future problems. [PATIENT MONITORING AND ADVERSE EVENTS REPORTING]	Yes

RADIOPHARMACEUTICALS

114. Facility has appropriate primary engineering controls and radioactivity containment and shielding. Location of primary engineering controls permitted in ISO Class 8 controlled environment. [RADIOPHARMACEUTICALS AS CSPs]	
115. Radiopharmaceuticals prepared as low-risk level CSPs with 12-hour or less BUD are prepared in a segregated compounding area. Segregated compounding area is designated with a line of demarcation. [RADIOPHARMACEUTICALS AS CSPs]	
116. Technetium-99m/Molybdenum-99 generators are eluted in ISO Class 8 conditions. [RADIOPHARMACEUTICALS AS CSPs]	

MISCELLANEOUS

117. Facility engaged in office use sterile compounding for human use is registered with FDA as an outsourcing facility. [FAC 64B16-27.700 (3)(g]	N/A
118. Compounding records are properly maintained. [FAC 64B16-28.140(4)]	Yes

119. When compounding activities require the manipulation of a patient's blood-derived or other biological material, the manipulations are clearly separated from routine material-handling procedures and equipment used in CSP preparation activities, and they are controlled by specific standard operating procedures in order to avoid any cross-contamination. [ENVIRONMENTAL QUALITY AND CONTROL : Placement of Primary Engineering Controls Within ISO Class 7 Buffer Areas]	N/A

SPECIAL PARENTERAL ENTERAL & EXTENDED SCOPE

120. Pharmacy technicians properly identified and supervised. [64B16-27.420, F.A.C.]	
121. Medication properly labeled. [465.0255, F.S.] [64B16-28.108, F.A.C.]	
122. Expired medications removed from the shelves. [64B16-28.110, F.A.C.]	
123. CQI Policy and Procedures and quarterly meetings. [766.101, F.S.] [64B16-27.300, F.A.C.]	
124. Prescriptions have the date dispensed and dispensing pharmacists. [893.04(1)(c) 6, F.S.] [64B16-28.140(3)(b), F.A.C.]	
125. Pharmacy maintains patient profile records. [64B16-27.800, F.A.C.]	
126. All controlled substance prescriptions contain information required. [893.04, F.S.]	
127. Prescriptions for controlled substances are on counterfeit-proof prescription pads or blanks purchased from a Department-approved vendor and the quantity and date meet the requirements of [456.42(2), F.S.].	
128. Controlled substance inventory taken on a biennial basis and available for inspection. [893.07(1)(a), F.S.]	
129. DEA 222 order forms properly completed. [893.07, F.S.]	
130. Controlled substance records and Rx information in computer system is retrievable. [21CFR 1306.22] [64B16-28.140, F.A.C.]	
131. Controlled substance records maintained for 4 years. [465.022(12)(b), F.S.]	
132. Certified daily log OR printout maintained. [21CFR 1306.22(b)(3)] [64B16-28.140(3)(b), F.A.C.]	
133. Pharmacy is reporting to the PDMP within 7 days of dispensing controlled substance. [893.055(4), F.S.]	
134. Pharmacy maintains invoices documenting that medicinal drugs were obtained from a Florida licensed distributor. 499.005 (14)	

Remarks:

This inspection occurred on 8.1.16. A corrective action plan is required for all deficiencies. Submit to inspector within 30 days of this inspection 9.1.16.

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge. I have received a copy of the Licensee Bill of Rights.

Investigator/Sr. Pharmacist Signature:

SHIHADEH, MONICA

M Shihadeh

Date:8/1/2016

Representative:

Enrique Hernandez

Date:8/1/2016

STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES
INV797-Sterile Compounding

File # 21072
Insp # 132001

NAME	PERMIT NUMBER	DATE OF INSPECTION
AMBIENT HEALTHCARE OF S. FLORIDA, INC	27913	08/07/2015
DOING BUSINESS AS		
AMBIENT HEALTHCARE OF S. FLORIDA, INC		
STREET ADDRESS	**TELEPHONE #**	**EXT**
15951 SW 41ST ST SUITE 500	954-389-1126	
CITY	**COUNTY**	**STATE/ZIP**
DAVIE	BROWARD	FL/33331

Additional Information

Business Operation Hours

M-T-W-TH-F Y	Weekly Hours 8:30 am to 5:30
Monday N	Monday Hours
Tuesday N	Tuesday Hours
Wednesday N	Wednesday Hours
Thursday N	Thursday Hours
Friday N	Friday Hours
Saturday N	Saturday Hours
Sunday N	Sunday Hours

Registered Pharmacist / Intern / Tech

License # PS49270	Licensee Name Shirley Elisbrun
License Type Registered Pharmacists	
License # PS36287	Licensee Name Vincent Ekebu
License Type Registered Pharmacists	
License # PS52096	Licensee Name Jacqueline Rodriguez
License Type Registered Pharmacists	
License # PS21110	Licensee Name Manuela Vega-Rivera
License Type Registered Pharmacists	
License # PS24556	Licensee Name Karen Hitchen
License Type Registered Pharmacists	

ACS Manager

Optional Information

Basic License Data - PSD

DEA Reg # BA7935490	

License Relations

Pharmacy Affiliate

ADLER, IAN	License #
BRONSON, DAVID	License #
DEBLASI, PAIGE	License #
FRENI, LAWRENCE	License #
KLEINMAN, IRA	License #
KRAMM, EDWARD P	License #
KRAMM, KATHEE M	License #

WILKINS, JOHN	License #
YORK, CHRISTOPHER	License #

RX DPT MGR/COR/POR

ELISBRUN, SHIRLEY	License # 49270

Special Sterile Compounding

AMBIENT HEALTHCARE OF S. FLORIDA, INC	License # 18740

INV797 - Sterile Compounding

LOW RISK

1. Low risk CSP's are properly identified: Aseptic manipulations within an ISO Class 5 environment using three or fewer sterile products and no more than two entries into any container. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Low-Risk Level CSPs]	Yes
2. Low Risk CSP's, in absence of passing sterility test, stored not more than 48 hours at controlled room temperature, 14 days at cold temperature, or 45 days in solid frozen state at -25° to -10° or colder. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Low-Risk Level CSPs]	Yes
3. Low Risk media-fill tests are completed at least annually by compounding personnel. Media-filled vials are appropriately incubated for 14 days. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Low-Risk Level CSPs] *3 employees are late on media fills. Please get them done ASAP and send to inspector*	No
4. Low Risk CSP's with 12 hour BUD are properly identified and comply with all four specific criteria. 1. PEC in Segregated Compounding area 2. Away from windows, doors , high traffic areas 3. Hygiene & garbing required, sinks not adjacent to PEC. 4. Cleaning & Disinfecting, Personnel training, Competency evaluation, Garbing, Aseptic work practices, Viable and non-viable environmental sampling apply. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Low-Risk Level CSPs]	N/A

MEDIUM RISK

5. Medium Risk CSP's are properly identified: Aseptic manipulations within an ISO Class 5 environment using prolonged and complex mixing and transfer, more than three sterile products and entries into any container, and pooling ingredients from multiple sterile products to prepare multiple CSPs. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Medium-Risk Level CSPs]	Yes
6. Medium Risk CSP's, In absence of passing sterility test, stored not more than 30 hours at controlled room temperature, 9 days at cold temperature, or 45 days in solid frozen state at -25° to -10° or colder. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Medium-Risk Level CSPs]	Yes
7. Medium Risk media-fill tests are completed at least annually by compounding personnel. Media-filled vials are appropriately incubated for 14 days. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Medium-Risk Level CSPs]	No

HIGH RISK

8. High Risk CSP's are properly identified: Confirmed presence of nonsterile ingredients and devices, or confirmed or suspected exposure of sterile ingredients for more than one hour to air quality inferior to ISO Class 5 before final sterilization. [CSP MICROBIAL CONTAMINATION RISK LEVELS : High-Risk Level CSPs]	
9. High Risk CSP's, in absence of passing sterility test are not stored more than 24 hours at controlled room temperature, 3 days at cold temperature, or 45 days in solid frozen state at -25° to -10° or colder. [CSP MICROBIAL CONTAMINATION RISK LEVELS : High-Risk Level CSPs]	
10. High Risk Media-fill tests have been completed at least semiannually by compounding personnel. Media-filled vials are appropriately incubated for 14 days. [CSP MICROBIAL CONTAMINATION RISK LEVELS : High-Risk Level CSPs]	
11. A 0.2-µm certified sterilizing membrane filter is used that is chemically and physically compatible with the CSP. Filtration is completed rapidly without filter replacement. Sterilization method is verified to achieve sterility for the quantity and type of containers. [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Sterilization of High-Risk Level CSPs by Filtration]	
12. Outsourced endotoxin testing results indicate that it is compliant with USP<85>. [BACTERIAL ENDOTOXINS TEST USP<85>]	
13. Is a USP<85> Endotoxin testing done on site? [BACTERIAL ENDOTOXINS TEST USP<85>]	
14. Endotoxin testing method is compliant? Indicate: Gel clot, chromogenic or turbidimetric? [BACTERIAL ENDOTOXINS TEST USP<85>]	
15. High Risk CSP's are within allowable limits for bacterial endotoxins. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Bacterial Endotoxin (Pyrogen) Testing]	
16. Sterilization method used has documentation that acceptable strength and purity of ingredients and integrity of containers is maintained. [CSP MICROBIAL CONTAMINATION RISK LEVELS : High-Risk Level CSPs]	
17. The manufacturer recommended filter integrity (e.g., bubble point) test is performed and documented for all sterilizing filters after filtering CSPs. [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Sterilization of High-Risk Level CSPs by Filtration]	
18. Autoclave cycle has been verified using appropriate biological indicators. Solutions are passed through a 1.2-µm or smaller filter into final containers to remove particulates before sterilization. [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Sterilization of High-Risk Level CSPs by Steam]	
19. Dry heat ovens used for sterilization have filtered forced air. Only those items that will be damaged by steam are sterilized by dry heat. [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Sterilization of High-Risk Level CSPs by Dry Heat]	
20. The description of dry heat sterilization conditions and duration for specific CSPs is included in written documentation in the compounding facility. The effectiveness of dry heat sterilization is verified using appropriate biological indicators and other confirmation. [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Sterilization of High-Risk Level CSPs by Dry Heat]	
21. Dry heat depyrogenation is used to render glassware or containers, such as vials free from pyrogens as well as viable microbes. The description of the dry heat depyrogenation cycle and duration for specific load items is included in written documentation in the compounding facility. The effectiveness of the dry heat depyrogenation cycle is verified using endotoxin challenge vials (ECVs). [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Depyrogenation by Dry Heat]	
22. Presterilization procedures for high-risk level CSPs, such as weighing and mixing, are completed in no worse than an ISO Class 8 environment. [ENVIRONMENTAL QUALITY AND CONTROL : Placement of Primary Engineering Controls Within ISO Class 7 Buffer Areas]	

23. Sterility testing is completed for all High-risk level CSPs prepared in batches of more than 25 identical containers, or exposed longer than 12 hours at 2° to 8°, and 6 hours at warmer than 8° before being sterilized. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Sterility Testing]	
24. Endotoxin testing is conducted for High-risk level CSP's that are prepared in batches of more than 25 identical containers, or exposed longer than 12 hours at 2° to 8°, and 6 hours at warmer than 8°, before being sterilized or in multidose containers for administration to multiple patients. (excluding those for inhalation and ophthalmic administration) [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Bacterial Endotoxin (Pyrogen) Testing]	

IMMEDIATE USE COMPOUNDING

25. Immediate-use compounding complies with all six specified criteria. 1. Low-risk sterile nonhazardous products or diagnostic radiopharmaceutical products from the manufacturers' original containers. Anti-neoplastics shall not be prepared as immediate-use CSPs because they are hazardous drugs. 2. Unless required for the preparation, the compounding procedure is a continuous process not to exceed 1 hour. 3. During preparation, aseptic technique is followed and, if not immediately administered, the finished CSP is under continuous supervision to minimize the potential for contact with nonsterile surfaces, introduction of particulate matter or biological fluids, mix-ups with other CSPs, and direct contact of outside surfaces. 4. Administration begins not later than 1 hour following the start of the preparation of the CSP. 5. Unless immediately and completely administered by the person who prepared it or immediate and complete administration is witnessed by the preparer, the CSP shall bear a label listing patient identification information, the names and amounts of all ingredients, the name or initials of the person who prepared the CSP, and the exact 1-hour BUD and time. 6. If administration has not begun within 1 hour following the start of preparing the CSP, the CSP shall be promptly, properly, and safely discarded. [IMMEDIATE-USE CSPs]	N/A

SINGLE/MULTIPLE DOSE CONTAINER BUD

26. Beyond-use date does not exceed 28 days for multiple-dose containers after initial opening or entry, unless specified otherwise by the manufacturer. [SINGLE-DOSE AND MULTIPLE-DOSE CONTAINERS]	Yes
27. Beyond-use time does not exceed 6 hours for closure sealed single-dose containers in ISO Class 5 or cleaner air after initial opening or entry, unless specified otherwise by the manufacturer. [SINGLE-DOSE AND MULTIPLE-DOSE CONTAINERS]	Yes
28. Beyond-use time does not exceed 1 hour for closure sealed single-dose containers after being opened or entered in worse than ISO Class 5 air. [SINGLE-DOSE AND MULTIPLE-DOSE CONTAINERS]	N/A
29. Single-dose ampules are discarded immediately after use. [SINGLE-DOSE AND MULTIPLE-DOSE CONTAINERS]	Yes

HAZARDOUS DRUGS

30. Hazardous drug buffer room is at least 0.01 inch water column negative pressure with 30 ACPH of HEPA filtered air. [HAZARDOUS DRUGS AS CSPs]	
31. Personnel compounding hazardous drugs wear appropriate personal protective equipment. [HAZARDOUS DRUGS AS CSPs]	
32. Appropriate primary engineering controls (BSCs and CACIs) are used for concurrent personnel protection and exposure of critical sites. [HAZARDOUS DRUGS AS CSPs]	
33. Hazardous drugs are stored separately from other inventory in a manner to prevent contamination and personnel exposure. [HAZARDOUS DRUGS AS CSPs]	
34 .At least 0.01 inch water column negative pressure and 12 air changes per hour in non-cleanrooms in which CACIs are located. FAC: USP Chapter 797 requires that: "When closed-system vial-transfer devices (CSTDs) (i.e., vial-transfer systems that allow no venting or exposure of hazardous substance to the environment) are used, they shall be used within an ISO Class 5 environment of a BSC or CACI. The use of the CSTD is preferred because of their inherent closed system process. In facilities that prepare a low volume of hazardous drugs, the use of two tiers of containment (e.g., CSTD within a BSC or CACI that is located in a non-negative pressure room) is acceptable." For purpose of said provision, a "low volume of hazardous drugs" is defined as less than 40 doses per month. [HAZARDOUS DRUGS AS CSPs]	
35. Hazardous drugs are handled with caution at all times using appropriate chemotherapy gloves during receiving, distribution, stocking, inventorying, preparing for administration, and disposal. Spill kits are available. [HAZARDOUS DRUGS AS CSPs]	
36. Hazardous drugs are prepared in an ISO Class 5 environment with protective engineering controls in place, following aseptic practices specified for the appropriate contamination risk levels. [HAZARDOUS DRUGS AS CSPs]	
37. Access to hazardous drug preparation areas is limited to authorized compounding personnel. [HAZARDOUS DRUGS AS CSPs]	
38. A pressure indicator is installed and differential pressures are monitored and documented daily for hazardous buffer room. [HAZARDOUS DRUGS AS CSPs]	
39. Annual documentation of hazardous drug training of personnel regarding storage, handling, containment techniques and disposal of hazardous drugs is available. [HAZARDOUS DRUGS AS CSPs]	
40. Compounding personnel of reproductive capability have confirmed in writing that they understand the risks of handling hazardous drugs. [HAZARDOUS DRUGS AS CSPs]	
41. Facility maintains appropriate disposal containers for all hazardous waste. [HAZARDOUS DRUGS AS CSPs]	

RADIOPHARMACEUTICALS

42. Facility has appropriate primary engineering controls and radioactivity containment and shielding. Location of primary engineering controls permitted in ISO Class 8 controlled environment. [RADIOPHARMACEUTICALS AS CSPs]	
43. Radiopharmaceuticals prepared as low-risk level CSPs with 12-hour or less BUD are prepared in a segregated compounding area. Segregated compounding area is designated with a line of demarcation. [RADIOPHARMACEUTICALS AS CSPs]	
44. Technetium-99m/Molybdenum-99 generators are eluted in ISO Class 8 conditions. [RADIOPHARMACEUTICALS AS CSPs]	
45. When compounding activities require the manipulation of a patient's blood-derived or other biological material (e.g., radiolabeling a patient's or a donor's white blood cells), the manipulations are clearly separated from routine material-handling procedures and equipment used in CSP preparation activities, and they are controlled by specific standard operating procedures in order to avoid any cross-contamination. [ENVIRONMENTAL QUALITY AND CONTROL : Placement of Primary Engineering Controls Within ISO Class 7 Buffer Areas]	

FACILITY DESIGN AND CERTIFICATION

46. Certification and testing of primary (LAFWs, BSCs, CAIs and CACIs) and secondary engineering controls (buffer and ante areas) have been performed by a qualified individual no less than every six months and whenever the device or room is relocated, altered, or major service to the facility is performed. Corrective action for deficiencies are documented. Certification procedures such as those outlined in the CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2006) are conducted under dynamic conditions. [ENVIRONMENTAL QUALITY AND CONTROL : Environmental Nonviable Particle Testing Program] *MTA certified ISO 8 Ante room; ISO 7 Buffer room 2 LAFW. At the time the Ante room and Buffer were not meeting the minimum pressure differentials. An air balancer was consulted and the pressure in the Ante room is now +.03"WC. The Buffer room is not maintaining pressure and this MUST be addressed and corrected ASAP*	Yes
47. Facility has pressure gauges or velocity meters to monitor the pressure differential or airflow between the buffer area and ante-area, and the ante-area and the general environment outside the compounding area. The results are reviewed and documented on a log at least daily or by a continuous recording device. The pressures differentials meet or exceed 5 Pa (0.02 inch water column (w.c.)). Alternatively, in facilities where low- and medium-risk level CSPs are prepared, differential airflow is maintained at a minimum velocity of 0.2 meter/second (40 fpm) across a line of demarcation between buffer area and ante-area. [ENVIRONMENTAL QUALITY AND CONTROL : Pressure Differential Monitoring] *The pressure differential between the Buffer room and Ante room is insufficient. An air balancer was consulted after the June certification but the room is currently at .005"wc which fails to meet the requirement. This needs to be corrected ASAP and the documentation sent to inspector.*	No
48. Primary engineering controls provide unidirectional (i.e., laminar) HEPA air at a velocity sufficient to prevent airborne particles from contacting critical sites. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
49. Air pattern analysis via smoke studies are conducted at the critical site to demonstrate unidirectional airflow and sweeping action over and away from the product under dynamic conditions. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
50. Clean rooms for nonhazardous and nonradioactive CSPs are supplied with HEPA filtered air that enters from ceilings with return vents low on walls, and that provides not less than 30 air changes per hour. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
51. The primary engineering controls are placed within a buffer area in such a manner as to avoid conditions that could adversely affect their operation. The PEC is placed out of the traffic flow and in a manner to avoid disruption from the HVAC system and room cross drafts. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
52. Primary engineering controls for nonhazardous and nonradioactive CSPs are located in buffer areas, except for CAIs that are proven to maintain ISO Class 5 air when particle counts are sampled 6 to 12 inches upstream of critical site exposure areas during performance of normal inward and outward transfer of materials, and compounding manipulations when such CAIs are located in air quality worse than ISO Class 7. [ENVIRONMENTAL QUALITY AND CONTROL : Placement of Primary Engineering Controls Within ISO Class 7 Buffer Areas]	Yes
53. Adequate recovery time for isolators to achieve ISO Class 5 air quality is allowed after material transfer before and during compounding operations. [ENVIRONMENTAL QUALITY AND CONTROL : Placement of Primary Engineering Controls Within ISO Class 7 Buffer Areas]	N/A
54. All HEPA filters are leak tested after installation and every six months thereafter. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
55. Activities and tasks carried out within the buffer area are limited to only those necessary when working within a controlled environment. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
56. Only the furniture, equipment, supplies, and other material required for the compounding activities to be performed are brought into the buffer room. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
57. Surfaces and essential furniture in buffer rooms or zones and clean rooms are nonporous, smooth, non-shedding, impermeable, cleanable, and resistant to disinfectants. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
58. The surfaces of ceilings, walls, floors, fixtures, shelving, counters, and cabinets in the buffer area are smooth, impervious, free from cracks and crevices, and non-shedding, thereby promoting cleanability, and minimizing spaces in which microorganisms and other contaminants may accumulate. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
59. Ceiling tiles are caulked around each perimeter and to walls to seal them to the support frame. The exterior lens surface of ceiling lighting fixtures is smooth, mounted flush, and sealed. All other penetrations through the ceiling or walls are sealed. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
60. The buffer area does not contain sources of water (sinks) or floor drains. Work surfaces are constructed of smooth, impervious materials, such as stainless steel or molded plastic, so that they are easily cleaned and disinfected. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
61. Carts are made of stainless steel wire, or nonporous plastic, or sheet metal construction with good quality, cleanable casters. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
62. Storage shelving, counters, and cabinets in the buffer area are smooth, impervious, free from cracks and crevices, non-shedding, cleanable, and disinfectable. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
63. When devices (e.g., computers and printers) and objects (e.g., carts and cabinets) are placed in buffer areas, air quality is verified by particle counts on certification. [ENVIRONMENTAL QUALITY AND CONTROL : ISO Class 5 Air Sources, Buffer Areas, and Ante-Areas]	Yes

QUALITY AND CONTROL

64. An appropriate environmental sampling plan has been developed for airborne viable particles based on a risk assessment of compounding activities performed. Volumetric air sampling is conducted every six months and sites include locations within each ISO Class 5 environment and in the ISO Class 7 and 8 areas, and the areas at greatest risk of contamination (e.g., work areas near the ISO Class 5 environment, counters near doors, pass-through boxes). The plan includes sample locations, method of collection, frequency of sampling, volume of air sampled, and time of day as related to activity in the compounding area and action levels. [ENVIRONMENTAL QUALITY AND CONTROL : Environmental Viable Airborne Particle Testing Program—Sampling Plan] *Environmental sampling is done by MTA. Passice air is conducted monthly by pharmacy personnel. You need to write an environmental sampling plan that includes the frequency of sampling(Q 6months), method of collection (impaction), locations, and time of day related to compounding activity (operational) and action levels (per USP<797>).*	No
65. Surface sampling is accomplished in all ISO classified areas on a periodic basis using TSA contact plates with lecithin and polysorbate 80 and/or swabs and is done at the conclusion of compounding. [ENVIRONMENTAL QUALITY AND CONTROL : Surface Cleaning and Disinfection Sampling and Assessment]	Yes
66. Evaluation of airborne microorganisms using volumetric collection methods in the controlled air environments is performed by properly trained individuals for all compounding risk levels. [ENVIRONMENTAL QUALITY AND CONTROL : Viable Air Sampling]	Yes
67. Volumetric air sampling using malt extract agar (MEA) or some other media that supports the growth of fungi is used in high-risk level compounding environments. [ENVIRONMENTAL QUALITY AND CONTROL : Growth Media]	N/A
68. For low-risk level CSPs with 12-hour or less BUD, air sampling is performed at locations inside the ISO Class 5 environment and other areas that are in close proximity to the ISO class 5 environment. [ENVIRONMENTAL QUALITY AND CONTROL : Viable Air Sampling]	N/A

69. The number of discrete colonies of microorganisms is counted and reported as colony-forming units (cfu) and documented on an environmental monitoring form. Counts from air monitoring are transformed into cfu/cubic meter of air and evaluated for adverse trends. [ENVIRONMENTAL QUALITY AND CONTROL : Incubation Period] *Monitoring forms are used for passive air plates, please make one of active air results*	No
70. Sampling data is collected and reviewed on a periodic basis as a means of evaluating the overall state of control of the compounding environment. [ENVIRONMENTAL QUALITY AND CONTROL : Action Levels, Documentation and Data Evaluation]	Yes
71. Competent microbiology personnel are consulted if an environmental sampling consistently shows elevated levels of microbial growth. If any mold, yeast, coagulase positive staphylococcus, or gram negative rods are detected immediate remediation and investigation into the cause and source was conducted. [ENVIRONMENTAL QUALITY AND CONTROL : Action Levels, Documentation and Data Evaluation]	N/A
72. Written procedures detail cleaning and disinfecting the sterile compounding areas including cleansers, disinfectants, and non-shedding wipe and mop materials. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas] *You are rotating cleaning solutions, the policy only addresses the bleach and alcohol. Please put in the rotation schedule, products, Vesphene, Sporicidin, and the fmixing instructions and application methods*	No
73. Surfaces in the LAFWs, BSCs, CAIs, and CACIs are cleaned and disinfected frequently, including at the beginning of each work shift, before each batch preparation is started, every 30 minutes during continuous compounding periods of individual CSPs, when there are spills, and when surface contamination is known or suspected from procedural breaches. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
74. A written procedure is in place for cleaning and disinfecting the Direct Compounding Areas. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
75. Cleaning and disinfecting occurs before compounding is performed. Items are removed from all areas to be cleaned, and surfaces are cleaned by removing loose material and residue from spills, e.g., water-soluble solid residues are removed with Sterile Water and low-shedding wipes. This shall be followed by wiping with a residue-free disinfecting agent, such as sterile 70% IPA, which is allowed to dry before compounding begins. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
76. Work surfaces in ISO Class 7 and 8 areas and segregated compounding areas are cleaned at least daily. IPA (70% isopropyl alcohol) remains on surfaces to be disinfected for at least 30 seconds before such surfaces are used to prepare CSPs. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
77. Floors in ISO Class 7 and 8 areas are mopped daily by trained personnel at a time when no aseptic operations are in progress using approved agents and procedures described in written SOP's. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas] *cleaning of floors is documented but dust on the ledges of the baseboards has not been cleaned. Corners of the floor are not adequately cleaned. Advise retraining of cleaning personnel and re-evaluating cleaning competency by observation. Please send corrective action plan to inspector and notify when retraining and re-evaluation is complete*	No
78. Shelving, walls, and ceilings in ante-areas are cleaned and disinfected at least monthly. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas] *June and July cleaning records do not document cleaning ofshelving, walls and ceiling. Dust on the returns and baseboards needs to be cleaned and disinfected ASAP*	No
79. Cleaning and disinfecting agents and methods of application are in accordance with written SOPs and followed by custodial and/or compounding personnel. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas] *SOP's donot address all of the cleaning agents employed in the compounding suite. Please add the dilution of Sporicidin and application methods and rotation schedule to SOP*	Yes
80. Cleaning materials, such as wipes, sponges, and mops, are non-shedding, preferably composed of synthetic micro fibers, and dedicated to use in the buffer area, ante-area, and segregated compounding areas and are not removed from these areas except for disposal. If cleaning materials are reused (e.g., mops), there are procedures based on manufacturer recommendations that ensure that the effectiveness of the cleaning device is maintained and repeated use does not add to the bioburden of the area being cleaned. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
81. Supplies and equipment removed from shipping cartons are wiped with a suitable disinfecting agent (e.g., sterile 70% IPA). [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
82. Disinfectant sprayed or wiped on a surface to be disinfected is allowed to dry, and during this time the item is not be used for compounding purposes. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
83. Sterile 70% IPA pads are used to disinfect the sterile entry points of packages and devices. Wetted gauze pads or other particle-generating material are not appropriate. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes

PERSONNEL CLEANSING, GARBING & COMPETENCY EVALUATION

84. Personnel preparing CSP's are free from rashes, sunburn, weeping sores, conjunctivitis, and active respiratory infections. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	Yes
85. Compounding personnel remove personal outer garments; cosmetics; artificial nails; hand, wrist, and body jewelry that can interfere with the fit of gowns and gloves; and visible body piercing above the neck. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	Yes
86. Facility has adequate supplies to meet PPE requirements of USP<797>. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	Yes
87. Garbing and hand hygiene are accomplished in the ante-area in order of dirtiest to cleanest: shoes or shoe covers, head and facial hair covers, face mask, fingernail cleansing, hand and forearm washing and drying; non-shedding gown. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	Yes
88. Sterile gloves are donned in the buffer room after hand cleansing with an alcohol-based product with persistent activity and hands are allowed to dry. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	Yes
89. Gloves are routinely disinfected with sterile 70% IPA after contacting nonsterile objects. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	Yes
90. Personnel repeat garbing and hand hygiene after they are exposed to direct contact contamination or worse than ISO Class 8 air. Gowns may be hung in the anteroom and reused during the same workshift. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	Yes
91. Personnel garbing requirements are followed for CAIs unless manufacturer provides written documentation based on validated testing that any components of PPE are not required to maintain sterility of CSPs. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	N/A
92. Documentation indicates compounding personnel have successfully completed didactic training, passed written competency assessments, undergone skill assessment using observational audit tools, and media-fill testing before any compounding personnel begin to prepare CSPs. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures] *Observational assessments for aseptic technique need to be done this month and send to inspector*	Yes

93. Compounding personnel who fail written tests, observational audits, or whose media-fill test vials have one or more units showing visible microbial contamination, are reinstructed and re-evaluated by expert compounding personnel to ensure correction of all aseptic work practice deficiencies. Compounding personnel pass all evaluations prior to resuming compounding of sterile preparations. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures]	N/A
94. Corrective action is documented for compounding personnel who fail written tests or media-fill test. [PERSONNEL TRAINING AND EVALUATION IN ASEPTIC MANIPULATIONS SKILLS]	N/A
95. Other cleaning personnel performing cleaning and disinfecting procedures (e.g. environmental) are thoroughly trained in proper hand hygiene, and garbing, cleaning, and disinfection procedures by a qualified aseptic compounding expert. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures]	N/A
96. Compounding personnel and other personnel responsible for cleaning routinely undergo performance evaluation of proper hand hygiene, garbing, and all applicable cleaning and disinfecting procedures conducted by a qualified aseptic compounding expert. Visual observation of hand hygiene, garbing and cleaning is documented and maintained to provide a permanent record and long-term assessment of personnel competency. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures] *The assessments are documented but the state of the room indicates that staff need retraining and re-assessments for cleaning and disinfecting. Please send to Inspecotr by COB 8-14-15*	Yes
97. Compounding personnel are visually observed annually or semiannually (high risk) during the process of performing hand hygiene, garbing procedures and aseptic technique. The visual observation is documented on a form for Assessing Hand Hygiene, Garbing and Aseptic Technique and maintained to provide a permanent record. [ENVIRONMENTAL QUALITY AND CONTROL : Garbing and Gloving Competency Evaluation] *Hand Hygeine and garbing has been done. Need assessments of Aseptic technique*	No
98. Immediately after the compounder completes the hand hygiene and garbing procedure, the evaluator collects a gloved fingertip and thumb sample from both hands of the compounder onto appropriate agar plates. The plates are incubated at 30-35° for 2–3 days. All compounding personnel have successfully completed an initial competency evaluation and gloved fingertip/thumb sampling procedure (0 cfu) no less than three times before initially being allowed to compound CSPs for human use. [ENVIRONMENTAL QUALITY AND CONTROL : Gloved Fingertip Sampling]	Yes
99. Re-evaluation of glove fingertip testing onto appropriate agar plates (Trypticase soy agar (TSA) with lecithin and polysorbate 80) for all compounding personnel occurs at least annually for low- and medium-risk level CSPs and semiannually for high-risk level CSPs before being allowed to continue compounding CSPs. Gloves shall not be disinfected with sterile 70% IPA prior to testing. The cfu action level is based on the total number of cfu on both gloves and not per hand. [ENVIRONMENTAL QUALITY AND CONTROL : Gloved Fingertip Sampling]	Yes

VERIFICATION

100. Facility has written procedures to verify correct identity, quality, amounts, and purities of ingredients used in CSPs. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Identity and Strength Verification of Ingredients]	Yes
101. Labels of CSPs contain name and address of pharmacy, correct names and amounts or concentrations of ingredients, total volumes, beyond-use dates, storage conditions, and route(s) of administration. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Identity and Strength Verification of Ingredients]	Yes
102. Facility has documentation that procedures have been followed to ensure sterility, purity, correct identities and amounts of ingredients, and stability. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Inspection of Solution Dosage Forms and Review of Compounding Procedures]	Yes
103. CSP's are visually inspected for abnormal particulate matter and color, and intact containers and seals. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Inspection of Solution Dosage Forms and Review of Compounding Procedures]	Yes
104. Beyond Use Dates are assigned using direct stability-indicating assays or authoritative literature that supports the assigned BUD. [STORAGE AND BEYOND-USE DATING : Determining Beyond-Use Dates]	Yes
105. Storage time of assembled bag and vial systems are according to the manufacturer recommendations. (eg Minibag plus, Addvantage, Add-ease) [STORAGE AND BEYOND-USE DATING : Proprietary Bag and Vial Systems]	Yes
106. Facility has written procedures for proper packaging, storage, and transportation conditions to maintain sterility, quality, purity, and strength of CSPs. [MAINTAINING STERILITY, PURITY, AND STABILITY OF DISPENSED AND DISTRIBUTED CSPs :]	Yes
107. Policies address packaging to maintain physical integrity, sterility, stability, and purity of CSPs. [MAINTAINING STERILITY, PURITY, AND STABILITY OF DISPENSED AND DISTRIBUTED CSPs : Packaging and Transporting CSPs]	Yes

DISPENSING/DISTRIBUTION

108. Modes of transport are used that maintain appropriate temperatures and prevent damage to CSPs. [MAINTAINING STERILITY, PURITY, AND STABILITY OF DISPENSED AND DISTRIBUTED CSPs : Packaging and Transporting CSPs]	Yes
109. Facility provides a multiple component formal training program to ensure patients and caregivers understand the proper storage, handling, use, and disposal of CSPs. [PATIENT OR CAREGIVER TRAINING] *Training is done my nursing staff*	Yes
110. Written standard procedures describe means for patients to ask questions and report concerns and adverse events with CSPs, and for compounding pharmacists to correct and prevent future problems. [PATIENT MONITORING AND ADVERSE EVENTS REPORTING]	Yes

USP <71> STERILITY TESTING

111. Outsourced sterility testing results indicate that it is compliant with USP<71>. A method not described in the USP may be used if validation demonstrates that the alternative is at least as effective and reliable. [STERILITY TEST USP<71>]	
112. Outsourced: The number of articles tested are appropriate according to USP<71>. [STERILITY TEST USP<71> : Number of Articles to Be Tested]	
113. Outsourced: The volume/quantity tested is according to USP<71>. [STERILITY TEST USP<71> : Number of Articles to Be Tested]	
114. On site: Membrane filtration is used whenever the nature of the product permits. Filters are rinsed according to USP<71>. Sterility testing results indicate that it is compliant with USP<71>. A method not described in the USP may be used if validation demonstrates that the alternative is at least as effective and reliable. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Sterility Testing]	
115. On site: Direct inoculation is done only when membrane filtration cannot be carried out. Volume to be inoculated does not exceed 10% of the culture media volume. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Sterility Testing]	
116. On site: The number of articles tested are appropriate according to USP<71>. [STERILITY TEST USP<71> : Number of Articles to Be Tested]	
117. On site: The volume/quantity tested is according to USP<71>. [STERILITY TEST USP<71> : Number of Articles to Be Tested]	
118. On site: A growth promotion test has been done on the media with the 5 specified organisms (not more than 100 CFU) according to USP<71>. [STERILITY TEST USP<71> : Growth Promotion Test of Aerobes, Anaerobes, and Fungi]	
119. On site: A USP<71> method suitability test has been done with appropriate inoculum, additives and rinses. [STERILITY TEST USP<71> : Method Suitability Test]	

120. On site: TSB or SCD is incubated at 20-25 C for 14 days (2 incubators present). [STERILITY TEST USP<71> : Culture Media and Incubation Temperatures]	
121. On site: FTM is incubated at 30-35 C for 14 days (2 incubators present). [STERILITY TEST USP<71> : Culture Media and Incubation Temperatures]	
122. On site: Sterility testing is documented including lot numbers and expiration dates of media. [FINISHED PREPARATION RELEASE CHECKS AND TESTS]	
123. Sterility testing reports are reviewed and appropriate actions taken and documented. [FINISHED PREPARATION RELEASE CHECKS AND TESTS]	

MISCELLANEOUS

124. Facility engaged in office use sterile compounding for human use is registered with FDA as an outsourcing facility. [FAC 64B16-27.700 (3)(g]	N/A
125. Compounding records are properly maintained. [FAC 64B16-28.140(4)]	Yes

Remarks:

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge. I have received a copy of the Licensee Bill of Rights.

Investigator/Sr. Pharmacist Signature:

CRANE, MARY

Date:8/7/2015

Representative:

Shirley Elisbrun

Date:8/7/2015

STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES

Florida HEALTH
WWW.DOH.STATE.FL.US

Standards of Practice for Compounding Sterile Preparations (CSPs)

ROUTINE [X] CHANGE LOC [ ] NEW [ ] CURRENTLY NOT OPERATING [ ] CHANGE OWNER [ ]

INSPECTION AUTHORITY - CHAPTER 465.017, CHAPTER 893.09 AND CHAPTER 456, FLORIDA STATUTES

File # 21072
Insp # 128947

NAME OF ESTABLISHMENT		PERMIT NUMBER		DATE OF INSPECTION
AMBIENT HEALTHCARE OF S. FLORIDA, INC		27913		8/5/2014
DOING BUSINESS AS		DEA NUMBER		PRESCRIPTION DEPARTMENT MANAGER
AMBIENT HEALTHCARE OF S. FLORIDA, INC		BA7935490		
STREET ADDRESS		TELEPHONE #	EXT.	
15951 SW 41ST ST SUITE 500		954-389-1126		
CITY	COUNTY	STATE/ZIP		PRESCRIPTION DEPARTMENT MANAGER LICENSE #
DAVIE	16	33331		18740

COMPOUNDING PERSONNEL	MEDIA FILLED TEST DATE	COMPOUNDING PERSONNEL	MEDIA FILLED TEST DATE
Catherine Khavandegard 12-5-13	Manuega- Vega- Rivera 6-27-14	Vincent E 7-11-14	
W Guillaume 5-30-14	A Montalvo 7-11-14	Katrina P 7/11/14	

		SATISFACTORY	N/A	YES	NO
High-Risk Level CSPs					
1	Sterilized high-risk preparations pass sterility test OR preparations are properly stored, prior to administration, not exceeding time periods specified in rule. [64B16-27.797(1)(i)4.]		X		
2	Personnel authorized to compound high-risk-level CSPs completed a media-filled test with high-risk test kit within the past 6 months (semiannually). [64B16-27.797(1)(i),F.A.C.]		X		
3	High risk sterile compounded preparations greater than 25 units have antimicrobial testing prior to dispensing [64B16-27.797(7)(a)3., F.A.C.]		X		
Medium and Low-Risk Level CSPs					
4	Medium-risk and low-risk preparations must pass sterility testing OR preparations are properly stored and do not exceed time periods specified in rule. [64B16-27.797(1)(n)4.; (o)4.]			X	
5	Personnel authorized to compound medium or low-risk level CSPs completed a media-filled test with medium-risk test kit within the past 12 months. [64B16-27.797(1)(n), F.A.C.]			X	
Barrier Isolator or Compounding Environment					
6	All sterile compounds prepared in barrier isolator which has been certified as ISO 5 by independent contractor. [64B16-27.797(5)(e), F.A.C.]		X		
7	Compounding environment appropriate for Risk Level (certification by independent qualified organization). Semi-annually for high risk, annual for medium and low-risk.			X	
	a) Anteroom/Ante area maintained within ISO class 8 [64B16-27.797(1)(a), F.A.C.]			X	
	b) Buffer area (clean room) maintained within ISO class 7 (separate room required for high-risk) [64B16-27.797(1)(f); (5)(a), F.A.C.]			X	
	c) Laminar Air Flow Hood(s) or class100 ISO room maintained within ISO class 5 [64B16-27.797(1)(k), F.A.C.]			X	
8	Buffer area does not contain sinks and drains. [64B16-27.797(1)(f), F.A.C.]			X	
Antineoplastic Drugs (Cytotoxins)					
9	Spill kits for antineoplastic agent spills. [64B16-27.797(5), F.A.C.]			X	
10	All cytotoxic preparations are compounded in a vertical flow, Class II, biological safety cabinet in a negative pressure room. [64B16-27.797(6), F.A.C.]			X	
11	Disposal of antineoplastic waste meets all applicable requirements. [64B16-27.797(6), F.A.C.]			X	
General Requirements					
12	P & P includes use of single/multidose containers not to exceed 797 guidelines. [64B16.27-797(4), F.A.C.]			X	
13	P & P includes verification of compounding accuracy and sterility. [64B16-27.797(4), F.A.C.]			X	
14	P & P includes personnel training and evaluation in aseptic manipulation skills. [64B16-27.797(4), F.A.C.]			X	
15	P & P includes environmental quality and control. [64B16-27.797(4), F.A.C.]			X	
16	Current reference material, hard copy or readily available online, are maintained. [64B16-27.797(5)(d), F.A.C.]			X	
17	Appropriate disposal containers. [64B16-27.797(5), F.A.C.]			X	
18	Appropriate temperature and transport devices. [64B16-27.797(5), F.A.C.]			X	
19	Adequate supplies (gloves, mask, etc.) to preserve a suitable environment for aseptic preparation and protective apparel for cytotoxins. [64B16-27.797(5)(6), F.A.C.]			X	
20	Documented on-going quality assurance program with audits at regular planned intervals. [64B16-27.797(7), F.A.C.]			X	
21	Compounding personnel skilled and trained based on observation. [64B16-27.797(7), F.A.C]			X	
22	Compounding records properly maintained [64B16-28.140(4), F.A.C.]			X	
23	Quantity of compounded drug is reasonable considering the intended use and nature of the practitioner's practice [64B16-27.700(3)(b), F.A.C.]		X		

Remarks: ENV certified 2 LAFW and 1 BSC to ISO 5 8-5-14
MTA certified rooms 6-27-14 ISO 8 Ante room ISO 7 buffer. The buffer room did not have adequate pressure differential to Ante room. Plans for clean room upgrade include replacing plastic strips with a solid door. Manometers must be installed to monitor pressures daily
The pharmacy has a BSC in the buffer room, a CSTD is used and less than 5 HD's are compounded per week. A negative pressure room is in the plan of the upgrade.
Monthly surface sampling is conducted using TSA w/ P80 and lecithin.

Annual observational assessments are done for cleaning and disinfecting; gowning and garbing and aseptic technique

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge. I have received a copy of the Licensee Bill of Rights.

PRINT NAME OF RECIPIENT Shirley Elisbrun R.Ph Pharm D

ID li100

Institutional Representative

08-05-2014
Date

Investigator/Sr. Pharmacist Signature

INV 797 Revised 12/12, 12/11 Created 8/11

USP 797 CERTIFICATION EXECUTIVE SUMMARY

Date	July 14, 2017	Report Number	3699-1
Technician	Michael Klann		
Device ID#	3623		
Customer	Axelacare Davie		
Address	15951 SW 41st Street Suite 500		
City State	Davie, FL 33331		

MEDICAL TECHNOLOGY ASSOCIATES

Contact	Henry Hernandez	Karen Hitchen
Telephone	(954) 389-1126 ext 105	
email address	ehernandez@briovarxinfusion.com	KHitchen@briovarxinfusion.com
PO#		

Notes: The Ante Room does not meet the minimum requirement of 20 air changes. The current volume of supply air is 243 CFM, which provides only 15 air changes. The Air Science Laminar Flow Hood S/N HLF72298 fails the HEPA Leak Test. There are multiple leaks and the filter will need to be replaced. MTA will provide a quote. Both of the Air Science Laminar Flow Hoods need the pre-filters, which are located on top of the hood, cleaned or replaced.

All testing is to be done under Dynamic conditions indicate the number of people working in the room during testing +2

Item	Criteria	Result		Pass / Fail
Overall Facility Certification	All SEC's certified to CETA CAG-003	Facility certified to criteria listed below		PASS
ISO classification / Particle Counts	Ante Room **without** Hazardous Room can be ISO 7 or 8	8		Pass
	Ante Room joined to Hazardous Buffer Room must be ISO 7	N/A		N/A
	Non Hazardous Buffer Room must be ISO 7	7		PASS
	Hazardous Buffer Room must be ISO 7	N/A		N/A
Air Changes	Ante Room **without** Hazardous Room recommended 20 ACPH	15		FAIL
	Ante Room joined to Hazardous Buffer Room must have 30 ACPH	N/A		N/A
	Non Hazardous Buffer Room must have 30 ACPH	33		PASS
	Hazardous Buffer Room must be ISO 7 must have 30 ACPH	N/A		N/A
Room Segregation / Pressurization	Ante Room must be at least 0.02"W.G positive to outside	0.0559		PASS
	Non Hazardous Buffer Rm must be at least 0.02" W.G to Ante Rm	0.0268		PASS
	Hazardous Buffer Room must be between -0.01 and -0.03"W.G	N/A		N/A
Smoke Test	All Rooms had airflow confirmed with visual smoke test	Smoke passed in correct directions		PASS
PEC	Tested to CETA CAG 002 / NSF 49 or MFG specification	3623-72298	HLF72298	FAIL
	Tested to CETA CAG 002 / NSF 49 or MFG specification	3623-72299	HLF72299	PASS
	Tested to CETA CAG 002 / NSF 49 or MFG specification	3623-172875	172875022216	PASS
	Tested to CETA CAG 002 / NSF 49 or MFG specification	3623-176245	176245092216	PASS

*Executive summary does not include results of viable air samples.

ANTE- ROOM SUMMARY

MEDICAL TECHNOLOGY ASSOCIATES

Date	July 14, 2017
Report #	3699-1
Device ID #	3623
Technician	Michael Klann
Customer	Axelacare Davie
Address	15951 SW 41st Street Suite 500
City State	Davie, FL 33331
Contact	Henry Hernandez / Karen Hitchen
Phone Number	(954) 389-1126 ext 105
PO Number	

Overall Status of Room

ISO 14644-1 **1999-E** Class **8** at .5 micron Status **Operational**

Meets CETA CAG-003-2006 rev 2010	[ ] Pass	[X] Fail	[ ] N/A
Meets USP 797 to Criteria Tested	[ ] Pass	[X] Fail	[ ] N/A

Notes: The Ante Room does not meet the minimum requirement of 20 air changes. The current volume of supply air is 243 CFM which provides only 15 air changes

Air Change Requirements:

Minimum 30 air changes required for ISO 7 and 20 air changes for ISO 8

Total Air Volume Supplied	243	CFM	Total Number of Air Changes	15	per hour	[ ] Pass	[X] Fail	[ ] N/A
Total Air Volume From PEC		CFM	Air Changes From PEC		per hour			[X] N/A

Differential Pressure and/or Displacement Velocity:

Minimum 0.02 inches positive to the outside area. Minimum 40 fpm is required if utilizing displacement method.

Pressure monitor Present? [X] YES [ ] NO [ ] N/A

Static Pressure or Velocity of Ante Room to Outside	0.0559	"W.G. or	N/A	fpm	[X] Pass	[ ] Fail	[ ] N/A
Static Pressure or Velocity of IV to Ante Room	0.0268	"W.G. or	N/A	fpm	[X] Pass	[ ] Fail	[ ] N/A
		"W.G. or	N/A	fpm	[ ] Pass	[ ] Fail	[X] N/A
		"W.G. or	N/A	fpm	[ ] Pass	[ ] Fail	[X] N/A

Ante Room Statistical Data 0 .5 micron Particles:

(Particle counts taken at 1 minute sample time at 1 CFM and include 0.5 micron particles and larger)

95% UCL is used to determine ISO classification when nine (9) or less particle count locations are taken.

Maximum number of .5 micron size particles allowed for ISO Class 7	352,000	particles per cubic meter
Maximum number of .5 micron size particles allowed for ISO Class 8	3,520,000	particles per cubic meter

ISO Class Achieved **8** Mean of Averages **3012** 95% UCL **5236** [X] Pass [ ] Fail [ ] N/A

HEPA Filter Leak Integrity Test:

Upstream concentration should be greater than 10µg/l and no leak greater than 0.01% when scanned. (See Data Page for more information.)

Number of filters scanned	1
Number of leaks detected	0
Number of leaks sealed	N/A

[X] Pass [ ] Fail [ ] N/A

Average Temperature and Relative Humidity:

Recommended Temperature < 68° F Measured **59.3** °F

Recommended Relative Humidity 30 to 65% Measured **61.7** %Rh

Smoke Study Performed:

Visual confirmation that air flows in the direction designed for the type of room. [X] Pass [ ] Fail [ ] N/A

*This test only performed on unidirectional / uniform rooms.

IV / BUFFER ROOM SUMMARY

MEDICAL TECHNOLOGY ASSOCIATES

Date	July 14, 2017
Report #	3699-1
Customer ID #	3623
Technician	Michael Klann
Customer	Axelacare Davie
Address	15951 SW 41st Street Suite 500
City State	Davie, FL 33331
Contact	Henry Hernandez
Phone Number	(954) 389-1126 ext 105
PO Number	

Overall Status of Room

ISO 14644-1 **1999-E** Class **7** at .5 micron Status **Operational**

Meets CETA CAG-003-2006 rev 2010 [X] Pass [ ] Fail [ ] N/A

Meets USP 797 to Criteria Tested [X] Pass [ ] Fail [ ] N/A

Notes:

Air Change Requirements:

Minimum 30 air changes required for ISO 7

Total Air Volume Supplied 1142 CFM — Total Number of Air Changes 33 per hour — [X] Pass [ ] Fail [ ] N/A

Total Air Volume From PEC 1561 CFM — Total Air Changes With PEC 78 per hour — [ ] N/A

Differential Pressure and/or Displacement Velocity:

Minimum 0.02 inches positive to the ante area or any other area. Minimum 40 fpm is required if utilizing displacement method.

Pressure monitor Present? [X] YES [ ] NO [ ] N/A

Static Pressure or Velocity of IV to Ante Room	0.0268	"W.G. or	N/A	fpm	[X] Pass	[ ] Fail	[ ] N/A
Static Pressure or Velocity of IV Room to Outside	N/A	"W.G. or	N/A	fpm	[ ] Pass	[ ] Fail	[X] N/A
	N/A				[ ] Pass	[ ] Fail	[X] N/A

IV Room Statistical Data 0 .5 micron Particles: (Particle counts taken at 1 minute sample time at 1 CFM and include 0.5 micron particles and larger)

95% UCL is used to determine ISO classification when nine (9) or less particle count locations are taken.

Maximum number of .5 micron size particles allowed for ISO Class 7 352,000 particles per cubic meter

ISO Class Achieved 7 — Mean of Averages 412 — 95% UCL 1174 — [X] Pass [ ] Fail [ ] N/A

HEPA Filter Leak Integrity Test:

Upstream concentration should be greater than 10µg/l and no leak greater than 0.01% when scanned. (See Data Page for more information.)

Number of filters scanned	3
Number of leaks detected	0
Number of leaks sealed	N/A

[X] Pass [ ] Fail [X] N/A

Average Temperature and Relative Humidity:

Recommended Temperature < 68° F — Measured 61.9 °F

Recommended Relative Humidity 30 to 65% — Measured 58.2 %Rh

Smoke Study Performed:

Visual confirmation that air flows in the direction designed for the type of room. [X] Pass [ ] Fail [ ] N/A

CLEANROOM INSPECTION DATA

MEDICAL TECHNOLOGY ASSOCIATES

Date	July 14, 2017	Time	8:20 AM
Technician	Michael Klann		
Customer ID#	3623		
Customer	Axelacare Davie		
Address	15951 SW 41st Street Suite 500		
City State	Davie, FL 33331		

Report Number 3699-1

Contact	Henry Hernandez /	Karen Hitchen
Telephone	(954) 389-1126 ext 105 /	
email address	ehernandez@briovarxinfusion.com /	KHitchen@briovarxinfusion.com
PO#		

ANTE ROOM DIMENSIONS AND PARTICLE COUNT STATISTICAL DATA

Room Dimensions recorded in inches ☐ Non-applicable

L	W	H
168	90	108

Room Area in square feet ft²	105.00	ft²
Room Area in square meters (m²)	9.75	m²
Room Volume in cubic feet (ft³)	945.00	ft³
Number of Sampling Locations	4	√m² rounded up

Calculations
(Length (in) X width (in)) x 1 ft²/144 in²
area (ft²) x 1 m²/10.764 ft²
(Length (in) X width (in) x Height (in) x 1 ft³/1728 in³

Ante Room Particle Count Statistical Data (Particle counts taken at 1 minute sample time at 1 CFM and include 0.5 micron particles and larger)

ISO Class	8	Mean of Averages	3012	95% UCL	5236	Standard Dev	1893	Standard Err.	N/A

IV ROOM DIMENSIONS AND PARTICLE COUNT STATISTICAL DATA

Room Dimensions recorded in inches ☐ Non-applicable

L	W	H
168	198	108

Room Area in square feet ft²	231.00	ft²
Room Area in square meters (m²)	21.46	m²
Room Volume in cubic feet (ft³)	2079.00	ft³
Number of Sampling Locations	5	

Calculations
(Length (in) X width (in)) x 1 ft²/144 in²
area (ft²) x 1 m²/10.764 ft²
(Length (in) X width (in) x Height (in) x 1 ft³/1728 in³
√m² rounded up

IV Room Particle Count Statistical Data (Particle counts taken at 1 minute sample time at 1 CFM and include 0.5 micron particles and larger)

ISO Class	7	Mean of Averages	412	95% UCL	1174	Standard Dev	924	Standard Err.	N/A

AIR SUPPLY VOLUME MEASUREMENT DATA

[X] Direct Measurement Method ☐ Velgrid Measurement Method/Multi point array ☐ Single point / velometer method

Calculate K factor for a filter when DIM cannot be measured: HEPA filter # _____ HEPA Filter Face Area _____ Measured CFM _____ Measured FPM _____

(K-Factor = measured cfm/calculated cfm) Calculated CFM _____ K-factor _____

Ante Room

		Location	Filter Dimensions				Sqft	K Factor	FPM	CFM
HEPA Filter # / Diffuser	1		24 L	48 W	D		7.0			243
HEPA Filter # / Diffuser			L	W	D		0.0			
HEPA Filter # / Diffuser			L	W	D		0.0			

IV Room

		Location	Filter Dimensions				Sqft	K Factor	FPM	CFM
HEPA Filter # / Diffuser	1		24 L	48 W	D		7.0			450
HEPA Filter # / Diffuser	2		24 L	48 W	D		7.0			224
HEPA Filter # / Diffuser	3		24 L	48 W	D		7.0			468
HEPA Filter # / Diffuser			L	W	D		0.0			

Report Number 3699-1

AIR CHANGE AND PRESSURE DATA

Ante Room

Room Volume 945 | Supply Air Total 243 | Air Changes Per minute 0.26 | Air Changes Per Hour 15

Total Air Volume from PEC | Total Air changes Per hour with PEC | [X] Non-applicable

Notes: Does not meet requirements

IV Room

Room Volume 2079 | Supply Air Total 1142 | Air Changes Per minute 0.55 | Air Changes Per Hour 33

Total Air Volume from PEC 1561 | Total Air changes Per hour with PEC 78 | [ ] Non-applicable

Notes:

Pressure/Velocity Monitors Installed? [X] YES [ ] NO [ ] N/A

Pressure monitor Installed and Functioning? [X] YES [ ] NO [ ] N/A

Static Pressure Ante to Outside 0.0559 "W.G. | Static Pressure IV to Ante Room 0.0268 "W.G. | Static Pressure to Chemo N/A "W.G.

Static Pressure to ____ measured ____ "W.G. | Static Pressure to ____ measured ____ "W.G.

Static Pressure to ____ measured ____ "W.G. | Static Pressure to ____ measured ____ "W.G.

Displacement

Displacement Average Ante Room to Outside N/A

Displacement Average IV room to Ante Room N/A

Displacement Average Ante Room to Chemo Room N/A

MTA strongly discourages the use of displacement and curtains. If curtains are utilized spread the curtains at least 24" and measure 48" above the floor complete a drawing and record the readings. Any customers using curtains shall be advised to install a door and if needed low wall registers to allow for pressure adjustments.

HEPA FILTER INTEGRITY TEST

(HEPA filters should be integrity tested at each certification with a minimum upstream challenge concentration of 10 micrograms per liter.)

Ante Room

	Upstream Challenge Location	Calculated Challenge	Measured challenge Before	Measured challenge After	Leak Detected	Leak Sealed
HEPA Filter # 1	Return in IV Room	15			[ ] Yes [X] No	[ ] Yes [ ] No [ ] Fail
					[ ] Yes [ ] No	[ ] Yes [ ] No [ ] Fail
					[ ] Yes [ ] No	[ ] Yes [ ] No [ ] Fail

IV Room

	Upstream Challenge Location	Calculated Challenge	Measured challenge Before	Measured challenge After	Leak Detected	Leak Sealed
HEPA Filter # 1	Return in IV Room	15			[ ] Yes [X] No	[ ] Yes [ ] No [ ] Fail
HEPA Filter # 2	Return in IV Room	15			[ ] Yes [X] No	[ ] Yes [ ] No [ ] Fail
HEPA Filter # 3	Return in IV Room	15			[ ] Yes [X] No	[ ] Yes [ ] No [ ] Fail
					[ ] Yes [ ] No	[ ] Yes [ ] No [ ] Fail

Report Number 3699-1

ADDITIONAL DATA

Average Noise Level N/A dBA Average Temperature N/A °F Average Relative Humidity Level N/A %Rh

Ceiling tiles sealed down/gasketed?	[X] YES	[ ] NO	[ ] N/A
Floors have coved edges and corners?	[X] YES	[ ] NO	[ ] N/A

Drawing of room complete?	[X] YES	[ ] NO	[ ] N/A
Profile of Viable Sample Locations Complete?	[X] YES	[ ] NO	[ ] N/A
Profile of Particle Count Locations Complete?	[X] YES	[ ] NO	[ ] N/A
Profile of Room HEPA Filters, Leak/Patches and challenge induction points complete?	[X] YES	[ ] NO	[ ] N/A
Profile of Room Pressures Complete?	[X] YES	[ ] NO	[ ] N/A
Profile of Room Air Supply / Return Complete?	[X] YES	[ ] NO	[ ] N/A
Profile of Temperature and Humidity Readings Complete?	[X] YES	[ ] NO	[ ] N/A

000052

Laminar Flow Hood Certification Report

Date	July 14, 2017
Report #	3699-2
Technician	Michael Klann
Customer	Axelacare Davie
Address	15951 SW 41st Street Suite 500
City State	Davie, FL 33331
Contact	Henry Hernandez / Karen Hitchen
Telephone	(954) 389-1126 ext 105 /
PO Number	

MEDICAL TECHNOLOGY ASSOCIATES

Overall Status [ ] Pass [X] Fail

[X] Requires Attention

Device ID#	3623-72298
Manufacturer	Air Science
Model	HLF-72
Serial Number	HLF72298
Device Location	IV Room

Notes: The HEPA filter has multiple leaks. The Filter needs to be replaced. MTA will provide a quote to remove and replace the HEPA Filter.
The pre=filters located on top the hood need to be cleaned or replaced.
Supply HEPA Filter Magnehelic Gauge Reading 0.70" W.C.

ACCEPTANCE CRITERIA

Supply Air Velocity Profile

	Min		Max		Readings taken at [ ] 6" [X] 12" from diffuser
Supply Velocity	80	fpm.	100	fpm.	Supply Velocity 92 fpm.

Individual point readings should be within +/- 20%.

					Recorded Low and High Values			
Individual Readings	73	Low	110	High	78	Low	106	High

Particulate Matter Profile

(Particle counts taken at 1 minute sample time at 1 CFM and include 0.5 micron particles and larger)

Maximum number of .5 micron size particles and above allowed for ISO Class 5 is 3520 particles per cubic meter

Average 0 95% UCL 0

ISO Class Achieved 5

HEPA Filter Leak Test

Adequate challenge concentration between 10 and 90 micrograms per liter. No leak should exceed 0.01% when scanned.

Upstream Concentration	N/A
Calculated Upstream Concentration	21
Number of leaks Detected	mltpl
Number of leaks Sealed	N/A

Smoke Test

Visual Verification that the laminarity of the air is undisturbed by items in the hood and activities in the room (cross drafts). **Under Dynamic Conditions**

Induction Leak and Backstreaming Test

Verifies that the device prevents particle intrusion into the clean space by induction through joints or Backstreaming from workspace openings.

FINAL RESULTS

Supply Air Velocity
[X] Pass [ ] Fail [ ] N/A

Uniformity
[X] Pass [ ] Fail [ ] N/A

Particle Counts
[X] Pass [ ] Fail [ ] N/A

HEPA Filter Integrity Test
[ ] Pass [X] Fail [ ] N/A

Smoke Test
[X] Pass [ ] Fail [ ] N/A

Induction Leak / Backstreaming Test
[ ] Pass [ ] Fail [X] N/A

INSPECTION DATA

Equipment Data

	Supply HEPA Filter							Pre-Filter						
1. Filter Size	(	1	)	24	X	72	X	6	(	3	)	16	X	20	X	1
2. Supply Area	10.69	sq.ft.							(| |)		X		X	
3. Supply Velocity	92	fpm.														
4. Volume	981	cfm.														

Supply Velocity Profile

88	87	96	78	94	92
98	89	102	101	90	101
94	82	80	85	88	106

Supply Velocity Average 92

HEPA Filter Integrity Test

Multiple Leaks

x x XX
x x

Particulate Matter Profile

#1	#2	#3
0	0	0

SUMMARY

MTA warrants that this air system was tested under the requirements as set forth in the following applicable standard(s):

- [ ] CAG--003-2006 v 11
- [ ] IES-RP-CC-002.3 Unidirectional-Flow, Clean-Air Devices
- [ ] Owners Specifications
- [ ] Manufacturer's Specifications
- [X] ISO 14644- 1 1999 (E); Class 5 at 0.5 um size particle, Status **Operational / Dynamic**

Status of System after Inspection:

- [ ] Certified to the Above Applicable Standard(s).
- [ ] Undergoing Corrective Action by MTA.
- [X] Does not meet the Above Applicable Standard(s).
- [ ] It is Recommended that this System be Corrected by the Owner Prior to any Additional Testing.

CERTIFICATE OF INSPECTION' expires 2 months from date of issue.

Medical Technology Asscoiates
6840 Cross Bayou Drive
Largo, FL 33777
Phone: (877) 569-8886
Fax: 727-548-8622

Laminar Flow Hood Certification Report

Date	July 14, 2017
Report #	3699-3
Technician	Michael Klann
Customer	Axelacare Davie
Address	15951 SW 41st Street Suite 500
City State	Davie, FL 33331
Contact	Henry Hernandez / Karen Hitchen
Telephone	(954) 389-1126 ext 105 /
PO Number	

MEDICAL TECHNOLOGY ASSOCIATES

Overall Status [X] Pass [ ] Fail [ ] Requires Attention

Device ID#	3623-72299
Manufacturer	Air Science
Model	HLF-72
Serial Number	HLF72299
Device Location	IV Room

Notes:

The pre-filters located on top the hood need to be cleaned or replaced.

Supply HEPA Filter Magnehelic Gauge Reading 0.70" W.C.

ACCEPTANCE CRITERIA

Supply Air Velocity Profile

	Min		Max		Readings taken at				
Supply Velocity	80	fpm.	100	fpm.		[ ] 6"	[X] 12" from diffuser	Supply Velocity	93 fpm.

Individual point readings should be within +/- 20%.

					Recorded Low and High Values			
Individual Readings	74	Low	111	High	77	Low	109	High

Particulate Matter Profile

(Particle counts taken at 1 minute sample time at 1 CFM and include 0.5 micron particles and larger)

Maximum number of .5 micron size particles and above allowed for ISO Class 5 is 3520 particles per cubic meter

Average 0 | 95% UCL 0

ISO Class Achieved 5

HEPA Filter Leak Test

Adequate challenge concentration between 10 and 80 micrograms per liter. No leak should exceed 0.01% when scanned.

Upstream Concentration	N/A
Calculated Upstream Concentration	20
Number of leaks Detected	0
Number of leaks Sealed	N/A

Smoke Test

Visual Verification that the laminarity of the air is undisturbed by items in the hood and activities in the room (cross drafts). **Under Dynamic Conditions**

Induction Leak and Backstreaming Test

Verifies that the device prevents particle intrusion into the clean space by induction through joints or Backstreaming from workspace openings.

FINAL RESULTS

	Pass	Fail	N/A
Supply Air Velocity	[X]	[ ]	[ ]
Uniformity	[X]	[ ]	[ ]
Particle Counts	[X]	[ ]	[ ]
HEPA Filter Integrity Test	[X]	[ ]	[ ]
Smoke Test	[X]	[ ]	[ ]
Induction Leak / Backstreaming Test	[ ]	[ ]	[X]

000056

INSPECTION DATA

Equipment Data

	Supply HEPA Filter						Pre-Filter					
1. Filter Size	(1)	24	X	72	X	6	(3)	14	X	21.5	X	1
							( )		X		X	

2. Supply Area 10.69 sq.ft.
3. Supply Velocity 93 fpm.
4. Volume 989 cfm.

Supply Velocity Profile

109	93	107	105	97	95
105	79	77	104	80	89
97	95	79	85	78	91

Supply Velocity Average 93

HEPA Filter Integrity Test

Zero Leaks

Particulate Matter Profile

#1	#2	#3
0	0	0

SUMMARY

MTA warrants that this air system was tested under the requirements as set forth in the following applicable standard(s):

- [ ] CAG--003-2006 v 11
- [ ] IES-RP-CC-002.3 Unidirectional-Flow, Clean-Air Devices
- [ ] Owners Specifications
- [X] Manufacturer's Specifications
- [X] ISO 14644- 1 1999 (E); Class 5 at 0.5 um size particle, Status **Operational / Dynamic**

Status of System after Inspection:

- [X] Certified to the Above Applicable Standard(s).
- [ ] Undergoing Corrective Action by MTA.
- [ ] Not Certified to the Above Applicable Standard(s).
- [ ] It is Recommended that this System be Corrected by the Owner Prior to any Additional Testing.

CERTIFICATE OF INSPECTION' expires 6 months from date of issue.

Medical Technology Asscoiates
6840 Cross Bayou Drive
Largo, FL 33777
Phone: (877) 569-8886
Fax: 727-548-8622

Laminar Flow Hood Certification Report

Date	July 14, 2017
Report #	3699-4
Technician	Michael Klann
Customer	Axelacare Davie
Address	15951 SW 41st Street Suite 500
City State	Davie, FL 33331
Contact	Henry Hernandez / Karen Hitchen
Telephone	(954) 389-1126 ext 105 /
PO Number	

MEDICAL TECHNOLOGY ASSOCIATES

Overall Status [X] Pass [ ] Fail [ ] Requires Attention

Device ID#	3623-172875
Manufacturer	NuAire
Model	NU-301-636
Serial Number	172875022216
Device Location	IV Room

Notes: Supply HEPA Filter Magnehelic Gauge Reading 0.60" W.C.

ACCEPTANCE CRITERIA

Supply Air Velocity Profile

	Min		Max		Readings taken at			
Supply Velocity	80	fpm.	100	fpm.	[ ] 6" [X] 12" from diffuser	Supply Velocity	94	fpm.

Individual point readings should be within +/- 20%.

					Recorded Low and High Values			
Individual Readings	76	Low	113	High	87	Low	103	High

Particulate Matter Profile

(Particle counts taken at 1 minute sample time at 1 CFM and include 0.5 micron particles and larger)

Maximum number of .5 micron size particles and above allowed for ISO Class 5 is 3520 particles per cubic meter

Average 0 | 95% UCL 0

ISO Class Achieved 5

HEPA Filter Leak Test

Adequate challenge concentration between 10 and 90 micrograms per liter. No leak should exceed 0.01% when scanned.

Upstream Concentration	N/A
Calculated Upstream Concentration	13
Number of leaks Detected	0
Number of leaks Sealed	N/A

Smoke Test

Visual Verification that the laminarity of the air is undisturbed by items in the hood and activities in the room (cross drafts). **Under Dynamic Conditions**

Induction Leak and Backstreaming Test

Verifies that the device prevents particle intrusion into the clean space by induction through joints or Backstreaming from workspace openings.

FINAL RESULTS

Supply Air Velocity
[X] Pass [ ] Fail [ ] N/A

Uniformity
[X] Pass [ ] Fail [ ] N/A

Particle Counts
[X] Pass [ ] Fail [ ] N/A

HEPA Filter Integrity Test
[X] Pass [ ] Fail [ ] N/A

Smoke Test
[X] Pass [ ] Fail [ ] N/A

Induction Leak / Backstreaming Test
[ ] Pass [ ] Fail [X] N/A

000058

INSPECTION DATA

Equipment Data

	Supply HEPA Filter	Pre-Filter
1. Filter Size	(1) 36 X 72 X 6	(2) 24 X 30 X 1
2. Supply Area	16.53 sq.ft.	( ) X X
3. Supply Velocity	94 fpm.	
4. Volume	1561 cfm.	

Supply Velocity Profile

90	93	90	96	92	89
95	89	87	101	92	89
100	103	96	98	99	101

Supply Velocity Average 94

HEPA Filter Integrity Test

Zero Leaks

Particulate Matter Profile

#1	#2	#3
0	0	0

SUMMARY

MTA warrants that this air system was tested under the requirements as set forth in the following applicable standard(s):

- [ ] CAG--003-2006 v 11
- [ ] IES-RP-CC-002.3 Unidirectional-Flow, Clean-Air Devices
- [ ] Owners Specifications
- [X] Manufacturer's Specifications
- [X] ISO 14644- 1 1999 (E); Class 5 at 0.5 um size particle, Status **Operational / Dynamic**

Status of System after Inspection:

- [X] Certified to the Above Applicable Standard(s).
- [ ] Undergoing Corrective Action by MTA.
- [ ] Not Certified to the Above Applicable Standard(s).
- [ ] It is Recommended that this System be Corrected by the Owner Prior to any Additional Testing.

CERTIFICATE OF INSPECTION' expires 6 months from date of issue.

Medical Technology Asscoiates
6840 Cross Bayou Drive
Largo, FL 33777
Phone: (877) 569-8886
Fax: 727-548-8622

Laminar Flow Hood Certification Report

Date	July 14, 2017
Report #	3699-5
Technician	Michael Klann
Customer	Axelacare Davie
Address	15951 SW 41st Street Suite 500
City State	Davie, FL 33331
Contact	Henry Hernandez / Karen Hitchen
Telephone	(954) 389-1126 ext 105 /
PO Number	

MEDICAL TECHNOLOGY ASSOCIATES

Overall Status [X] Pass [ ] Fail [ ] Requires Attention

Device ID#	3623-176245
Manufacturer	NuAire
Model	NU S301-836
Serial Number	176245092216
Device Location	IV Room

Notes: Supply HEPA Filter Magnehelic Gauge Readings 0.60" W.C. and 0.50" W.C.

ACCEPTANCE CRITERIA

Supply Air Velocity Profile

Readings taken at [ ] 6" [X] 12" from diffuser

	Min		Max				
Supply Velocity	80	fpm.	100	fpm.	Supply Velocity	95	fpm.

Individual point readings should be within +/- 20%.

					Recorded Low and High Values			
Individual Readings	76	Low	114	High	87	Low	104	High

Particulate Matter Profile

(Particle counts taken at 1 minute sample time at 1 CFM and include 0.5 micron particles and larger)

Maximum number of .5 micron size particles and above allowed for ISO Class 5 is 3520 particles per cubic meter

Average 0 | 95% UCL 0

ISO Class Achieved 5

HEPA Filter Leak Test

Adequate challenge concentration between 10 and 90 micrograms per liter. No leak should exceed 0.01% when scanned.

Upstream Concentration	N/A
Calculated Upstream Concentration	20
Number of leaks Detected	0
Number of leaks Sealed	N/A

Smoke Test

Visual Verification that the laminarity of the air is undisturbed by items in the hood and activities in the room (cross drafts). **Under Dynamic Conditions**

Induction Leak and Backstreaming Test

Verifies that the device prevents particle intrusion into the clean space by induction through joints or Backstreaming from workspace openings.

FINAL RESULTS

	Pass	Fail	N/A
Supply Air Velocity	[X]	[ ]	[ ]
Uniformity	[X]	[ ]	[ ]
Particle Counts	[X]	[ ]	[ ]
HEPA Filter Integrity Test	[X]	[ ]	[ ]
Smoke Test	[X]	[ ]	[ ]
Induction Leak / Backstreaming Test	[ ]	[ ]	[X]

000060

INSPECTION DATA

Equipment Data

	Supply HEPA Filter	Pre-Filter
1. Filter Size	(2) 36 X 48 X 6	(2) 24 X 30 X 1
2. Supply Area	10.86 sq.ft.	( ) X X
3. Supply Velocity	95 fpm.	
4. Volume	1034 cfm.	

Supply Velocity Profile

97	91	87	102	90	94	103	104
90	94	91	94	94	101	99	100
95	94	93	89	92	99	95	97

Supply Velocity Average 95

HEPA Filter Integrity Test

Zero Leaks

Particulate Matter Profile

#1	#2	#3
0	0	0

SUMMARY

MTA warrants that this air system was tested under the requirements as set forth in the following applicable standard(s):

- [ ] CAG--003-2006 v 11
- [ ] IES-RP-CC-002.3 Unidirectional-Flow, Clean-Air Devices
- [ ] Owners Specifications
- [X] Manufacturer's Specifications
- [X] ISO 14644- 1 1999 (E); Class 5 at 0.5 um size particle, Status **Operational / Dynamic**

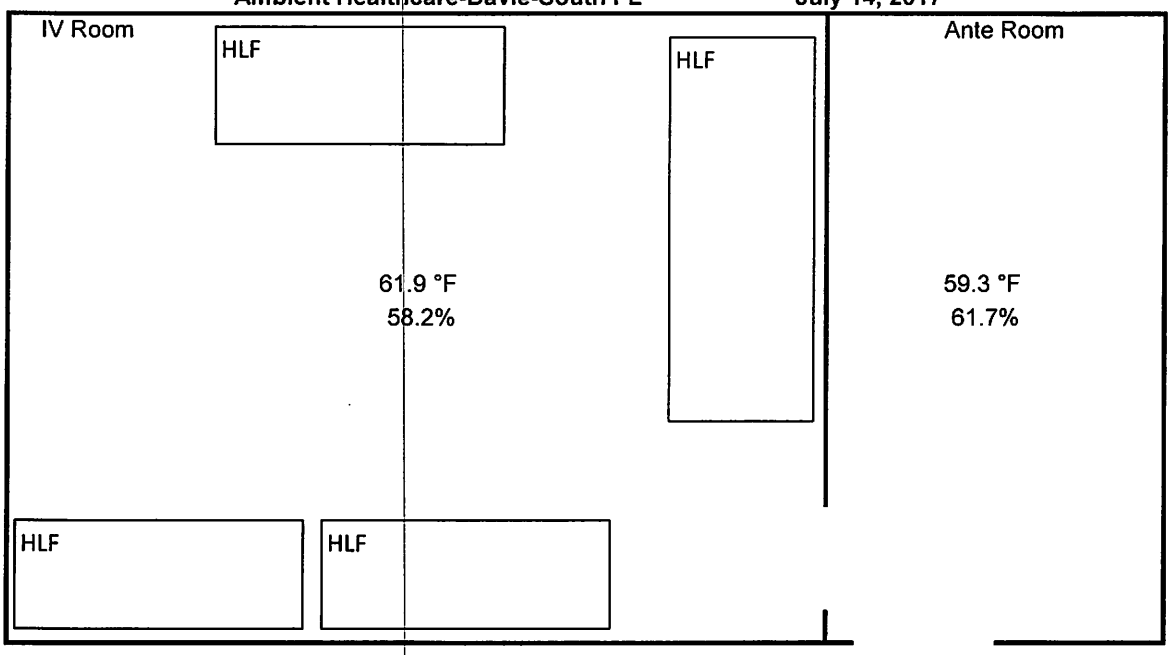
Status of System after Inspection:

- [X] Certified to the Above Applicable Standard(s).
- [ ] Undergoing Corrective Action by MTA.
- [ ] Not Certified to the Above Applicable Standard(s).
- [ ] It is Recommended that this System be Corrected by the Owner Prior to any Additional Testing.

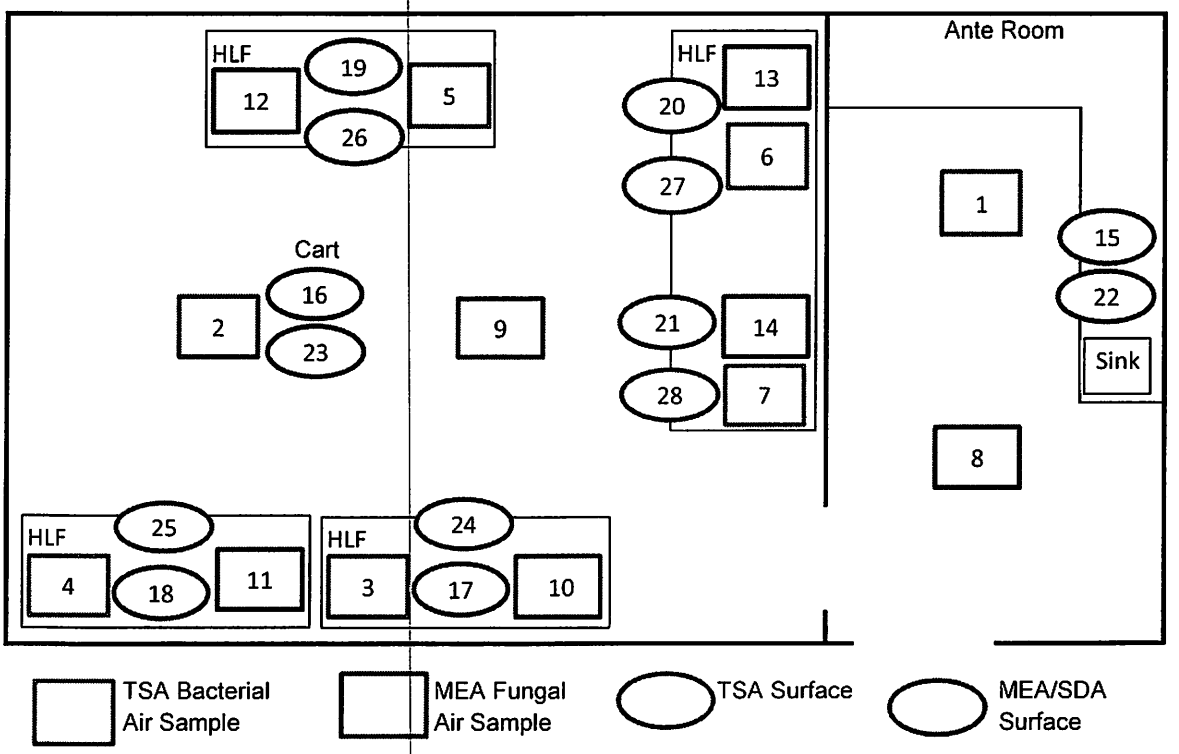
CERTIFICATE OF INSPECTION' expires 6 months from date of issue.

Medical Technology Asscoiates
6840 Cross Bayou Drive
Largo, FL 33777
Phone: (877) 569-8886
Fax: 727-548-8622

Ambient Healthcare-Davie-South FL July 14, 2017



Temperature and Humidity Readings



Viable Air Sample Locations

Month: August 2017

STERILE PRODUCTS COMPLEX
Santitation and Maintenance Log

PIC or Pharm Mgr Review: Davie

000062

	Area	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
DAILY* **																																
Disenfectant expiration date checked		MF	MF	MF	MF			MF	MF	MF	MF	MF	NS	NS	MF	MF	MF	MF	MF	NS	NS	AG	MF	AG	MF							
All counter tops, work surfaces, window sills	SPC	MF	MF	MF	MF			MF	MF	MF	MF	MF	NS	NS	MF	MF	MF	MF	MF	NS	NS	AG	MF	AG	MF							
Interior of Hoods	SPC	MF	MF	MF	MF			MF	MF	MF	MF	MF	NS	NS	MF	MF	MF	MF	MF	NS	NS	AG	MF	AG	MF							
Empty and clean waste receptacles	SPC	MF	MF	MF	MF			MF	MF	MF	MF	MF	NS	NS	MF	MF	MF	MF	MF	NS	NS	AG	MF	AG	MF							
TPN pump (cleaning)**	CR	MF	MF	MF	MF			MF	MF	MF	MF	MF	NS	NS	MF	MF	MF	MF	MF	NS	NS	AG	MF	AG	MF							
TPN pump (calibration)**	CR	MF	MF	MF	MF			MF	MF	MF	MF	MF	NS	NS	MF	MF	MF	MF	MF	NS	NS	AG	MF	AG	MF							
Compounding pump(s) (cleaning) [TPN Cmpd / Syr Filling]		MF	MF	MF	MF			MF	MF	MF	MF	MF	NS	NS	MF	MF	MF	MF	MF	NS	NS	AG	MF	AG	MF							
Compounding pump(s) (calibration) [TPN Cmpd / Syr Filling]		MF	MF	MF	MF			MF	MF	MF	MF	MF	NS	NS	MF	MF	MF	MF	MF	NS	NS	AG	MF	AG	MF							
Wire carts and tote bins	SPC	MF	MF	MF	MF			MF	MF	MF	MF	MF	NS	NS	MF	MF	MF	MF	MF	NS	NS	AG	MF	AG	MF							
Mop floor and baseboards	SPC	MF	MF	MF	MF			MF	MF	MF	MF	MF	NS	NS	MF	MF	MF	MF	MF	NS	NS	AG	MF	AG	MF							
Change Tacky Mats	SPC	MF	MF	MF	MF			MF	MF	MF	MF	MF	NS	NS	MF	MF	MF	MF	MF	NS	NS	AG	MF	AG	MF							
Pressure Gauge Reading 1 (0.02 -0.05")	CR-AR	.04	.04	.04	.03			.04	.04	.04	.04	.04	.04	.05	.04	.04	.04	.04	.04	.04	.04	.04	N/A	.04	.04							
Pressure Gauge Reading 2 (0.02 -0.05")	AR-Rx	.05	.05	.05	.04			.05	.05	.05	.05	.05	.03	.05	.06	.06	.06	.06	.06	.06	.06	.06	.06	.04	.06							
Pressure Gauge Reading 3 (0.01 -0.03").	HZ-AR																															
(Document actual reading of pressure)																																
WEEKLY (if appropriate to your location)																																
Change temperature charts	SPC																															
Disenfect waste receptalces, totes, carts	SPC																															
MONTHLY																																
All equipment, carts, etc., in SPC	SPC							MF																								
Entire SPC: **** Walls	SPC							MF																								
Ceilings	SPC							N/A																								
Lights	SPC							N/A																								
Exterior of hoods	CR-HZ							MF																								
Telephones	SPC							N/A																								
TPN pump (volumetric accuracy)								MF																								
All door handles; glass surfaces	SPC							MF																								
Hand dryer (if applicable)	AR							N/A																								
Scrub sink	AR							MF																								
Inspect and change pre-filters								MF																								
Air Sampling / Surface Sampling Completed	SPC							MF																								
Large (or small) Volume Sterility Sample																																
Cleaning equipment								MF																								
INITIALS								MF																								

**** All ledges (eg window sills, doors, cove molding) should be wiped down so that they are free of dust or any particles.
All surfaces under and behind hoods should also be inspected.

Note: Please check each task done and initial in last row

*** Daily cleaning performed at start of day on Compounding Days

** Mixing Pump cleaned/calibrated at start of day if equipment will be used

* AR = anteroom CR = Cleanroom HZ = Hazardous Drug Cmpd Room (if applicable) Rx = Pharmacy Work Area SPC = Sterile Products Complex

Cleaning Solution Used: _____

Disenfectant Expiration Date: _____

EXHIBIT #5

9580.F1

Revised: 08/2015

Month: July 2017

STERILE PRODUCTS COMPLEX
Sanitation and Maintenance Log

PIC or Pharm Mgr Review: Davie

Holiday

	Area	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
DAILY* **																																
Disenfectant expiration date checked				MF		MF	MF	MF	KD		MF	MF	MF	MF	MF			MF	MF	MF	MF	MF	MF	MF	MF	MF	MF	MF	MF	MF	MF	MF
All counter tops, work surfaces, window sills	SPC			MF		MF	MF	MF	KD		MF	MF	MF	MF	MF			MF	MF	MF	MF	MF	MF	MF	MF	MF	MF	MF			MF
Interior of Hoods	SPC			MF		MF	MF	MF	KD		MF	MF	MF	MF	MF			MF	MF	MF	MF	MF	MF	MF	MF	MF	MF	MF			MF
Empty and clean waste receptacles	SPC			MF		MF	MF	MF	KD		MF	MF	MF	MF	MF			MF	MF	MF	MF	MF	MF	MF	MF	MF	MF	MF			MF
TPN pump (cleaning)**	CR			MF		MF	MF	MF	KD		MF	MF	MF	MF	MF			MF	MF	MF	MF	MF	MF	MF	MF	MF	MF	MF			MF
TPN pump (calibration)**	CR			MF		MF	MF	MF	KD		MF	MF	MF	MF	MF			MF	MF	MF	MF	MF	MF	MF	MF	MF	MF	MF			MF
Compounding pump(s) (cleaning) [TPN Cmpd / Syr Filling]				MF		MF	MF	MF	KD		MF	MF	MF	MF	MF			MF	MF	MF	MF	MF	MF	MF	MF	MF	MF	MF			MF
Compounding pump(s) (calibration) [TPN Cmpd / Syr Filling]				MF		MF	MF	MF	KD		MF	MF	MF	MF	MF			MF	MF	MF	MF	MF	MF	MF	MF	MF	MF	MF			MF
Wire carts and tote bins	SPC			MF		MF	MF	MF	KD		MF	MF	MF	MF	MF			MF	MF	MF	MF	MF	MF	MF	MF	MF	MF	MF			MF
Mop floor and baseboards	SPC			MF		MF	MF	MF	KD		MF	MF	MF	MF	MF			MF	MF	MF	MF	MF	MF	MF	MF	MF	MF	MF			MF
Change Tacky Mats	SPC			MF		MF	MF	MF	KD		MF	MF	MF	MF	MF			MF	MF	MF	MF	MF	MF	MF	MF	MF	MF	MF			MF
Pressure Gauge Reading 1 (0.02 -0.05")	CR-AR			.04		.04	.04	.04	.04		.04	.04	.04	.04	.04			.04	.04	.04	.04	.04	.04	.04	.04	.04	.04	.04			.04
Pressure Gauge Reading 2 (0.02 -0.05")	AR-Rx			.07		.06	.06	.06	.06		.06	.06	.06	.06	.06			.06	.06	.06	.06	.06	.06	.06	.06	.06	.06	.06			.06
Pressure Gauge Reading 3 (0.01 -0.03"). (Document actual reading of pressure)	HZ-AR																															
WEEKLY (if appropriate to your location)																																
Change temperature charts	SPC																															
Disenfect waste receptalces, totes, carts	SPC																															
MONTHLY																																
All equipment, carts, etc., in SPC	SPC								KP																							
Entire SPC: **** Walls	SPC								KP																							
Ceilings	SPC								N/A																							
Lights	SPC								N/A																							
Exterior of hoods	CR-HZ								KP																							
Telephones	SPC								N/A																							
TPN pump (volumetric accuracy)									KP																							
All door handles; glass surfaces	SPC								KP																							
Hand dryer (if applicable)	AR								N/A																							
Scrub sink	AR								KP																							
Inspect and change pre-filters									KP Next change 8																							
Air Sampling / Surface Sampling Completed	SPC								KP																							
Large (or small) Volume Sterility Sample																																
Cleaning equipment									KP																							
INITIALS									KP																							

**** All ledges (eg window sills, doors, cove molding) should be wiped down so that they are free of dust or any particles.
All surfaces under and behind hoods should also be inspected.

Note: Please check each task done and initial in last row

*** Daily cleaning performed at start of day on Compounding Days

** Mixing Pump cleaned/calibrated at start of day if equipment will be used

* AR = anteroom CR = Cleanroom HZ = Hazardous Drug Cmpd Room (if applicable) Rx = Pharmacy Work Area SPC = Sterile Products Complex

Cleaning Solution Used: _____

Disenfectant Expiration Date: _____

Month: June 2017

STERILE PRODUCTS COMPLEX
Santitation and Maintenance Log

PIC or Pharm Mgr Review: Davie

DAILY***	Area	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Disenfectant expiration date checked		NS	MF			MF	MF	MF	MF	MF	NS	NS	MF	MF	MF	MF	MF	NS		MF	MF	MF	MF	MF	AG	AG	MF	MF	MF	MF	MI	
All counter tops, work surfaces, window sills	SPC	NS	MF			MF	MF	MF	MF	MF	NS	NS	MF	MF	MF	MF	MF	NS		MF	MF	MF	MF	MF	AG	AG	MF	MF	MF	MF		
Interior of Hoods	SPC	NS	MF			MF	MF	MF	MF	MF	NS	NS	MF	MF	MF	MF	MF	NS		MF	MF	MF	MF	MF	AG	AG	MF	MF	MF	MF		
Empty and clean waste receptacles	SPC	NS	MF			MF	MF	MF	MF	MF	NS	NS	MF	MF	MF	MF	MF	NS		MF	MF	MF	MF	MF	AG	AG	MF	MF	MF	MF		
TPN pump (cleaning)**	CR	NS	MF			MF	MF	MF	MF	MF	NS	NS	MF	MF	MF	MF	MF	NS		MF	MF	MF	MF	MF	AG	AG	MF	MF	MF	MF		
TPN pump (calibration)**	CR	NS	MF			MF	MF	MF	MF	MF	NS	NS	MF	MF	MF	MF	MF	NS		MF	MF	MF	MF	MF	AG	AG	MF	MF	MF	MF		
Compounding pump(s) (cleaning) [TPN Cmpd / Syr Filling]		NS	MF			MF	MF	MF	MF	MF	NS	NS	MF	MF	MF	MF	MF	NS		MF	MF	MF	MF	MF	AG	AG	MF	MF	MF	MF		
Compounding pump(s) (calibration) [TPN Cmpd / Syr Filling]		NS	MF			MF	MF	MF	MF	MF	NS	NS	MF	MF	MF	MF	MF	NS		MF	MF	MF	MF	MF	AG	AG	MF	MF	MF	MF		
Wire carts and tote bins	SPC	NS	MF			MF	MF	MF	MF	MF	NS	NS	MF	MF	MF	MF	MF	NS		MF	MF	MF	MF	MF	AG	AG	MF	MF	MF	MF		
Mop floor and baseboards	SPC	NS	MF			MF	MF	MF	MF	MF	NS	NS	MF	MF	MF	MF	MF	NS		MF	MF	MF	MF	MF	AG	AG	MF	MF	MF	MF		
Change Tacky Mats	SPC	NS	MF			MF	MF	MF	MF	MF	NS	NS	MF	MF	MF	MF	MF	NS		MF	MF	MF	MF	MF	AG	AG	MF	MF	MF	MF		
Pressure Gauge Reading 1 (0.02 -0.05")	CR-AR	.04	.04			0.06	0.04	0.05	0.05	.05	.04	.04	.03	.04	.04			.06	.06	.05	.05	.05	.05	.05	.04	0.04	.04	.01	.04	.04		
Pressure Gauge Reading 2 (0.02 -0.05")	AR-Rx	.07	0.06			0.08	0.06	0.06	0.06	.06	.07	.07	.07	.06	.06			.03	.04	.04	.04	.04	.04	.04	.04	.04	.05	.05	.05	.05		
Pressure Gauge Reading 3 (0.01 -0.03"). (Document actual reading of pressure)	HZ-AR																															
WEEKLY (if appropriate to your location)																																
Change temperature charts	SPC																															
Disenfect waste receptalces, totes, carts	SPC																															
MONTHLY																																
All equipment, carts, etc., in SPC	SPC				KP																											
Entire SPC: **** Walls	SPC																															
Ceilings	SPC																															
Lights	SPC																															
Exterior of hoods	CR-HZ																															
Telephones	SPC																															
TPN pump (volumetric accuracy)					KP																											
All door handles; glass surfaces	SPC				KP																											
Hand dryer (if applicable)	AR																															
Scrub sink	AR																															
Inspect and change pre-filters																																
Air Sampling / Surface Sampling Completed	SPC				KP																											
Large (or small) Volume Sterility Sample																																
Cleaning equipment																																
INITIALS																																

Note: Please check each task done and initial in last row

**** All ledges (eg window sills, doors, cove molding) should be wiped down so that they are free of dust or any particles.
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** Mixing Pump cleaned/calibrated at start of day if equipment will be used

* AR = anteroom CR = Cleanroom HZ = Hazardous Drug Cmpd Room (if applicable) Rx = Pharmacy Work Area SPC = Sterile Products Complex

Cleaning Solution Used: _____

Disenfectant Expiration Date: _____

9580.F1

Revised: 08/2015

590000

Month: May 2017

STERILE PRODUCTS COMPLEX
Santitation and Maintenance Log

PIC or Pharm Mgr Review: Darie

	Area	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
DAILY* **																																
Disenfectant expiration date checked		RS	RJ	AG	RJ	RJ	RJ	RJ	AG	AG	AG	NS	AG	NS	NS	RJ	NS	AG	NS	NS			RS	RJ	MF	MF	MF	AG	AG	NS	MF	MF
All counter tops, work surfaces, window sills	SPC	RS	RJ	AG	RJ	RJ	RJ	RJ	AG	AG	AG	NS	AG	NS	NS	RJ	NS	NS	NS	NS			RS	RJ	MF	MF	MF	AG	AG	NS	MF	MF
Interior of Hoods	SPC	RS	RJ	AG	RS	RJ	RJ	RJ	AG	AG	AG	NS	AG	NS	NS	RJ	NS	AG	NS	NS			RJ	RJ	MF	MF	MF	AG	AG	AG	MF	MF
Empty and clean waste receptacles	SPC	RS	RJ	AG	RJ	RJ	RJ	RJ	AG	AG	AG	NS	AG	NS	NS	RJ	NS	AG	NS	NS			RJ	RJ	MF	MF	MF	AG	AG	AG	MF	MF
TPN pump (cleaning)**	CR	RJ	RJ	AG	RJ	RJ	RJ	RJ	AG	AG	AG	NS	AG	NS	NS	RJ	NS	AG	NS	NS			RJ	RJ	MF	MF	MF	AG	AG	AG	MF	MF
TPN pump (calibration)**	CR	RS	RJ	AG	RJ	RS	RJ	RJ	AG	AG	AG	NS	AG	NS	NS	RJ	NS	AG	NS	NS			RJ	RJ	MF	MF	MF	AG	AG	AG	MF	MF
Compounding pump(s) (cleaning) [TPN Cmpd / Syr Filling]		RJ	RJ	AG	RJ	RS	RJ	RJ	AG	AG	AG	NS	AG	NS	NS	RJ	NS	AG	NS	NS			RJ	RJ	MF	MF	MF	AG	AG	AG	MF	MF
Compounding pump(s) (calibration) [TPN Cmpd / Syr Filling]		RJ	RJ	AG	RS	RS	RJ	RJ	AG	AG	AG	NS	AG	NS	NS	RJ	NS	AG	NS	NS			RS	RJ	MF	MF	MF	AG	AG	AG	MF	MF
Wire carts and tote bins	SPC	RJ	RJ	AG	RS	RS		RJ	AG	AG	AG	NS	AG	NS	NS	RJ	NS	AG	NS	NS			RJ	RJ	MF	MF	MF	AG	AG	AG	MF	MF
Mop floor and baseboards	SPC	RJ	RJ	AG	RS	RS	RJ	RJ	AG	AG	AG	NS	AG	NS	NS	RJ	NS	AG	NS	NS			RJ	RJ	MF	MF	MF	AG	AG	AG	MF	MF
Change Tacky Mats	SPC	RJ	RJ	AG	RJ	RJ	RJ	RJ	AG	AG	AG	NS	AG	NS	NS	RJ	NS	AG	NS	NS			RJ	RJ	MF	MF	MF	AG	AG	AG	MF	MF
Pressure Gauge Reading 1 (0.02 -0.05")	CR-AR	.04	.04	.03	.04	.04	.04	.04	.03	.05	.07	.07	.05	.07	.07	.04	.07	.05	.07	.07			.07	.07	.07	.04	.04	.05	.04	.05	.04	.04
Pressure Gauge Reading 2 (0.02 -0.05")	AR-Rx	.065	.065	.05	.065	.06	.05	.055	.05	.05	.05	.05	.03	.039	.033	.055	.032	.05	.03	.03			.03	.06	.05	.05	.07	.05	.07	.07	.04	.04
Pressure Gauge Reading 3 (0.01 -0.03"). (Document actual reading of pressure)	HZ-AR																															
WEEKLY (if appropriate to your location)																																
Change temperature charts	SPC																															
Disenfect waste receptalces, totes, carts	SPC																															
MONTHLY																																
All equipment, carts, etc., in SPC	SPC	KP																														
Entire SPC: **** Walls	SPC	KP																														
Ceilings	SPC																															
Lights	SPC																															
Exterior of hoods	CR-HZ																															
Telephones	SPC																															
TPN pump (volumetric accuracy)																																
All door handles; glass surfaces	SPC	KP																														
Hand dryer (if applicable)	AR																															
Scrub sink	AR																															
Inspect and change pre-filters																																
Air Sampling / Surface Sampling Completed	SPC	KP																														
Large (or small) Volume Sterility Sample																																
Cleaning equipment																																
INITIALS		KP																														

**** All ledges (eg window sills, doors, cove molding) should be wiped down so that they are free of dust or any particles.
All surfaces under and behind hoods should also be inspected.

*** Daily cleaning performed at start of day on Compounding Days

** Mixing Pump cleaned/calibrated at start of day if equipment will be used

* AR = anteroom CR = Cleanroom HZ = Hazardous Drug Cmpd Room (if applicable) Rx = Pharmacy Work Area SPC = Sterile Products Complex

Note: Please check each task done and initial in last row

Cleaning Solution Used: _____

Disenfectant Expiration Date: _____

9580 F1

Revised: 08/2015

Month: April 2017

STERILE PRODUCTS COMPLEX
Santitation and Maintenance Log

PIC or Pharm Mgr Review: Davie

990000

	Area	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
DAILY* **																																
Disenfectant expiration date checked		RJ	RS	AG	RJ		RJ	RJ							NS	NS	NS	KP	NS	NS	NS	NS	AG	AG	AG	AG	AG	NS	AG	KP	KP	
All counter tops, work surfaces, window sills	SPC	RJ	RS	AG	RS		RJ	RJ							NS	NS	NS	KP	NS	NS	NS	NS	AG	AG	AG	AG	AG	NS	AG	KP	KP	
Interior of Hoods	SPC	RJ	RJ	AG	RJ		RJ	RJ							NS	NS	NS	KP	NS	NS	NS	NS	AG	AG	AG	AG	AG	NS	AG	KP	KP	
Empty and clean waste receptacles	SPC	RJ	RJ	AG	RJ		RJ	RJ							NS	NS	NS	KP	NS	NS	NS	NS	AG	AG	AG	AG	AG	NS	AG	KP	KP	
TPN pump (cleaning)**	CR	RJ	RJ	AG	RJ		RJ	RJ							NS	NS	NS	KP	NS	NS	NS	NS	AG	AG	AG	AG	AG	NS	AG	KP	KP	
TPN pump (calibration)**	CR	RJ	RJ	AG	RJ		RJ	RJ							NS	NS	NS	KP	NS	NS	NS	NS	AG	AG	AG	AG	AG	NS	AG	KP	KP	
Compounding pump(s) (cleaning) [TPN Cmpd / Syr Filling]		RJ	RJ	AG	RJ		RJ	RJ							NS	NS	NS	KP	NS	NS	NS	NS	AG	AG	AG	AG	AG	NS	AG	KP	KP	
Compounding pump(s) (calibration) [TPN Cmpd / Syr Filling]		RJ	RJ	AG	RJ		RJ	RJ							NS	NS	NS	KP	NS	NS	NS	NS	AG	AG	AG	AG	AG	NS	AG	KP	KP	
Wire carts and tote bins	SPC	RJ	RJ	AG	RJ		RJ	RJ							NS	NS	NS	KP	NS	NS	NS	NS	AG	AG	AG	AG	AG	NS	AG	KP	KP	
Mop floor and baseboards	SPC	RJ	RJ	AG	RJ		RJ	RJ							NS	NS	NS	KP	NS	NS	NS	NS	AG	AG	AG	AG	AG	NS	AG	KP	KP	
Change Tacky Mats	SPC	RJ	RJ	AG	RJ		RJ	RJ							NS	NS	NS	KP	NS	NS	NS	NS	AG	AG	AG	AG	AG	NS	AG	KP	KP	
Pressure Gauge Reading 1 (0.02 -0.05")	CR-AR	—	—	—	—		—	—							—	—	—	.04	—	.04	.04	.04	.03	.03	.03	.04	.04	.04	.04	.04	.04	
Pressure Gauge Reading 2 (0.02 -0.05")	AR-Rx	.06	.07	.09	.06		.06	.06							.06	.07	.06	.07	.07	.07	.07	.07	.10	.10	.13	.07	.09	.07	.07	.07	.07	
Pressure Gauge Reading 3 (0.01 -0.03")	HZ-AR																															
(Document actual reading of pressure)																																
WEEKLY (if appropriate to your location)																																
Change temperature charts	SPC																															
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MONTHLY																																
All equipment, carts, etc., in SPC	SPC																															
Entire SPC: **** Walls	SPC																															
Ceilings	SPC																															
Lights	SPC																															
Exterior of hoods	CR-HZ																									AG						
Telephones	SPC																									—						
TPN pump (volumetric accuracy)																										AG						
All door handles; glass surfaces	SPC																									AG						
Hand dryer (if applicable)	AR																									—						
Scrub sink	AR																									AG						
Inspect and change pre-filters																										—						
Air Sampling / Surface Sampling Completed	SPC																									AG						
Large (or small) Volume Sterility Sample																										KP						
Cleaning equipment																										AG						
INITIALS																										AG						

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* AR = anteroom CR = Cleanroom HZ = Hazardous Drug Cmpd Room (if applicable) Rx = Pharmacy Work Area SPC = Sterile Products Complex

Note: Please check each task done and initial in last row

Cleaning Solution Used: _____

Disenfectant Expiration Date: _____

"CONFIDENTIAL INFORMATION"

ISU LABELED/SEALED CD

RECORDS SEALED*

Patient records which identify patient by name are sealed pursuant to Section 456.057(9)(a), Florida Statutes.

CASES NO.: PH 2017-15122 & 2017-15123_ _____

SUBJECT: AMBIENT HEALTHCARE & ENRIQUE HERNANDEZ, R Ph_____

INVESTIGATOR: SYLMA STINSON_____

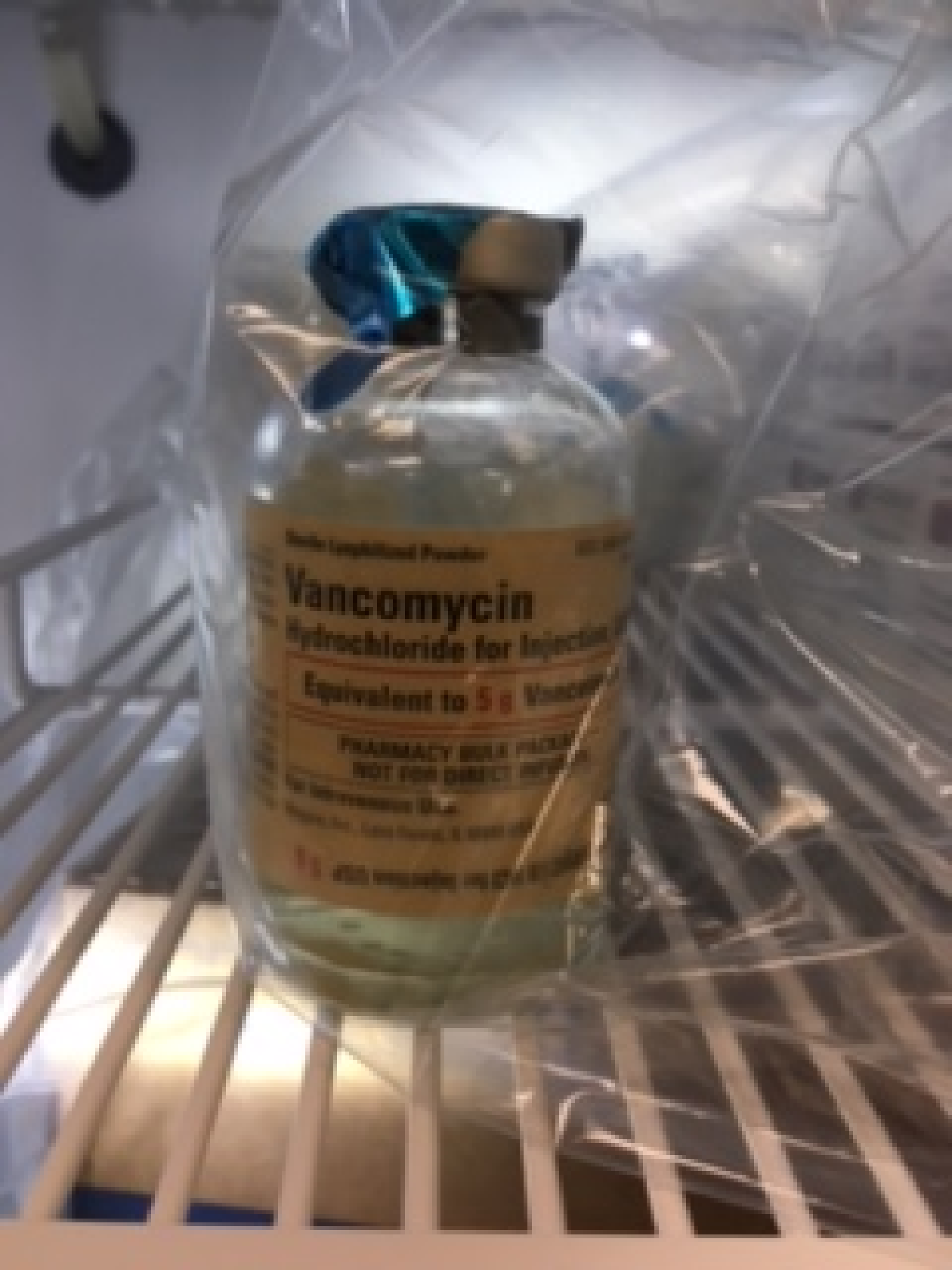
EXHIBIT : # – One (1) CD containing Twenty (20) pictures taken during pharmacy inspection, from the Inspector

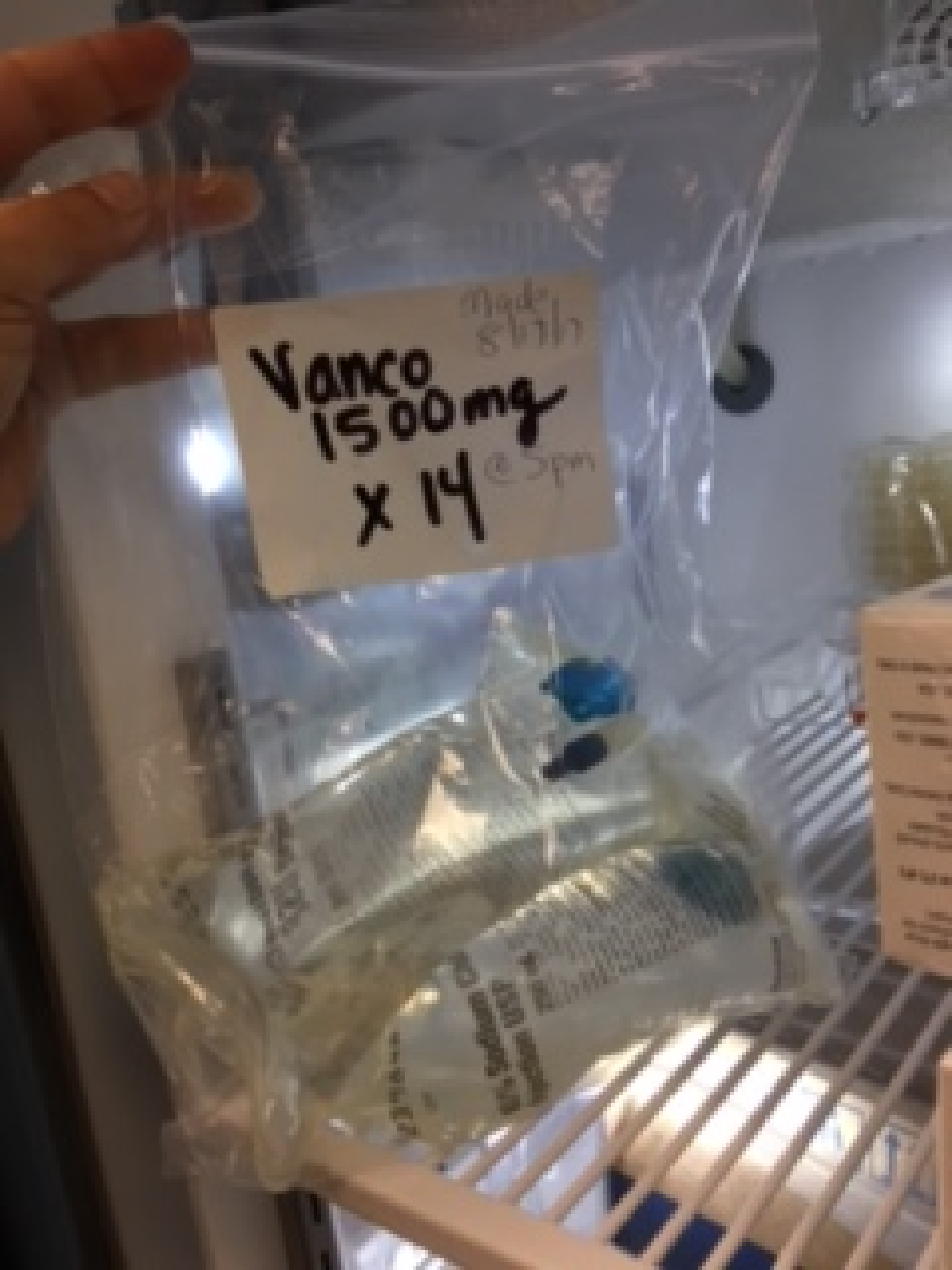
THE CD WILL BE FORWARDED IN A SEPARATE PACKAGE TO PSU, VIA FEDERAL EXPRESS.

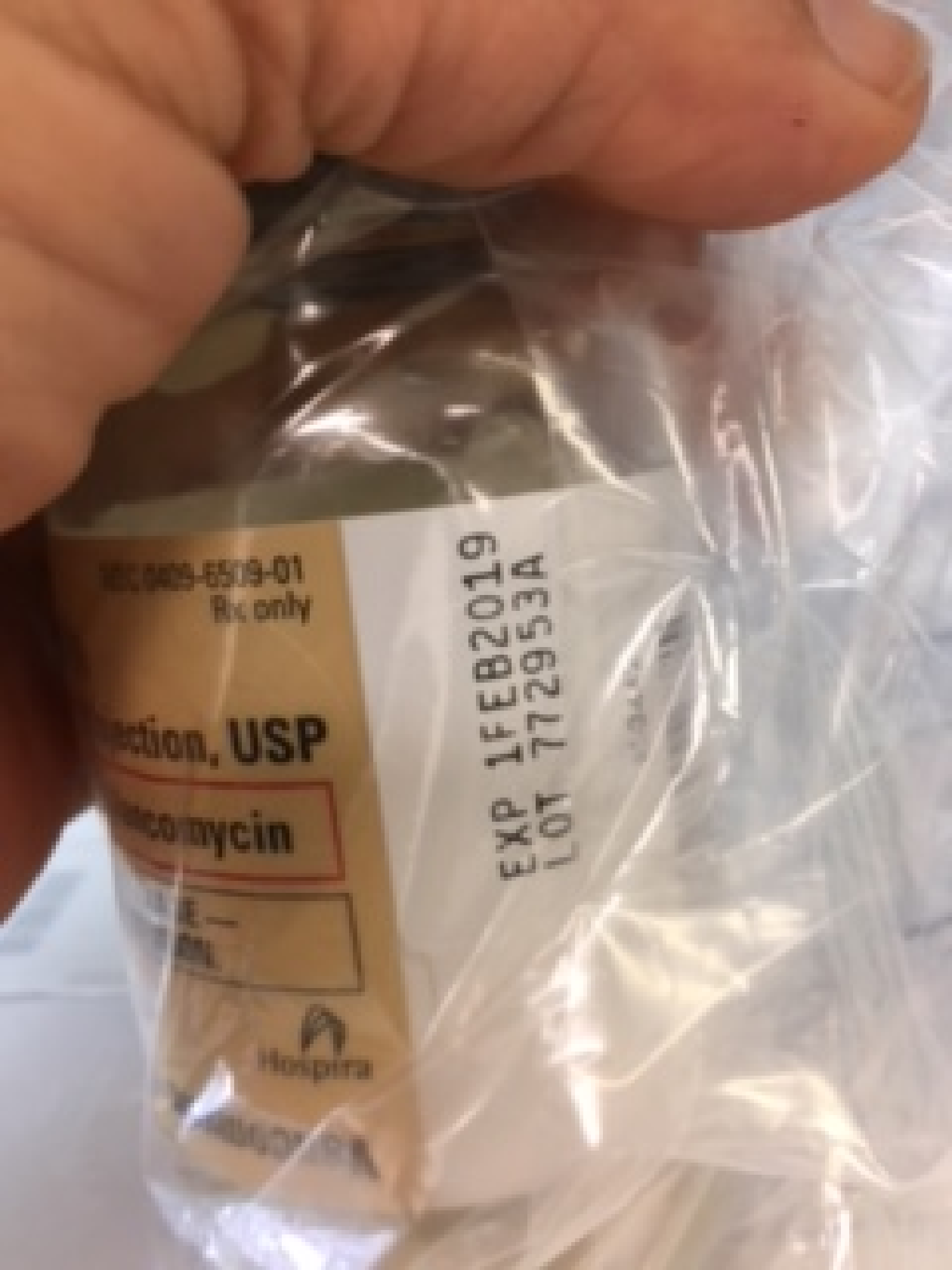
PAGES:

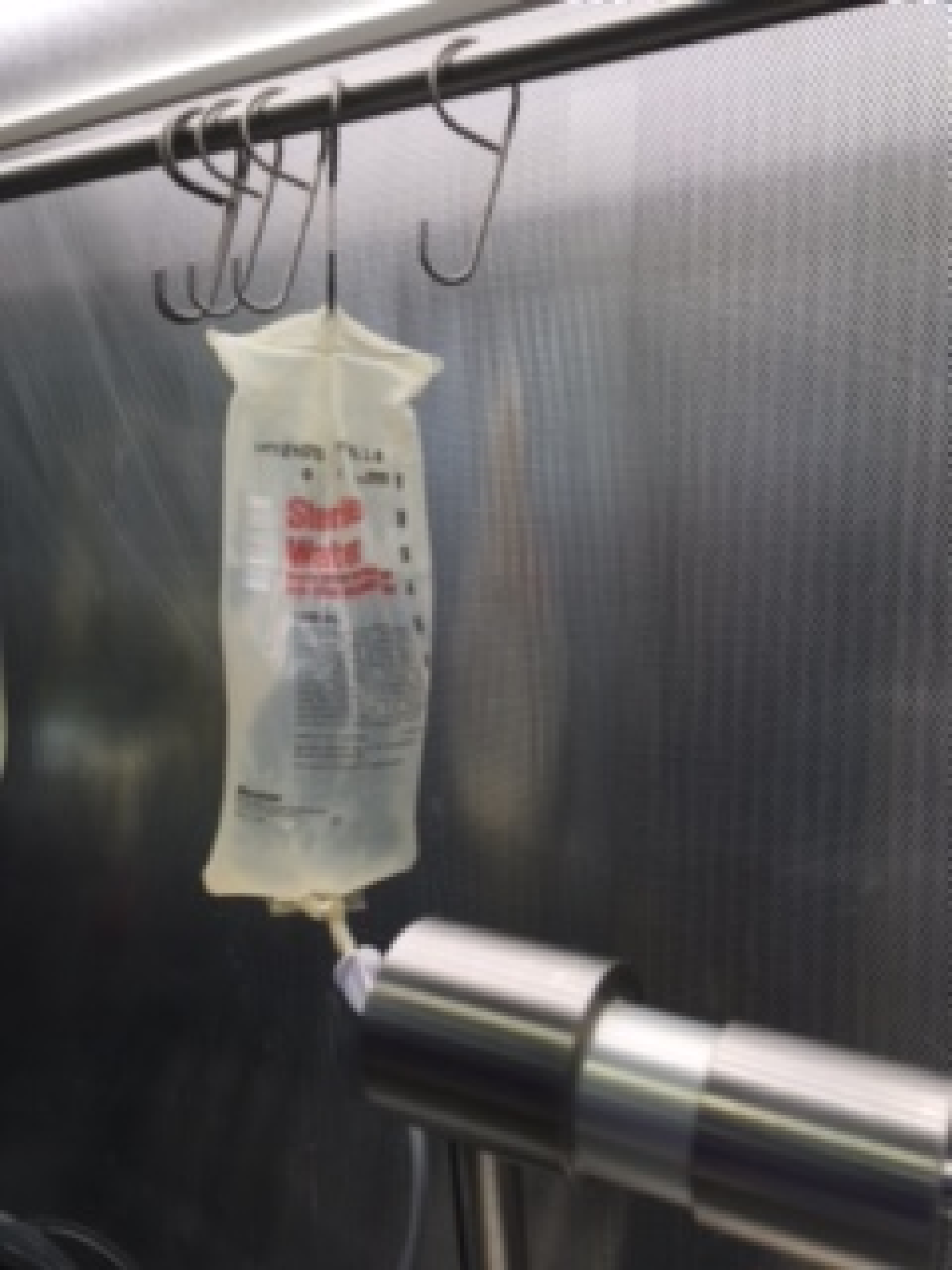
*See (1) CD in Exhibit #

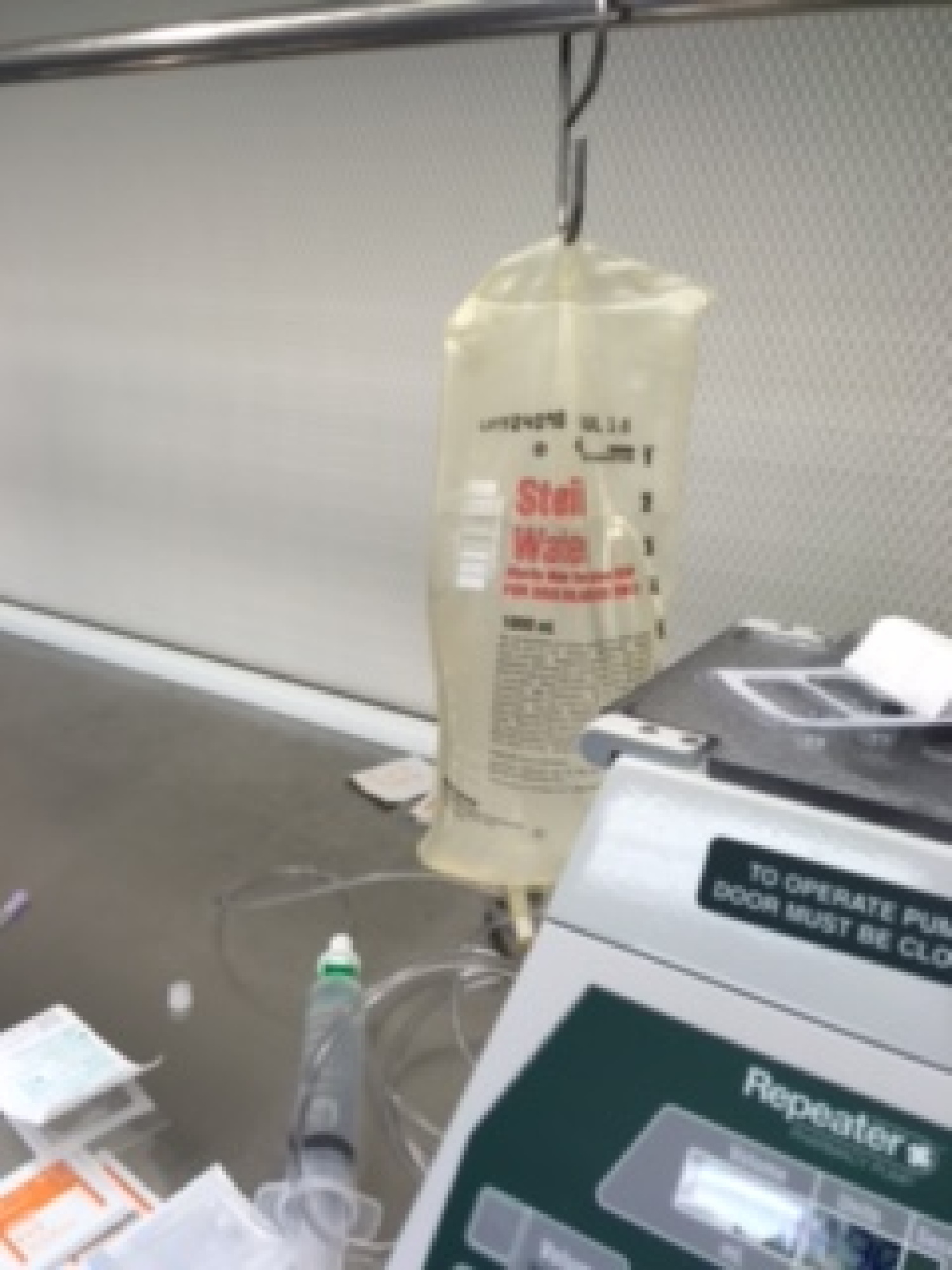
2017-15122, AMBIENT HEALTHCARE OF FLA.
2017-15123 ENRIQUE HERNANDEZ, APH
20 Pictures of Pharmacy Inspection
From Inspector
STAPLES
DVD-R
120 minutes
4.7 GB
www.product-supp
6x speed
6x compatible
aples.com


Vancomycin


Vanco
1500mg
x 14


Rx only
ction, USP
Hospira
EXP 1FEB2019
LOT 7729534




Steri
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DOOR MUST BE CLO
Repeater

SUBJECT:	Maintenance of the Sterile Products Complex	REFERENCE #:	9580
DEPARTMENT	Pharmacy Operations	EFFECTIVE DATE:	01/01/2015
APPROVED BY:	VP Pharmacy Operations	REVIEWED DATE:	09/11/2014 08/30/2017
		APPROVED DATE:	10/26/2014
REVISIONS:		REVISION DATE:	04/15/2015 05/15/2015 08/14/2015 06/06/2016 01/03/2017 02/01/2017 08/31/2017

SCOPE

This policy and procedure applies to pharmacies or other entities under the ownership or control of BriovaRx Infusion Services (the Company).

PURPOSE

To provide guidelines for the proper cleaning and maintenance of the sterile products complex including the ante room, hazardous drug compounding room (if applicable) and cleanroom.

POLICY

1. Cleaning and disinfection procedures will follow requirements set forth by USP <797> and the State Board of pharmacy.

2. Pharmacists and/or technicians will clean and disinfect the direct compounding area (s) in accordance with USP <797> guidelines and as per the procedures outlined below.

3. Only approved cleaning solutions shall be used for disinfects. Expiration dates of cleaning solutions shall follow USP <797> and CDC guidelines.
    - A. Approved disinfects are as follows:
        - CLOROX® ONE STEP GERMICIDAL CLEANER
        - PREEMPT® RTU DISINFECTANT SOLUTION
        - SPORICIDIN® DISINFECTANT SOLUTION
        - PERIDOX® RTU SPORICIDAL DISINFECTANT
        - CONFLIKT® (May be used in place of Lophene and Cidecon in Calif.)

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EXHIBIT #7

4. Solutions utilized for cleaning and disinfection can be rotated in accordance with USP <797> guidelines.

5. Disinfectant agents will have a broad spectrum of coverage including bacterial, viral, fungal, spore and tuberculocidal activity.

6. Manufacturer guidelines for surface contact times will be followed. See Attachment 9580A1 for dwell times.

7. The rotation of an effective sporicidal is encouraged (bleach). It is prudent to augment the daily use of a bactericidal disinfectant with weekly or monthly use of a sporicidal agent. The daily application of sporicidal agents is not generally favored because of their tendency to corrode equipment and because of the potential safety issues with chronic operator exposure. Other disinfectant rotation schemes may be supported on the basis of a review of the historical environmental monitoring history.

8. A list of USP 797 approved disinfectant solutions can be found in Appendix II of the USP Compendium. Only Ready to Use (RTU) solutions should be used. A list of available RTU solutions can be found on the MSD product list, under the USP 797 tab. (Intranet > Pharmacy > Purchasing > MSD > USP 797). If a bleach solution is used, it should be followed by a residue-free disinfecting agent such as sterile 70% isopropyl alcohol as bleach does not remove all proteins.

9. A log shall be kept documenting the date and initials of the pharmacist or technician who performed the cleaning.

10. No cleaning operations are to be performed during compounding.

11. The sterile products complex will be cleaned following any certification, relocation or re-arrangement of PECs, repairs or power outages.

12. Equipment/materials:

   a. Sponge mop/bucket appropriately labeled for the floors of the workroom and the compounding room. Mops are to be stored off the floor on dedicated hooks

   b. Bucket, mops and squeegee appropriately labeled for the walls, cabinets, sink, etc., of the gowning room, workroom, and compounding.

   c. Ideally, disposable mop heads shall be used and discarded per manufacturer's recommendations. Should non-disposable mop heads be used, they will be discarded weekly and replaced by a new mop-head.

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d. Tacky roll mop or equivalent.

e. Cleaning agents. All solutions should be available in ready to use formulations (RTU). (See MSD product list under USP 797 tab)

PROCEDURE

1. Daily Maintenance and Cleaning Schedule

   a. Record date and time of observation

   b. Record temperatures

   c. Record SPC room pressure differentials

   d. Clean and disinfect all work surfaces within the direct compounding area (DCA), such as bars, hooks, counter tops, etc., at the beginning and end of each shift and just prior to commencing sterile compounding activities, not longer than 30 minutes following the previous surface disinfection when ongoing compounding activities are occurring, after spills, and when surface contamination is known or suspected.

      1) First, the surface shall first be cleaned with sterile water for irrigation or injection to remove proteins and residue,

      2) Then sterile 70% isopropyl alcohol shall be used for disinfection.

   e. Totes dedicated to the cleanroom and staging room shall be wiped down with 70% isopropyl alcohol before entering the cleanroom.

   f. Other surfaces in the clean room to be cleaned daily, and as needed: clean room floor, counters, door handles, window sills and ledges and other easily cleanable work surfaces.

   g. Waste receptacles shall be emptied, cleaned daily and as needed.

   h. Gowning/Ante Room

      1) Clean floor
      2) Empty all waste receptacles
      3) Clean sink, hand dryer and soap dispenser
      4) Clean door and window with 70% Isopropyl Alcohol
      5) Change tacky mat

   i. Floors: Mop to remove all dirt, dust or debris. Assure the area along baseboards and corners are thoroughly cleaned.

   j. All equipment located in the clean room and/or ante room will be cleaned daily.

2. Weekly Maintenance and Cleaning Schedule

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a. Change any required temperature logs

b. Any weekly cleaning the branch deems necessary to maintain the integrity of the sterile complex.

c. Any State Board of Pharmacy required weekly cleaning.

3. Monthly Maintenance and Cleaning Schedule

   a. Walls, ceilings and storage shelves are cleaned monthly (**weekly for California Pharmacies**) and as necessary. The order of cleaning will be as follows:

      1) Compounding rooms

      2) Gowning/Ante room

   b. Within each room the following order of cleaning will be followed:

      1) The ceiling will be cleaned first (when scheduled) starting at a point farthest from the door toward the door.

      2) The walls will be cleaned next starting from the wall farthest from the door.

   c. Storage shelves will be emptied and cleaned and disinfected monthly and as needed.

   d. Any bins or totes need to be emptied, cleaned and disinfected monthly and as needed.

   e. All cleaning activity is to be recorded on the cleaning logs and stored with Pharmacy QA/QC records.

4. Identify the disinfectant used as well as its expiration date on the cleaning log.

5. As part of the monthly maintenance schedule the pharmacy shall perform passive air and surface sampling; please reference policy 9701 Environmental Monitoring for specific information.

6. As part of monthly maintenance schedule the pharmacy shall perform based on types of patients compounded a large volume or small volume parenteral end-product testing; please reference policy 9621 Admixture End product sterility testing for specific information.

7. The Pharmacist-in-Charge (PIC) or Pharmacy Manager to review and sign/date each month.

EXHIBITS/ATTACHMENTS

9580A1 Disinfectant dwell times

FORMS

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9580F1 Log SPC Sanitation and Maintenance Log
9580F2 Log SPC Sanitation and Maintenance Log (CA) (optional)

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SUBJECT:	Maintenance of Primary Engineering Controls (PECs)	REFERENCE #:	9581
DEPARTMENT	Pharmacy Operations	EFFECTIVE DATE:	01/01/2015
APPROVED BY:	VP Pharmacy Operations	REVIEWED DATE:	09/12/2014
		APPROVED DATE:	10/26/2014
REVISIONS:		REVISION DATE:	04/15/2015 04/28/2016 01/03/2017

SCOPE

This policy and procedure applies to pharmacies or other entities under the ownership or control of BriovaRX Infusion (the Company).

PURPOSE

To establish standards regarding the cleaning and maintenance of primary engineering controls (PECs) to ensure the integrity of the HEPA filters and to minimize the introduction of particles or microbial flora into the compounded sterile parenteral product.

DEFINITIONS

Primary Engineering Control (PEC): A device or room that provides an ISO Class 5 environment for the exposure of critical sites when compounding CSPs. Such devices include, but may not be limited to, laminar airflow workbenches (LAFWs) or horizontal laminar airflow hoods, biological safety cabinets (BSCs), compounding aseptic isolators (CAIs), and compounding aseptic containment isolators (CACIs).

Biological Safety Cabinet (BSC):- A ventilated cabinet for CSPs, personnel, product, and environmental protection having an open front with inward airflow for personnel protection, downward high-efficiency particulate air (HEPA)-filtered laminar airflow for product protection, and HEPA-filtered exhausted air for environmental protection.

Compounding Aseptic Containment Isolator (CACI): A form of isolator specifically designed for compounding pharmaceutical ingredients or preparations. It is designed to maintain an aseptic compounding environment within the isolator throughout the compounding and material transfer processes. Air exchange into the isolator from the surrounding environment should not occur unless the air has first passed through a microbial retentive filter (HEPA minimum).[reference: CETA Applications Guide for the Use of Compounding Isolators in Compounding Sterile Preparations in Healthcare Facilities, CAG-001-2005, Controlled Environment Testing Association (CETA), November 8, 2005.]

ADDITIONAL RESOURCES

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ISO 14644-1:1999 Cleanrooms and associated controlled environments -- Part 1: Classification of air cleanliness

ISO 14644-2:2000 Cleanrooms and associated controlled environments -- Part 2: Specifications for testing and monitoring to prove continued compliance with ISO 14644-1

POLICY

1. Standards shall be compliant with USP <797> guidelines.

2. Infusion guidelines will be established regarding the type of flow hood to be used for specific parenteral products

3. The type of compounding performed dictates the type of flow hood that is to be utilized.

4. A traditional horizontal laminar flow hood, laminar airflow workbench or CACI can be used to compound parenteral nutrition solutions, large volume parenterals (LVP) with IV additives and any small volume parenterals. Ideally the PEC is located in a positive pressure room.

5. Antineoplastic/cytotoxic drugs are not to be compounded in a horizontal flow hood.

6. At a minimum a Class II Type A, biological safety cabinet (BSC) is to be used for the compounding of all cytotoxic agents. Ideally located in a negative pressure room.

7. Clean room area is to be designated to restrict access, decrease disturbances in the airflow and reduce the introduction of particles to the area. Only authorized, trained staff should be permitted access.

8. All PECs in the clean room should remain operational 24 hours a day to prevent airborne microbial and particulate contamination of the HEPA filters and work surfaces.

9. The PEC will be cleaned following any certification, relocation or re-arrangement of PECs, repairs or power outages.

PROCEDURE

1. Air Sampling:

    a. Air sampling will be performed in areas most prone to contamination during compounding activities. Sampling activities will be done such that a sufficient volume of air (400 – 1000 liters) shall be tested.

    b. Air quality sampling will be completed by a certified outside agency every 6 months, in accordance with USP <797> guidelines, for sterile compounding areas used to low- and medium-risk preparations. Testing will include viable air sampling

2. Maintenance Requirements and General Information

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a. The pre-filters in the horizontal flow hoods (i.e. cabinet type PEC) should be changed monthly, or more frequently if necessary due to working conditions. This is to be documented on the appropriate clean room maintenance form.

b. Objects are NEVER to be inserted into the hood grill.

c. The HEPA filter in the PECs must be replaced and disposed of by a qualified company that is certified to perform this activity. The BSC will be recertified after each filter change.

d. When compounding, care must be exercised to prevent spills, squirting or aerosolized products from coming in contact with the HEPA filter area. When expressing air from a syringe, NEVER point the syringe toward the HEPA filter.

e. Monitoring of infection-related readmissions and staff validation failures must be performed on an ongoing basis to identify unexplained or sudden HEPA filter failures. If a potential trend of identified relationship is suspected between infection or staff validation failures, the flow hood must be immediately recertified to ensure that the flow hood is not the cause.

f. Leave the PEC blower operating at all times. If the PEC blower must be turned off, compounding is not performed until the blower is turned on and operating for 30 minutes and all internal surfaces are cleaned thoroughly with a disinfectant.

3. Certification of Primary Engineering Controls (PECs)

a. PECs are tested and certified semi-annually (i.e. every six months) or applicable state Board of Pharmacy regulations

b. PECs will be recertified when:

1) In the event the flow hood/BSC is relocated;

2) There is the possibility the filter is damaged or its integrity is in question; or

3) There is consistent failure by different staff of the flow hood validation tests requires immediate recertification

c. Testing and certification are performed by an independent testing agency. Certification procedures such as those outlined in the CETA certification Guide for Sterile Compounding Facilities (CAG-003-2006) shall be used.

d. Minimal Tests:

HEPA filter leak test by polydispersed dioctylphthalate (DOP) particles
Velocity profile test
Air Volume test
Face velocity test
Airflow smoke patterns test
Smoke intrusion/induction test

Particle count
Viable air sampling including identification of colony growth

e. The certificate issued by the independent testing agency is prominently displayed in the pharmacy.

f. Certification reports are permanently retained in a readily retrievable file

4. Infection Control:

a. The interior surfaces of the BSC and laminar flow hoods should be cleaned thoroughly with disinfectant solution at the start of each workday, once every shift and as needed. Follow this procedure:

b. The panels in the horizontal laminar airflow hoods, CACI or laminar airflow workbenches should be cleaned from top to bottom and from back to front, using side-to side overlapping strokes, in the following manner:

- Top panel of the hood or cabinet (ceiling)
- Back panel of the hood or cabinet or plastic panel
- Bar and hangers
- Side panels of the hood or cabinet or plastic panels
- Work surface (bench)

c. The flow hood surfaces must be cleaned immediately after spills, and as needed with a clean tightly woven, solid wipe.

d. Non-shedding cloths used to clean hood surfaces shall be discarded after use.

5. Biological Safety Cabinet Decontamination and Cleaning:

a. The BSC should be cleaned and decontaminated on a regular basis, depending on the frequency of use and whenever there is a spill or the BSC is serviced or moved. Typically once monthly for low volume chemo compounding and once weekly for high volume chemo compounding. Only individuals involved in the decontamination should be in the clean room at the time of decontamination.

b. Decontamination of a BSC is limited to removal of contamination from a non-disposable surface (cabinet) to a disposable surface (gauze). It is recommended to use an agent such as “Surface Safe” to inactivate any hazardous drug, followed by sterile water to remove the contamination, followed by sterile alcohol to disinfect the surfaces.

c. During decontamination, the operator will wear a disposable, closed-front gown, disposable latex or allergy resistant gloves covered by disposable utility gloves, safety goggles and a disposable respirator. The area blower must be running during this time period.

d. Decontamination should be done from the top to bottom (areas of lesser contamination to greater). Never spray anything into the HEPA filter.

e. The work tray, drain spillage area and HEPA filter front grille should all be thoroughly cleaned. The work tray can be lifted and placed against the back wall for cleaning of the undersurface of the tray and bottom spillage area of the BSC. Both sides of the HEPA filter front grilled can be cleaned by removing the grille. Never touch the HEPA filter or expose the filter to water.

f. All areas must be cleaned with disinfectant solution. If a cleaning agent other than water is used, rinse with sterile water.

g. Upon completion, all items used to decontaminate the BSC should be disposed of according to hazardous waste policies and procedures.

h. After cleaning and decontaminating the BSC must sit for 30 minutes before commencement of compounding.

RECORDS

Pharmacy QA maintenance records

FORMS

Clean room maintenance forms

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SUBJECT:	Environmental Monitoring	REFERENCE #:	9701
DEPARTMENT	Pharmacy Operations	EFFECTIVE DATE:	01/01/15
APPROVED BY:	VP Pharmacy Operations	REVIEWED DATE:	09/12/14 05/29/17 08/31/17
		APPROVED DATE:	11/26/14
REVISIONS:		REVISION DATE:	01/13/2017 06/01/2017 08/31/2017

SCOPE

This policy and procedure applies to pharmacies or other entities under the ownership or control of BriovaRx Infusion Services (the Company).

PURPOSE

To establish guidelines regarding the conditions to be maintained in the compounding environment and the routine testing and measuring to ensure the quality of the compounding environment.

POLICY

1. All clean room equipment used in the provision of patient care is to be used, maintained and monitored in accordance with manufacturer guidelines.

2. Cleanroom and anteroom areas shall be ventilated in accordance with USP <797> guidelines.

3. The blowers of LAFWs, BSCs or CACIs will be kept on 24 hours per day.

   If blower is turned off, it must be on for a minimum of 30 minutes before a compounding session takes place.

4. The Sterile Products Complex and Primary Engineering Controls (PECs) will be certified every 6 months by a qualified, independent, 3rd party contractor. The contracting certification company will certify the sterile complex based on the CETA CAG-003-2006 Certification Guide for Sterile Compounding Facilities. **The minimum tests performed will be defined by USP <797>. A list of the minimum tests performed can be found in the attached "Exhibit A" at the end of this policy**.

5. Company contracted Certification Company will provide a detailed report to the Pharmacy Manager and Pharmacy clinical services within 14 days of SPC testing. Any tests reported as falling outside minimum requirements of test area, or identified as failing, will have a detailed remediation plan established immediately by the Clinical Pharmacy department and activity completed by the Pharmacy manager. Remediation plans will include activity outlined in the procedure section of this

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policy and may include additional activity as necessary, i.e., new equipment, room modifications, etc. All follow-up testing will be scheduled by the Pharmacy manager and remediation report provided and reviewed within 14 days.

6. Passive air sampling and surface testing will be conducted monthly in pharmacies that perform only low and medium-risk compounding and weekly for pharmacies that perform high-risk compounding.

7. Newly constructed and remodeled cleanrooms will be triple cleaned prior to a full sterile complex certification by a qualified 3rd party contractor. After the certification is complete, passive air and surface sampling will be performed daily for 3 consecutive days by branch staff. NO STERILE COMPOUNDING WILL BE PERFORMED UNTIL PRELIMINARY RESULTS ARE OBTAINED FROM THE CERTIFIER AND RESULTS FROM THE PASSIVE AIR AND SURFACE SAMPLING ARE REVIEWED AND DEEMED ACCEPTABLE.

8. Sampling sites should include locations within ISO Class 5, ISO Class 7 and ISO Class 8 areas

9. The SPC environment will be monitored for temperature, pressure and humidity.

10. Medication storage areas, including refrigerators and freezers will be monitored for temperature

11. Automated compounding devices (ACD) will be monitored for accuracy

PROCEDURE

1. Ideally, all temperature, pressure and humidity monitoring should be automated (i.e., continuous monitoring) or monitored by an outside vendor such as the branch's security company. Pharmacist in Charge may delegate temperature excursion notifications and daily monitoring, however they are ultimately responsible for review of the temperature log and instituting appropriate action if an excursion is identified.

2. Temperature Monitoring

   a. Accepted ranges for temperatures are as follows:

1)	Room Temperature:	15°C to 30°C (59°F to 86°F)
2)	Controlled Room Temperature:	20°C to 25°C (68°F to 77°F)
3)	Refrigerated or Cold:	2°C to 8°C (35°F to 46°F)
4)	Frozen:	-25°C to -10°C (-13°F to 14°F)
5)	Incubator:	20°C to 25°C (68°F to 77°F) or 30°C to 35°C (86°F to 95°F)

Note: Incubator temperature should be based on manufacturer's recommendation for the particular product used.

b. Temperatures for the SPC and all drug storage areas are to be logged daily, excluding days that the pharmacy is not open and staff is not present.

c. The temperature of the incubator is to be logged daily, excluding days that the pharmacy is not open and staff is not present.

d. Any drug storage area or device that falls outside of the accepted ranges (as defined in Section a.) for greater than 30 minutes, and cannot be explained due to operational-related reasons (e.g. door to the refrigerator was left open) must be evaluated by a qualified service or repair technician. Excursions and follow-up action are to be recorded on form 9701.F5

e. If it is determined that a product has been exposed to temperatures outside the appropriate storage range, the Pharmacist in Charge is to determine the length of time of the temperature excursion and potential effect on drug integrity. This information may be obtained in a drugs package insert, or directly from the drug manufacturer. All information is to be documented and maintained with monthly temperature monitoring records.

f. If it is determined that the temperature excursion results in a drug being unacceptable for patient use, the Pharmacist in Charge is to segregate the affected drug(s) and contact the VP of Pharmacy. Appropriate action will be determined regarding the return or destruction of the product, and as outlined in Policy #7420 handling of unacceptable drugs.

3. SPC Pressure and Humidity Monitoring

a. A minimum positive pressure differential of 0.02-0.05 inch water column between the cleanroom and ante-room and from the ante-room to the general environment outside the compounding area (pharmacy prep/storage area).

b. A negative pressure differential of 0.01 inch water column is required between the ante-room and the hazardous (chemo) compounding clean room.

c. Exception: An ISO class 5 or better CAI with documentation from the manufacturer that the CAI does not need to be used within an ISO class 7 or better environment.

d. Humidity in the SPC should be maintained between 30% and 65% relative humidity.

e. Pressures differentials and humidity readings for the SPC are to be logged daily, excluding days that the pharmacy is not open and staff is not present.

4. Surface Sampling

a. Surface testing should be completed either the first full week of each month for low-medium risk compounds or around the same day each week for high-risk compounds. Testing will be done at random times throughout the day and at the conclusion of a compounding session.

b. Surface sampling is to be done in all Primary Engineering Controls (PEC) and in randomly selected locations in the clean room, ante room and hazardous drug compounding room (if applicable).

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c. Surfaces to be tested should include each PEC work surface, carts, walls, door handles, pass-through boxes. Test areas should be cleaned immediately after sample is taken with Sterile IPA.

c. When sampling laminar flow hoods, the test will be done at least 6 inches inside the hood. The area tested should vary from month to month.

d. The testing surfaces should not be re-cleaned or disinfected beyond normal daily cleaning policy (prior to compounding and between batches.)

e. Follow the manufacturer's directions for either the paddles or agar plates. When testing the surface of the hoods and/or rooms do not slide the agar plate or device across

f. Using a permanent ink marker, label the sample container with the date collected, location tested and initials.

g. TSA contact plates or swabs with lecithin and polysorbate 80 added to neutralize the disinfectant will be used. Either the contact plates or device are incubated per manufacturer's recommendations or for 48 to 72 hours (2 to 3 days) at 30-35°C (86-95°F). A sealed, sterile agar plate or device is placed in the incubator to serve as a control.

h. Evaluation of test results

1) At the completion of the incubation period, remove the contact plate or device from the incubator and visually count the number of colony forming units (CFUs).

2) The detected number of CFU should be zero for all laminar flow work benches.

3) Locations sampled in the rooms may contain CFUs.

4) Based on the grid below, action may need to be taken

Location	Base Line CFU (no add'l action needed)	Alert CFU (action must be taken)
Primary Engineering Controls (ISO Class 5)	0	Greater than 3
Clean Room Locations (ISO Class 7)	Less than 3	Greater than 5
Ante Room Locations (ISO Class 8)	Less than 25	Greater than 50

5) If the alert thresholds have been met, the affected area will be immediately cleaned and the area retested the next day.

6) If the affected area again tests positive, the agar strip or settling plate will be sent for bacterial identification. Results will be forwarded to VP of Pharmacy.

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a) If after two tests, a PEC continues to test positive, it will be put out of use and a professional certifier brought in investigate reasons as to why.

7) Surface sampling will be documented on the Environmental Monitoring – Surface Sampling Log

5. Passive Air Sampling

a. Passive air sampling should be completed either the first full week of each month for low-medium risk compounds or around the same day each week for high-risk compounds. Testing will be done at random times, throughout the day. Examples might be at the start of shift one month (after cleaning has been done) and at the end of the day after the conclusion of a compounding session, another month (to test during worst case conditions).

b. Passive air sampling is to be done in all Primary Engineering Controls (PEC) and in randomly selected locations in the clean room, ante room and hazardous drug compounding room (if applicable).

c. When sampling laminar flow hoods, the test will be done at least 6 inches inside the hood. The area tested should vary from quarter to quarter.

d. Follow the manufacturer's directions for either the paddles or agar plates. Exposure to the agar should be approximately one (1) hour unless agar gets excessively dry, then decrease exposure time to one-half (½) hour.

e. Using a permanent ink marker, label the sample container with the date collected, location tested and initials.

g. The devices are incubated per manufacturer's recommendations or for 48 to 72 hours (2 to 3 days) at 30-35°C (86-95°F). A sealed, sterile agar plate or device is placed in the incubator to serve as a control.

h. Evaluation of test results

1) At the completion of the incubation period, remove the contact plate or device from the incubator and visually count the number of colony forming units (CFUs).

2) The detected number of CFU should be zero for all laminar flow work benches.

3) Locations sampled in the rooms may contain CFUs.

4) Based on the grid below, action may need to be taken

Location	Base Line CFU (no add'l action needed)	Alert CFU (action must be taken)
Primary Engineering Controls (ISO Class 5)	0	Greater than 1

Clean Room Locations (ISO Class 7)	Less than 3	Greater than 5
Ante Room Locations (ISO Class 8)	Less than 25	Greater than 50

5) If the alert thresholds have been met, the affected area will be immediately cleaned and the area retested the next day.

6) If the affected area again tests positive, the agar strip or settling plate will be sent for bacterial identification. Results will be forwarded to National Director for Pharmacy Services.

   a) If after two tests, a PEC continues to test positive, it will be put out of use and a professional certifier brought in investigate reasons as to why.

7) Surface sampling will be documented on the Environmental Monitoring – Air Sampling Log

6. The Pharmacy Director may assign the test sampling and documentation to another Pharmacist or Technician. The Pharmacy Director is ultimately responsible for reviewing test results and documentation.

7. Any positive results (growth) must be reported to Pharmacy Manager immediately. Compounding should not be continued until the test area is disinfected per policy and immediate re-testing is conducted.

8. A complete evaluation should be conducted to check HEPA filters, room air sources, cleaning solutions/protocols, equipment used in the hood and other possible sources of contamination.

9. All cleanroom certification reports and results will be reviewed immediately by Pharmacy Manager and Clinical Pharmacy services. Any failing results will have a detailed remediation plan established and follow up testing as necessary. If it is determined that SPC is unsafe to continue sterile compounding activity, the room will be shut down immediately and branch emergency back-up plans implemented. Any required Regulatory notifications will be handled by the company Clinical and Regulatory departments. If necessary, a company initiated recall of product will follow policy #7420.

10. All results will be reported to QA committee or QA manager for monthly/ quarterly review and Performance Improvement activity.

RECORDS

Pharmacy QC/QA records
9581 Maintenance of Primary Engineering Control (PEC)
9582 Maintenance of Equipment (SPC)

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FORMS

9701.F1 Temperature Monitoring Log
9701.F2 Temperature Monitoring - Incubator
9701.F3 Environmental Monitoring - Surface Sampling
9701.F4 Environmental Monitoring - Air Sampling
9701.F5 Refrigerator and Drug Storage temperature Excursion Log

EXHIBIT A

The following tests should be completed during each cleanroom certification:

Air Flow Testing:

Air pressure differentials showing the flow of air with a schematic

HEPA filter test for leaks using an aerosol challenge test

HEPA filter test for airflow (cfm)

Air changes per hour (ACPH) in buffer, ante and negative pressure rooms

Air Particle Testing:

Impaction Volumetric Air Sampling

Non-viable particles –

In both PEC and SEC (primary and secondary engineering controls) with adequate sampling to provide an accurate picture of the sterile complex

Viable particle sampling –

Samples should be exposed to TSA for bacterial testing and MEA for fungal testing. Minimum of 1 each in PEC and 1-2 samples in SEC depending on size of the room. The volume of air sampled will be 1000 liters using electronic air sampling equipment. Test results will be reported as CFU's/cubic meter air.

Smoke Tests:

Performed in the ISO 5 area to determine laminar air flow, turbulence, dead spaces, and retrograde flow from outside the ISO 5 area into the ISO 5 area. Performed under dynamic conditions and summarized by the certifier. Video documentation should be obtained if required by State BOP regulation.

Surface Testing:

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One sample in each PEC, pass through, and a representation of tables, shelves in the buffer and ante areas as determined by branch. Surface testing will consist of media specific for bacteria such as TSA with lecithin and polysorbate 80 added to deactivate disinfectants and MEA or SDA which is specific for fungal growth.

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Axelacare Davie

15951 SW 41st Street Suite 500

Davie, FL 33331

Report # 3699-1

USP 797 Pharmacy Clean Room
Compliancy Inspection

July 14, 2017

MEDICAL TECHNOLOGY ASSOCIATES

Questions or Problems Please Contact our o ice at or corp mtausa com

MTA Corporate Headquarters: 6840 Cross Bayou Drive, Largo, FL 33777 • Phone 727-548-8600 • Fax 727-548-8622

EXHIBIT #8

MEDICAL TECHNOLOGY ASSOCIATES
PHARMACY / LABORATORY DIVISION

Cross ayou Dri e
ar o

Phone
ax

The Pharmacy Division of MTA, Inc. completed a Pharmacy Clean Room Compliancy Inspection at your facility. All testing will determine if the room meets or exceeds USP 797 code compliance and other applicable federal, state and local requirements.

The following Clean Room tests were performed and are reported:

- HEPA Filter Integrity Test
- Supply Air Flow Volumes
- Air Changes Per Hour
- Air Flow Analysis
- Room Pressures Differentials
- Airborne Particle Count Classification per ISO 14644-1 @ 0.5 microns
- Microbiological Analysis (Viable Count)

The test results documented within this report have not been modified or changed unless noted. Results are confidential and reported directly to the responsible staff members. If there are questions or concerns pertaining to the report we will be happy to arrange a meeting with you and/or your staff.

USP 797 CERTIFICATION EXECUTIVE SUMMARY

Date	July 14, 2017	Report Number	3699-1
Technician	Michael Klann		
Device ID#	3623		
Customer	Axelacare Davie		
Address	15951 SW 41st Street Suite 500		
City State	Davie, FL 33331		

MEDICAL TECHNOLOGY ASSOCIATES

Contact	Henry Hernandez	Karen Hitchen
Telephone	(954) 389-1126 ext 105	
email address	ehernandez@briovarxinfusion.com	KHitchen@briovarxinfusion.com
PO#		

Notes: The Ante Room does not meet the minimum requirement of 20 air changes. The current volume of supply air is 243 CFM, which provides only 15 air changes. The Air Science Laminar Flow Hood S/N HLF72298 fails the HEPA Leak Test. There are multiple leaks and the filter will need to be replaced. MTA will provide a quote. Both of the Air Science Laminar Flow Hoods need the pre-filters, which are located on top of the hood, cleaned or replaced.

All testing is to be done under Dynamic conditions indicate the number of people working in the room during testing 2

Item	Criteria	Result		Pass / Fail
Overall Facility Certification	All SEC's certified to CETA CAG-003	Facility certified to criteria listed below		**PASS**
ISO classification / Particle Counts	Ante Room **without** Hazardous Room can be ISO 7 or 8	8		**Pass**
	Ante Room joined to Hazardous Buffer Room must be ISO 7	N/A		N/A
	Non Hazardous Buffer Room must be ISO 7	7		**PASS**
	Hazardous Buffer Room must be ISO 7	N/A		N/A
Air Changes	Ante Room **without** Hazardous Room recommended 20 ACPH	15		**FAIL**
	Ante Room joined to Hazardous Buffer Room must have 30 ACPH	N/A		N/A
	Non Hazardous Buffer Room must have 30 ACPH	33		**PASS**
	Hazardous Buffer Room must be ISO 7 must have 30 ACPH	N/A		N/A
Room Segregation / Pressurization	Ante Room must be at least 0.02"W.G positive to outside	0.0559		**PASS**
	Non Hazardous Buffer Rm must be at least 0.02" W.G to Ante Rm	0.0268		**PASS**
	Hazardous Buffer Room must be between -0.01 and -0.03"W.G	N/A		N/A
Smoke Test	All Rooms had airflow confirmed with visual smoke test	Smoke passed in correct directions		**PASS**
PEC	Tested to CETA CAG 002 / NSF 49 or MFG specification	3623-72298	HLF72298	**FAIL**
	Tested to CETA CAG 002 / NSF 49 or MFG specification	3623-72299	HLF72299	**PASS**
	Tested to CETA CAG 002 / NSF 49 or MFG specification	3623-172875	172875022216	**PASS**
	Tested to CETA CAG 002 / NSF 49 or MFG specification	3623-176245	176245092216	**PASS**

*Executive summary does not include results of viable air samples.

CHAIN OF CUSTODY

Date	July 14, 2017	Time of Testing	8:20 AM
Report #	3699-1		
Technician	Michael Klann		
Customer	Axelacare Davie		
Address	15951 SW 41st Street Suite 500		
City State	Davie, FL 33331		
Contact	Henry Hernandez	Karen Hitchen	
Telephone	(954) 389-1126 ext 105		
Customer #	3623		

MEDICAL TECHNOLOGY ASSOCIATES

Toll Free (877) 569-8886
Phone (727) 548-8600
Fax (727) 548-8622
www.mtausa.com
6840 Cross Bayou Drive
Largo, FL 33777

Occupancy State During Testing	Operational
Email Address to Send Report:	labreports@mtausa.com

Notes: Semi-Annual Impaction Air Sampling

Buck Sampler

Media/Agar Type	Tryptic Soy Agar		
Lot #	156809	Exp. Date	16-Aug-17

Sample ID	Sample Location/ Device ID	ISO Class	Sample Volume
1	Ante Room	8	1000L
2	IV Room	7	1000 L
3	HLF72298	5	1000 L
4	HLF-72299	5	1000 L
5	HLF-172875	5	1000 L
6	HLF-176245 Left	5	1000 L
7	HLF-176245 Right	5	1000 L
Control	Control		

Media/Agar Type	Malt Extract		
Lot #	162279	Exp. Date	09-Aug-17

Sample ID	Sample Location	ISO Class	Sample Volume
8	Ante Room	8	1000L
9	IV Room	7	1000 L
10	HLF72298	5	1000 L
11	HLF-72299	5	1000 L
12	HLF-172875	5	1000 L
13	HLF-176245 Left	5	1000 L
14	HLF-176245 Right	5	1000 L
Control	Control		

CHAIN OF CUSTODY

Date	July 14, 2017	Time of Testing	8:20 AM
Report #	3699-1		
Technician	Michael Klann		
Customer	Axelacare Davie		
Address	15951 SW 41st Street Suite 500		
City State	Davie, FL 33331		
Contact	Henry Hernandez	Karen Hitchen	
Telephone	(954) 389-1126 ext 105		
Customer #	3623		

MEDICAL TECHNOLOGY ASSOCIATES

Toll Free (877) 569-8886
Phone (727) 548-8600
Fax (727) 548-8622
www.mtausa.com
6840 Cross Bayou Drive
Largo, FL 33777

Occupancy State During Testing	Operational
Email Address to Send Report:	labreports@mtausa.com

Notes: Semi-Annual Surface Sampling

Buck Sampler

Media/Agar Type	Tryptic Soy Agar		
Lot #	150354	Exp. Date	31-Jul-17

Sample ID	Sample Location/ Device ID	ISO Class	Sample Volume
15	Ante Room Counter	8	Surface
16	IV Room Cart	7	Surface
17	HLF72298	5	Surface
18	HLF-72299	5	Surface
19	HLF-172875	5	Surface
20	HLF-176245 Left	5	Surface
21	HLF-176245 Right	5	Surface
Control	Control		

Media/Agar Type	MEA/SDA		
Lot #	145768	Exp. Date	20-Jul-17

Sample ID	Sample Location	ISO Class	Sample Volume
22	Ante Room Counter	8	Surface
23	IV Room Cart	7	Surface
24	HLF72298	5	Surface
25	HLF-72299	5	Surface
26	HLF-172875	5	Surface
27	HLF-176245 Left	5	Surface
28	HLF-176245 Right	5	Surface
Control	Control		

Section 1

USP 797 Pharmacy

Ante Room and IV Room Summary Reports

ANTE-ROOM SUMMARY

Date	July 14, 2017	
Report #	3699-1	
Device ID #	3623	
Technician	Michael Klann	
Customer	Axelacare Davie	
Address	15951 SW 41st Street Suite 500	
City State	Davie, FL 33331	
Contact	Henry Hernandez	Karen Hitchen
Phone Number	(954) 389-1126 ext 105	
PO Number		

erall Status o Room

ISO 14644-1 ____ Class ____ at .5 micron Status **perational**

Meets CETA CAG-003-2006 rev 2010 ☐ Pass ☐ Fail ☐ N/A

Meets USP 797 to Criteria Tested ☐ Pass ☐ Fail ☐ N/A

Notes: The Ante Room does not meet the minimum requirement of 20 air changes. The current volume of supply air is 243 CFM which provides only 15 air changes

Air Chan e Re uirements:

Minimum 30 air changes required for ISO 7 and 20 air changes for ISO 8

Total Air Volume Supplied	243	CFM	Total Number of Air Changes	15	per hour	☐ Pass	☐ Fail	☐ N/A
Total Air Volume From PEC		CFM	Air Changes From PEC		per hour			☐ N/A

Di erential Pressure and or Displacement elocity:

Minimum 0.02 inches positive to the outside area. Minimum 40 fpm is required if utilizing displacement method.

Pressure monitor Present? ☐ YES ☐ NO ☐ N/A

Static Pressure or Velocity of Ante Room to Outside	0.0559	"W.G. or	N/A	fpm	☐ Pass	☐ Fail	☐ N/A
Static Pressure or Velocity of IV to Ante Room	0.0268	"W.G. or	N/A	fpm	☐ Pass	☐ Fail	☐ N/A
		"W.G. or	N/A	fpm	☐ Pass	☐ Fail	☐ N/A
		"W.G. or	N/A	fpm	☐ Pass	☐ Fail	☐ N/A

Ante Room Statistical Data micron Particles: (Particle counts taken at 1 minute sample time at 1 CFM and include 0.5 micron particles and larger)

95% UCL is used to determine ISO classification when nine (9) or less particle count locations are taken.

Maximum number of .5 micron size particles allowed for ISO Class 7 352,000 particles per cubic meter

Maximum number of .5 micron size particles allowed for ISO Class 8 3,520,000 particles per cubic meter

ISO Class Achieved		Mean of Averages	3012	95% UCL	5236	☐ Pass	☐ Fail	☐ N/A

PA ilter ea nte rity Test:

Upstream concentration should be greater than 10µg/l and no leak greater than 0.01% when scanned. (See Data Page for more information.)

Number of filters scanned	1							
Number of leaks detected	0							
Number of leaks sealed	N/A					☐ Pass	☐ Fail	☐ N/A

A era e Temperature and Relati e umidity:

Recommended Temperature < 68° F	Measured	59.3	°F	
Recommended Relative Humidity 30 to 65%	Measured	61.7	%Rh	

Smo e Study Per ormed:

Visual confirmation that air flows in the direction designed for the type of room. ☐ Pass ☐ Fail ☐ N/A

*This test only performed on unidirectional / uniform rooms.

IV / BUFFER ROOM SUMMARY

Date	July 14, 2017
Report #	3699-1
Customer ID #	3623
Technician	Michael Klann
Customer	Axelacare Davie
Address	15951 SW 41st Street Suite 500
City State	Davie, FL 33331
Contact	Henry Hernandez
Phone Number	(954) 389-1126 ext 105
PO Number	

erall Status o Room

ISO 14644-1 ____ Class ____ at .5 micron Status **perational**

Meets CETA CAG-003-2006 rev 2010 ☐ Pass ☐ Fail ☐ N/A

Meets USP 797 to Criteria Tested ☐ Pass ☐ Fail ☐ N/A

Notes:

Air Chan e Re uirements:

Minimum 30 air changes required for ISO 7

Total Air Volume Supplied	1142	CFM	Total Number of Air Changes	33	per hour	☐ Pass	☐ Fail	☐ N/A
Total Air Volume From PEC	1561	CFM	Total Air Changes With PEC	78	per hour			☐ N/A

Di erential Pressure and or Displacement elocity:

Minimum 0.02 inches positive to the ante area or any other area. Minimum 40 fpm is required if utilizing displacement method.

Pressure monitor Present? ☐ YES ☐ NO ☐ N/A

Static Pressure or Velocity of IV to Ante Room	0.0268	"W.G. or	N/A	fpm	☐ Pass	☐ Fail	☐ N/A
Static Pressure or Velocity of IV Room to Outside	N/A	"W.G. or	N/A	fpm	☐ Pass	☐ Fail	☐ N/A
	N/A				☐ Pass	☐ Fail	☐ N/A

Room Statistical Data micron Particles: (Particle counts taken at 1 minute sample time at 1 CFM and include 0.5 micron particles and larger)

95% UCL is used to determine ISO classification when nine (9) or less particle count locations are taken.

Maximum number of .5 micron size particles allowed for ISO Class 7 352,000 particles per cubic meter

ISO Class Achieved		Mean of Averages	412	95% UCL	1174	☐ Pass	☐ Fail	☐ N/A

PA ilter ea nte rity Test:

Upstream concentration should be greater than 10µg/l and no leak greater than 0.01% when scanned. (See Data Page for more information.)

Number of filters scanned	3			☐ Pass	☐ Fail	☐ N/A
Number of leaks detected	0					
Number of leaks sealed	N/A					

A era e Temperature and Relati e umidity:

Recommended Temperature < 68° F	Measured	61.9	°F	
Recommended Relative Humidity 30 to 65%	Measured	58.2	%Rh	

Smo e Study Per ormed:

Visual confirmation that air flows in the direction designed for the type of room. ☐ Pass ☐ Fail ☐ N/A

Section 2

USP 797 Pharmacy

Report Data Inludes Calibration Data

CLEANROOM INSPECTION DATA

Date	July 14, 2017	Time	8:20 AM
Technician	Michael Klann		
Customer ID#	3623		
Customer	Axelacare Davie		
Address	15951 SW 41st Street Suite 500		
City State	Davie, FL 33331		

		Report Number	3699-1
Contact	Henry Hernandez /		Karen Hitchen
Telephone	(954) 389-1126 ext 105 /		
email address	ehernandez@briovarxinfusion.com /		KHitchen@briovarxinfusion.com
PO#			

ANTE ROOM DIMENSIONS AND PARTICLE COUNT STATISTICAL DATA

Room Dimensions recorded in inches ☐ **Non-applicable**

L	W	H
168	90	108

Room Area in square feet ft²	105.00	ft²	Calculations
Room Area in square meters (m²)	9.75	m²	(Length (in) X width (in)) x 1 ft²/144 in²
Room Volume in cubic feet (ft³)	945.00	ft³	area (ft²) x 1 m²/10.764 ft²
Number of Sampling Locations	4		(Length (in) X width (in) x Height (in) x 1 ft³/1728 in³
			√m² rounded up

Ante Room Particle Count Statistical Data (Particle counts taken at 1 minute sample time at 1 CFM and include 0.5 micron particles and larger)

ISO Class	Mean of Averages	95% UCL	Standard Dev	Standard Err.
8	3012	5236	1893	N/A

IV ROOM DIMENSIONS AND PARTICLE COUNT STATISTICAL DATA

Room Dimensions recorded in inches ☐ **Non-applicable**

L	W	H
168	198	108

Room Area in square feet ft²	231.00	ft²	Calculations
Room Area in square meters (m²)	21.46	m²	(Length (in) X width (in)) x 1 ft²/144 in²
Room Volume in cubic feet (ft³)	2079.00	ft³	area (ft²) x 1 m²/10.764 ft²
Number of Sampling Locations	5		(Length (in) X width (in) x Height (in) x 1 ft³/1728 in³
			√m² rounded up

IV Room Particle Count Statistical Data (Particle counts taken at 1 minute sample time at 1 CFM and include 0.5 micron particles and larger)

ISO Class	Mean of Averages	95% UCL	Standard Dev	Standard Err.
7	412	1174	924	N/A

AIR SUPPLY VOLUME MEASUREMENT DATA

X Direct Measurement Method ☐ Velgrid Measurement Method/Multi point array ☐ Single point / velometer method

Calculate K factor for a filter when DIM cannot be measured: HEPA filter # _____ HEPA Filter Face Area _____ Measured CFM _____ Measured FPM _____

(K-Factor = measured cfm/calculated cfm) Calculated CFM _____ K-factor _____

Ante Room

		Location	Filter Dimensions			Sqft.	K Factor	FPM	CFM
HEPA Filter # / Diffuser	1		24 L	48 W	D	7.0			243
HEPA Filter # / Diffuser			L	W	D	0.0			
HEPA Filter # / Diffuser			L	W	D	0.0			

IV Room

		Location	Filter Dimensions			Sqft.	K Factor	FPM	CFM
HEPA Filter # / Diffuser	1		24 L	48 W	D	7.0			450
HEPA Filter # / Diffuser	2		24 L	48 W	D	7.0			224
HEPA Filter # / Diffuser	3		24 L	48 W	D	7.0			468
HEPA Filter # / Diffuser			L	W	D	0.0			

Report Number: 3699-1

AIR CHANGE AND PRESSURE DATA

Ante Room

Room Volume	Supply Air Total	Air Changes Per minute	Air Changes Per Hour
945	243	0.26	15

Total Air Volume from PEC: | Total Air changes Per hour with PEC: | X Non-applicable

Notes: Does not meet requirements

IV Room

Room Volume	Supply Air Total	Air Changes Per minute	Air Changes Per Hour
2079	1142	0.55	33

Total Air Volume from PEC: 1561 | Total Air changes Per hour with PEC: 78 | Non-applicable

Notes:

Pressure/Velocity Monitors Installed? X YES NO N/A

Pressure monitor Installed and Functioning? X YES NO N/A

Static Pressure Ante to Outside: 0.0559 "W.G. | Static Pressure IV to Ante Room: 0.0268 "W.G. | Static Pressure to Chemo: N/A "W.G.

Static Pressure to: measured "W.G. | Static Pressure to: measured "W.G.

Static Pressure to: measured "W.G. | Static Pressure to: measured "W.G.

Displacement

Displacement Average Ante Room to Outside: N A

Displacement Average IV room to Ante Room: N A

Displacement Average Ante Room to Chemo Room: N/A

MTA strongly discourages the use of displacement and curtains. If curtains are utilized spread the curtains at least 24" and measure 48" above the floor complete a drawing and record the readings. Any customers using curtains shall be advised to install a door and if needed low wall registers to allow for pressure adjustments.

HEPA FILTER INTEGRITY TEST

(HEPA filters should be integrity tested at each certification with a minimum upstream challenge concentration of 10 micrograms per liter.)

Ante Room

		Upstream Challenge Location	Calculated Challenge	Measured challenge Before	Measured challenge After	Leak Detected		Leak Sealed		
HEPA Filter #	1	Return in IV Room	15			Yes	No	Yes	No	Fail
						Yes	No	Yes	No	Fail
						Yes	No	Yes	No	Fail

IV Room

		Upstream Challenge Location	Calculated Challenge	Measured challenge Before	Measured challenge After	Leak Detected		Leak Sealed		
HEPA Filter #	1	Return in IV Room	15			Yes	No	Yes	No	Fail
HEPA Filter #	2	Return in IV Room	15			Yes	No	Yes	No	Fail
HEPA Filter #	3	Return in IV Room	15			Yes	No	Yes	No	Fail
						Yes	No	Yes	No	Fail

Report Number 3699-1

ADD T NA DATA

Average Noise Level N/A dBA Average Temperature N/A °F Average Relative Humidity Level N/A %Rh

Ceiling tiles sealed down/gasketed?	YES	NO	N/A
Floors have coved edges and corners?	YES	NO	N/A

Drawing of room complete?	YES	NO	N/A
Profile of Viable Sample Locations Complete?	YES	NO	N/A
Profile of Particle Count Locations Complete?	YES	NO	N/A
Profile of Room HEPA Filters, Leak/Patches and challenge induction points complete?	YES	NO	N/A
Profile of Room Pressures Complete?	YES	NO	N/A
Profile of Room Air Supply / Return Complete?	YES	NO	N/A
Profile of Temperature and Humidity Readings Complete?	YES	NO	N/A

Medical Technology Associates, Inc.
6840 Cross Bayou Drive
Largo, FL 33777
Toll Free: 877-569-8886
Fax: 727-548-8622

The list below is a list of the equipment that the MTA technician has on hand for use while performing work at your facility. Some of the equipment may or may not have been utilized. All instruments are calibrated by the manufacturer or other qualified vendor at least on an annual basis. All the instruments have been calibrated using Calibration Standards which are NIST (National Institute of Standards and Technology) traceable. If you need copies of the actual calibration certificate please contact our corporate office at: (877) 569-8886 or corp@mtausa.com

Technician	Michael Klann

CALIBRATION DATA

Equipment	Manufacturer	Model #	Serial #	Calibration Date	Calibration Due
Particle Counter	Particle Measurement Systems	LasairIII_310C	117734	Dec-16	Dec-17
Thermal Anemometer	TSI	9565-P	9565P1416020	Nov-16	Nov-17
Photometer	Tech Services	PH-4	2290	Aug-16	Aug-17
Balometer	Alnor/TSI	EBT 730	EBT731631009	Jul-16	26-Jul-17
Air Volume Capute hood					
Air Sampler	Buck	B30120	C101736	daily	daily
Air Sampler	Buck	B30120	C101839	daily	daily

Section 3

USP 797 Pharmacy

Hood Reports

Laminar Flow Hood Certification Report

Date	July 14, 2017
Report #	3699-2
Technician	Michael Klann
Customer	Axelacare Davie
Address	15951 SW 41st Street Suite 500
City State	Davie, FL 33331
Contact	Henry Hernandez / Karen Hitchen
Telephone	(954) 389-1126 ext 105 /
PO Number	

MEDICAL TECHNOLOGY ASSOCIATES

erall Status ☐ **Pass** ☐ **ail**

☐ **Re uires Attention**

Device ID#	3623-72298
Manufacturer	Air Science
Model	HLF-72
Serial Number	HLF72298
Device Location	IV Room

Notes: The HEPA filter has multiple leaks. The Filter needs to be replaced. MTA will provide a quote to remove and replace the HEPA Filter.

The pre=filters located on top the hood need to be cleaned or replaced.

Supply HEPA Filter Magnehelic Gauge Reading 0.70" W.C.

ACC PTANC CR T R A

Supply Air elocity Pro ile

	Min		Max		Readings taken at ☐ 6" ☐ 12" from diffuser		
Supply Velocity	80	fpm.	100	fpm.	Supply Velocity	92	fpm.

Individual point readings should be within +/- 20%.

					Recorded Low and High Values			
Individual Readings	73	Low	110	High	78	Low	106	High

Particulate atter Pro ile

(Particle counts taken at 1 minute sample time at 1 CFM and include 0.5 micron particles and larger)

Maximum number of .5 micron size particles and above allowed for ISO Class 5 is 3520 particles per cubic meter

Average	0	95% UCL	0
ISO Class Achieved			

PA ilter ea Test

Adequate challenge concentration between 10 and 90 micrograms per liter. No leak should exceed 0.01% when scanned.

Upstream Concentration	N/A
Calculated Upstream Concentration	21
Number of leaks Detected	mltpl
Number of leaks Sealed	N/A

Smo e Test

Visual Verification that the laminarity of the air is undisturbed by items in the hood and activities in the room (cross drafts). **nder Dynamic Conditions**

nduction ea and ac streamin Test

Verifies that the device prevents particle intrusion into the clean space by induction through joints or Backstreaming from workspace openings.

NA R S TS

Supply Air elocity
☐ Pass ☐ Fail ☐ N/A

ni ormity
☐ Pass ☐ Fail ☐ N/A

Particle Counts
☐ Pass ☐ Fail ☐ N/A

PA ilter nte rity Test
☐ Pass ☐ Fail ☐ N/A

Smo e Test
☐ Pass ☐ Fail ☐ N/A

nduction ea ac streamin Test
☐ Pass ☐ Fail ☐ N/A

NSP CT N DATA

uipment Data

	Supply HEPA Filter					Pre-Filter				
1. Filter Size	(1)	24	X	72	X 6	(3)	16	X 20	X	1
2. Supply Area	10.69 sq.ft.					( )		X	X	
3. Supply Velocity	92 fpm.									
4. Volume	981 cfm.									

Supply elocity Pro ile

88	87	96	78	94	92
98	89	102	101	90	101
94	82	80	85	88	106

Supply Velocity Average 92

PA ilter nte rity Test

Multiple Leaks

x x XX
x x

Particulate atter Pro ile

#1	#2	#3
0	0	0

SUMMARY

MTA warrants that this air system was tested under the requirements as set forth in the following applicable standard(s):

- [ ] CAG--003-2006 v 11
- [ ] IES-RP-CC-002.3 Unidirectional-Flow, Clean-Air Devices
- [ ] Owners Specifications
- [ ] Manufacturer's Specifications
- [X] ISO 14644- ___ 1999 (E); Class ___ at _____ um size particle, Status **perational Dynamic**

Status of System after Inspection:

- [ ] Certified to the Above Applicable Standard(s).
- [ ] Undergoing Corrective Action by MTA.
- [X] Does not meet the Above Applicable Standard(s).
- [ ] It is Recommended that this System be Corrected by the Owner Prior to any Additional Testing.

CERTIFICATE OF INSPECTION' expires ___ months from date of issue.

Medical Technology Asscoiates
6840 Cross Bayou Drive
Largo, FL 33777
Phone: (877) 569-8886
Fax: 727-548-8622

Laminar Flow Hood Certification Report

Date	July 14, 2017
Report #	3699-3
Technician	Michael Klann
Customer	Axelacare Davie
Address	15951 SW 41st Street Suite 500
City State	Davie, FL 33331
Contact	Henry Hernandez / Karen Hitchen
Telephone	(954) 389-1126 ext 105 /
PO Number	

MEDICAL TECHNOLOGY ASSOCIATES

erall Status ☐ **Pass** ☐ **ail**

☐ **Re uires Attention**

Device ID#	3623-72299
Manufacturer	Air Science
Model	HLF-72
Serial Number	HLF72299
Device Location	IV Room

Notes:

The pre-filters located on top the hood need to be cleaned or replaced.

Supply HEPA Filter Magnehelic Gauge Reading 0.70" W.C.

ACC PTANC CR T R A

Supply Air elocity Pro ile

	Min		Max		Readings taken at ☐ 6" ☐ 12" from diffuser		
Supply Velocity	80	fpm.	100	fpm.	Supply Velocity	93	fpm.

Individual point readings should be within +/- 20%.

					Recorded Low and High Values			
Individual Readings	74	Low	111	High	77	Low	109	High

Particulate atter Pro ile

(Particle counts taken at 1 minute sample time at 1 CFM and include 0.5 micron particles and larger)

Maximum number of .5 micron size particles and above allowed for ISO Class 5 is 3520 particles per cubic meter

Average	0	95% UCL	0
ISO Class Achieved			

PA ilter ea Test

Adequate challenge concentration between 10 and 90 micrograms per liter. No leak should exceed 0.01% when scanned.

Upstream Concentration	N/A
Calculated Upstream Concentration	20
Number of leaks Detected	0
Number of leaks Sealed	N/A

Smo e Test

Visual Verification that the laminarity of the air is undisturbed by items in the hood and activities in the room (cross drafts). **nder Dynamic Conditions**

nduction ea and ac streamin Test

Verifies that the device prevents particle intrusion into the clean space by induction through joints or Backstreaming from workspace openings.

NA R S TS

Supply Air elocity
☐ Pass ☐ Fail ☐ N/A

ni ormity
☐ Pass ☐ Fail ☐ N/A

Particle Counts
☐ Pass ☐ Fail ☐ N/A

PA ilter nte rity Test
☐ Pass ☐ Fail ☐ N/A

Smo e Test
☐ Pass ☐ Fail ☐ N/A

nduction ea ac streamin Test
☐ Pass ☐ Fail ☐ N/A

NSP CT N DATA

uipment Data

	Supply HEPA Filter				Pre-Filter			
1. Filter Size	(1) 24	X 72	X 6		(3) 14	X 21.5	X 1	
2. Supply Area	10.69 sq.ft.				( )	X	X	
3. Supply Velocity	93 fpm.							
4. Volume	989 cfm.							

Supply elocity Pro ile

109	93	107	105	97	95
105	79	77	104	80	89
97	95	79	85	78	91

Supply Velocity Average 93

PA ilter nte rity Test

Zero Leaks

Particulate atter Pro ile

#1	#2	#3
0	0	0

SUMMARY

MTA warrants that this air system was tested under the requirements as set forth in the following applicable standard(s):

- [ ] CAG--003-2006 v 11
- [ ] IES-RP-CC-002.3 Unidirectional-Flow, Clean-Air Devices
- [ ] Owners Specifications
- [X] Manufacturer's Specifications
- [X] ISO 14644- ___ 1999 (E); Class ___ at _____ um size particle, Status **perational Dynamic**

Status of System after Inspection:

- [X] Certified to the Above Applicable Standard(s).
- [ ] Undergoing Corrective Action by MTA.
- [ ] Not Certified to the Above Applicable Standard(s).
- [ ] It is Recommended that this System be Corrected by the Owner Prior to any Additional Testing.

CERTIFICATE OF INSPECTION' expires ___ months from date of issue.

Laminar Flow Hood Certification Report

Date	July 14, 2017
Report #	3699-4
Technician	Michael Klann
Customer	Axelacare Davie
Address	15951 SW 41st Street Suite 500
City State	Davie, FL 33331
Contact	Henry Hernandez / Karen Hitchen
Telephone	(954) 389-1126 ext 105 /
PO Number	

MEDICAL TECHNOLOGY ASSOCIATES

erall Status ☐ **Pass** ☐ **ail**

☐ **Re uires Attention**

Device ID#	3623-172875
Manufacturer	NuAire
Model	NU-301-636
Serial Number	172875022216
Device Location	IV Room

Notes:

Supply HEPA Filter Magnehelic Gauge Reading 0.60" W.C.

ACC PTANC CR T R A

Supply Air elocity Pro ile

	Min		Max	
Supply Velocity	80	fpm.	100	fpm.

Readings taken at ☐ 6" ☐ 12" from diffuser

Supply Velocity	94	fpm.

Individual point readings should be within +/- 20%.

Individual Readings	76	Low	113	High

Recorded Low and High Values				
87	Low	103	High	

Particulate atter Pro ile (Particle counts taken at 1 minute sample time at 1 CFM and include 0.5 micron particles and larger)

Maximum number of .5 micron size particles and above allowed for ISO Class 5 is 3520 particles per cubic meter

Average	0	95% UCL	0

ISO Class Achieved

PA ilter ea Test

Adequate challenge concentration between 10 and 90 micrograms per liter. No leak should exceed 0.01% when scanned.

Upstream Concentration	N/A
Calculated Upstream Concentration	13
Number of leaks Detected	0
Number of leaks Sealed	N/A

Smo e Test

Visual Verification that the laminarity of the air is undisturbed by items in the hood and activities in the room (cross drafts). **nder Dynamic Conditions**

nduction ea and ac streamin Test

Verifies that the device prevents particle intrusion into the clean space by induction through joints or Backstreaming from workspace openings.

NA R S TS

Supply Air elocity
☐ Pass ☐ Fail ☐ N/A

ni ormity
☐ Pass ☐ Fail ☐ N/A

Particle Counts
☐ Pass ☐ Fail ☐ N/A

PA ilter nte rity Test
☐ Pass ☐ Fail ☐ N/A

Smo e Test
☐ Pass ☐ Fail ☐ N/A

nduction ea ac streamin Test
☐ Pass ☐ Fail ☐ N/A

NSP CT N DATA

uipment Data

	Supply HEPA Filter					Pre-Filter				
1. Filter Size	(1)	36	X	72	X 6	(2)	24	X 30	X	1
2. Supply Area	16.53 sq.ft.					( )		X	X	
3. Supply Velocity	94 fpm.									
4. Volume	1561 cfm.									

Supply elocity Pro ile

90	93	90	96	92	89
95	89	87	101	92	89
100	103	96	98	99	101

Supply Velocity Average 94

PA ilter nte rity Test

Zero Leaks

Particulate atter Pro ile

#1	#2	#3
0	0	0

SUMMARY

MTA warrants that this air system was tested under the requirements as set forth in the following applicable standard(s):

- [ ] CAG--003-2006 v 11
- [ ] IES-RP-CC-002.3 Unidirectional-Flow, Clean-Air Devices
- [ ] Owners Specifications
- [X] Manufacturer's Specifications
- [X] ISO 14644- ___ 1999 (E); Class ___ at _____ um size particle, Status **perational Dynamic**

Status of System after Inspection:

- [X] Certified to the Above Applicable Standard(s).
- [ ] Undergoing Corrective Action by MTA.
- [ ] Not Certified to the Above Applicable Standard(s).
- [ ] It is Recommended that this System be Corrected by the Owner Prior to any Additional Testing.

CERTIFICATE OF INSPECTION' expires ___ months from date of issue.

Laminar Flow Hood Certification Report

Date	July 14, 2017
Report #	3699-5
Technician	Michael Klann
Customer	Axelacare Davie
Address	15951 SW 41st Street Suite 500
City State	Davie, FL 33331
Contact	Henry Hernandez / Karen Hitchen
Telephone	(954) 389-1126 ext 105 /
PO Number	

MEDICAL TECHNOLOGY ASSOCIATES

erall Status ☐ **Pass** ☐ **ail**

☐ **Re uires Attention**

Device ID#	3623-176245
Manufacturer	NuAire
Model	NU S301-836
Serial Number	176245092216
Device Location	IV Room

Notes:

Supply HEPA Filter Magnehelic Gauge Readings 0.60" W.C. and 0.50" W.C.

ACC PTANC CR T R A

Supply Air elocity Pro ile

	Min		Max	
Supply Velocity	80	fpm.	100	fpm.

Readings taken at ☐ 6" ☐ 12" from diffuser

Supply Velocity	95	fpm.

Individual point readings should be within +/- 20%.

Individual Readings	76	Low	114	High

Recorded Low and High Values				
87	Low		104	High

Particulate atter Pro ile (Particle counts taken at 1 minute sample time at 1 CFM and include 0.5 micron particles and larger)

Maximum number of .5 micron size particles and above allowed for ISO Class 5 is 3520 particles per cubic meter

Average	0	95% UCL	0
ISO Class Achieved			

PA ilter ea Test

Adequate challenge concentration between 10 and 90 micrograms per liter. No leak should exceed 0.01% when scanned.

Upstream Concentration	N/A
Calculated Upstream Concentration	20
Number of leaks Detected	0
Number of leaks Sealed	N/A

Smo e Test

Visual Verification that the laminarity of the air is undisturbed by items in the hood and activities in the room (cross drafts). **nder Dynamic Conditions**

nduction ea and ac streamin Test

Verifies that the device prevents particle intrusion into the clean space by induction through joints or Backstreaming from workspace openings.

NA R S TS

Supply Air elocity
☐ Pass ☐ Fail ☐ N/A

ni ormity
☐ Pass ☐ Fail ☐ N/A

Particle Counts
☐ Pass ☐ Fail ☐ N/A

PA ilter nte rity Test
☐ Pass ☐ Fail ☐ N/A

Smo e Test
☐ Pass ☐ Fail ☐ N/A

nduction ea ac streamin Test
☐ Pass ☐ Fail ☐ N/A

NSP CT N DATA

uipment Data

	Supply HEPA Filter				Pre-Filter			
1. Filter Size	(2) 36	X 48	X 6		(2) 24	X 30	X 1	
2. Supply Area	10.86 sq.ft.				( )	X	X	
3. Supply Velocity	95 fpm.							
4. Volume	1034 cfm.							

Supply elocity Pro ile

97	91	87	102		90	94	103	104
90	94	91	94		94	101	99	100
95	94	93	89		92	99	95	97

Supply Velocity Average 95

PA ilter nte rity Test

Zero Leaks

Particulate atter Pro ile

#1	#2	#3
0	0	0

SUMMARY

MTA warrants that this air system was tested under the requirements as set forth in the following applicable standard(s):

- [ ] CAG--003-2006 v 11
- [ ] IES-RP-CC-002.3 Unidirectional-Flow, Clean-Air Devices
- [ ] Owners Specifications
- [X] Manufacturer's Specifications
- [X] ISO 14644- ___ 1999 (E); Class ___ at _____ um size particle, Status **perational Dynamic**

Status of System after Inspection:

- [X] Certified to the Above Applicable Standard(s).
- [ ] Undergoing Corrective Action by MTA.
- [ ] Not Certified to the Above Applicable Standard(s).
- [ ] It is Recommended that this System be Corrected by the Owner Prior to any Additional Testing.

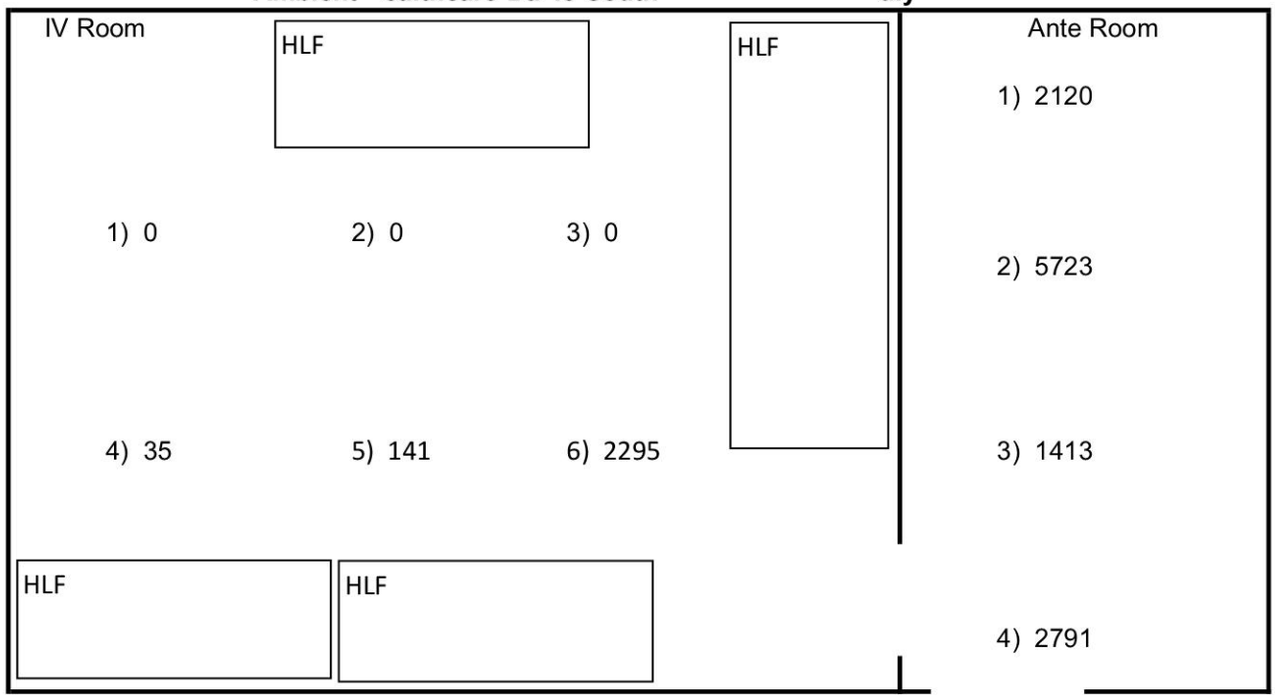
CERTIFICATE OF INSPECTION' expires ___ months from date of issue.

Section 4

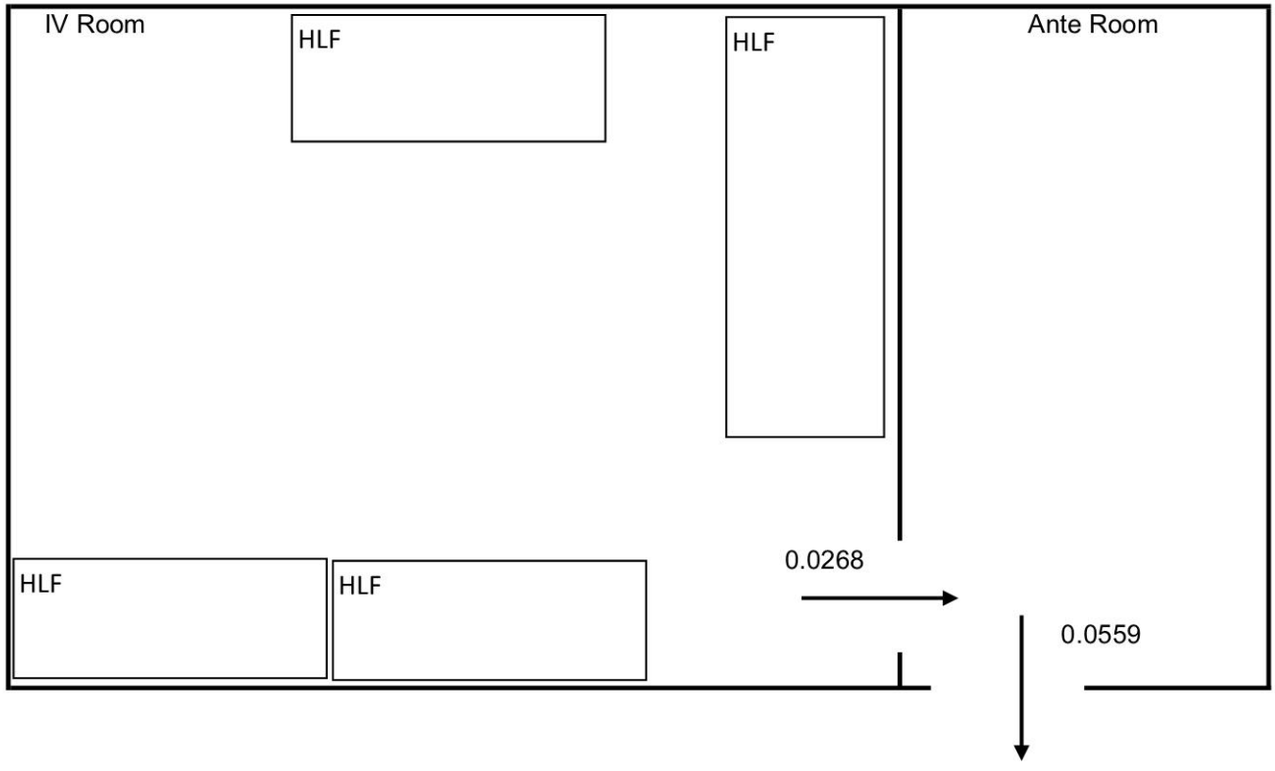
USP 797 Pharmacy

Drawings

Ambient ealthcare Da ie South uly

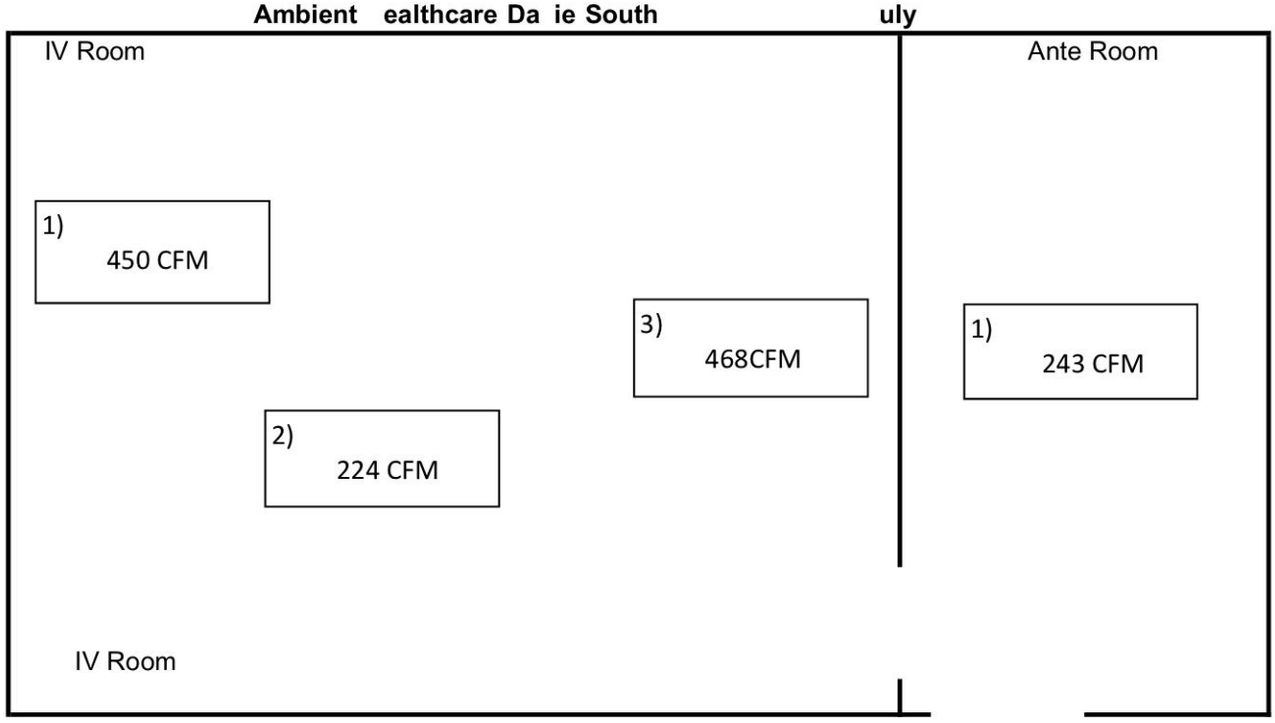


Particulate atter Pro ile
Particle Counts are in particles per cubic meter microns



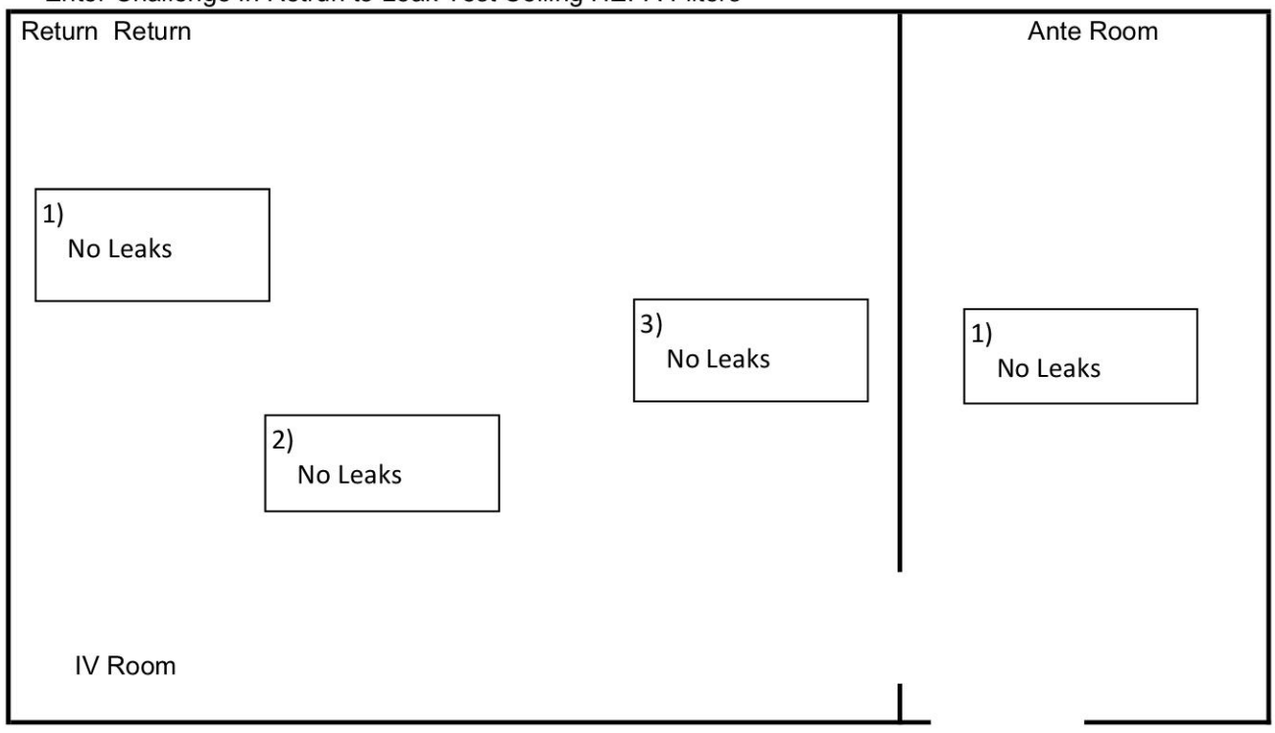
Pressure Di erential Readin s

Ambient ealthcare Da ie South uly



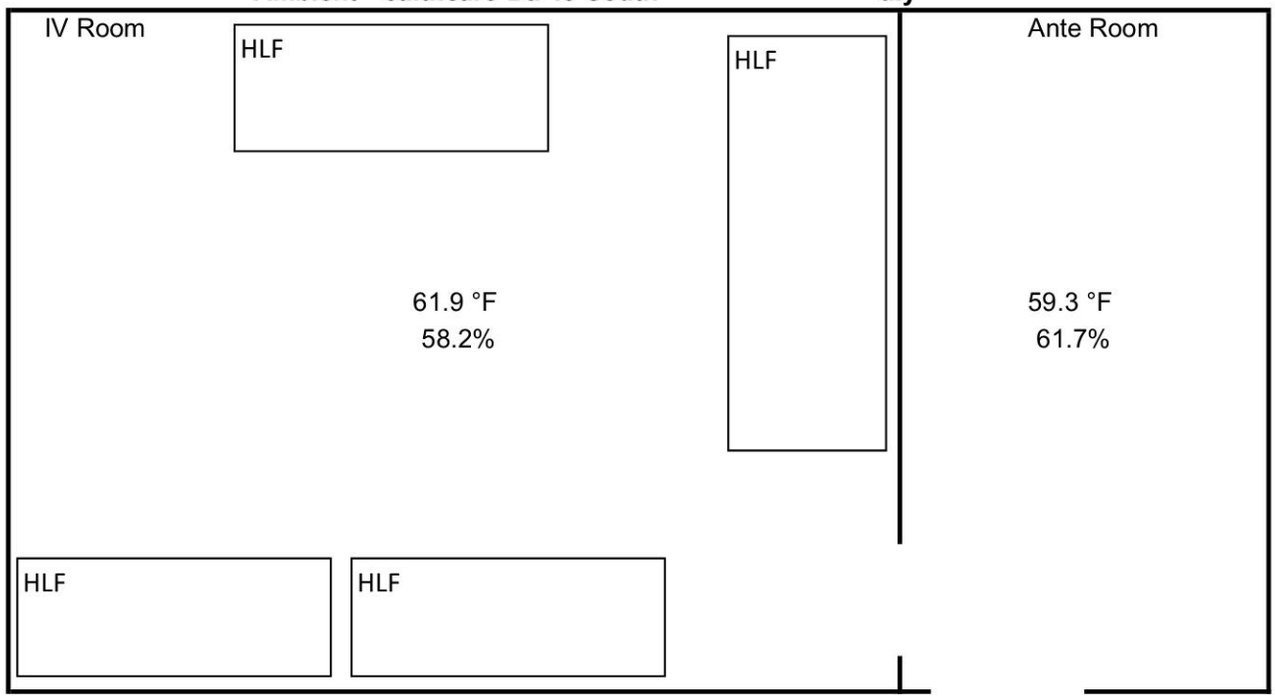
Supply Air olume in C

Enter Challenge in Retrun to Leak Test Ceiling HEPA Filters

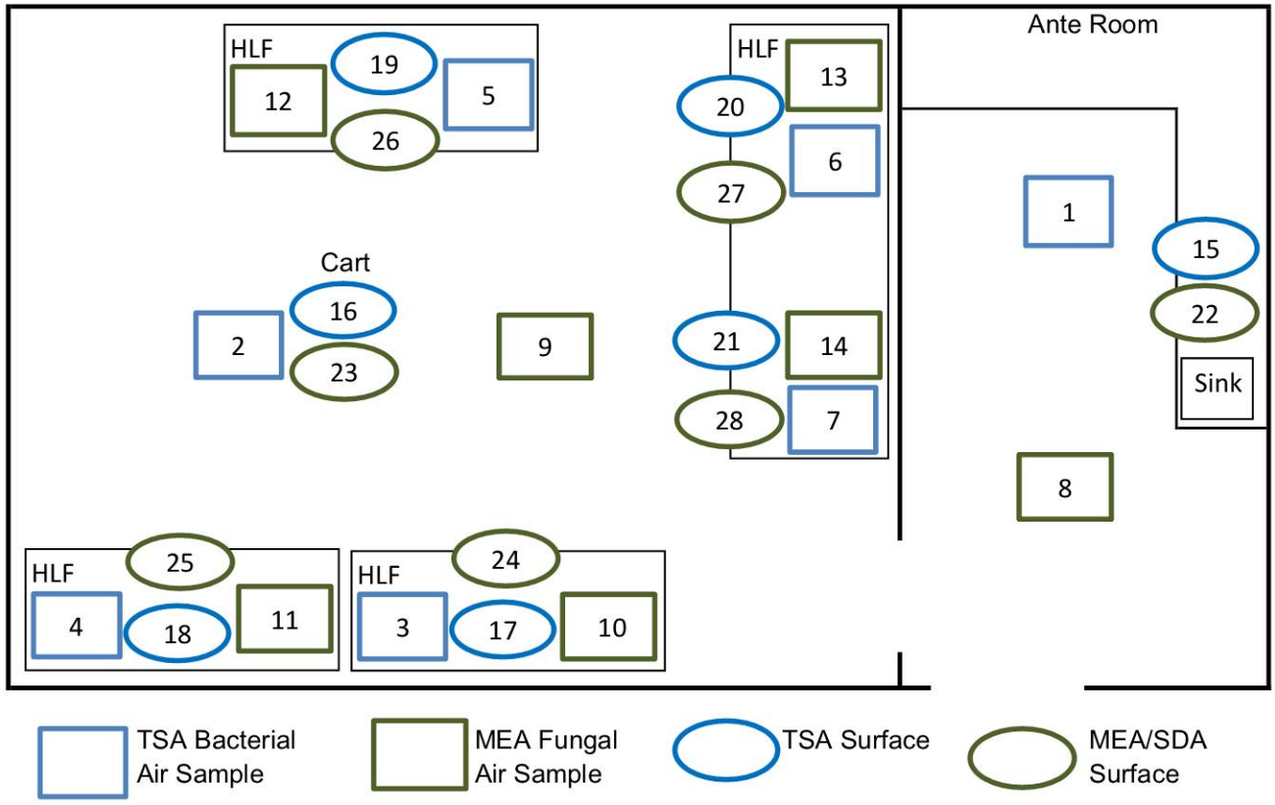


PA ilter ea Test

Ambient ealthcare Da ie South uly



Temperature and umidity Readin s



iable Air Sample ocations

Detergent/Disinfectant
Technical Data Sheet
EPA Reg. No. 1839-83-56753

- BRIEF DESCRIPTION -

Conflikt Detergent Disinfectant is a pre-diluted, ready-to-use quaternary ammonium based disinfectant that exhibits antibacterial, antiviral, antifungal, mildewstat, and deodorizing capabilities. It is especially formulated with surfactants for cleaning and sanitizing inanimate hard surfaces – glass, plastics, stainless steel, ceramics, laminates, etc. Conflikt meets OSHA Bloodborne Pathogens Standard and approved by USDA.

- USE PROTOCOL -

Use Conflikt Detergent Disinfectant full strength to clean and sanitize areas where contamination is a problem: contaminated glass and plastic labware, bench tops, sinks, hoods, floors, walls, autoclaves, etc. The detergent base offers excellent cleaning and free-rinsing properties. An effective mildewstat, Conflikt may be used to clean walls and floors in humid, mildew-promoting environments – warehouses, production areas, etc. Conflikt Detergent Disinfectant has a pleasant fresh odor well tolerated in work areas.

- ACTIVE INGREDIENTS -

n-Alkyl (60% C_{14}, 30% C_{16}, 5% C_{12}, 5% C_{18}) dimethyl benzyl ammonium chlorides……..0.105%
n-Alkyl (68% C_{12}, 32% C_{14}) dimethyl ethylbenzyl ammonium chlorides ….....0.105%
Inert Ingredients …….……99.790%

-EFFICACY-

Efficacy tests have demonstrated that the Conflikt Detergent Disinfectant formulation is an effective bactericide, virucide, and fungicide in the presence of organic soil (5% blood serum).

TUBERCULOCIDAL ACTIVITY. Conflikt exhibits disinfectant efficacy against Mycobacterium tuberculosis BCG (*Mycobacterium bovis*) in 5 minutes at 20° Centigrade when used as directed on previously cleaned hard non-porous inanimate surfaces.

VIRUCIDAL ACTIVITY. Conflikt, when used on environmental, inanimate, non-porous surfaces, exhibits effective virucidal activity against:

(10 minutes): Canine Parvovirus, Hepatitis A Virus (HAV), Poliovirus Type 1
(5 minutes): Hepatitis B Virus (HBV), Hepatitis C virus (HCV), Bovine Viral Diarrhea Virus (BVDV)
(2 minutes): Human Coronavirus, SARS associated Coronavirus, Avian Influenza A (strains H3N2 and H9N2) Kills pandemic 2009 H1N1 Influenza A virus
(**3 minutes)**: Paramyxovirus (Mumps), Rhinovirus type 39, Rotavirus
(1 minute): HIV-1 (associated with AIDS)
(30 seconds): Norovirus (Norwalk virus), Feline Calicivirus, Rabies virus

BACTERICIDAL ACTIVITY. When used as directed, Conflikt meets the requirements for hospital use and exhibits effective disinfectant activity (**3 minute** contact time) against the organisms:

Pseudomonas aeruginosa,
Staphylococcus aureus,
Escherchia coli (ATCC 11229)
Escherchia coli O157:H7
Corynebacterium ammoniagenes
Salmonella (choleraesuis) enterica
Salmonella (typhi) enterica
Listeria monocytogenes
Yersinia enterocolitica
Enterococcus faeccium
Streptococcus pyogenes

ANTIBIOTIC-RESISTANT BACTERICIDAL ACTIVITY
Methicillin resistant Staphylococcus aureus (MSRA)
Vancomycin resistant Enterococcus faeclais (VRE)
Vancomycin Intermediate resistant Staphylococcus aureus(VISA)
*Methicillin resistant Staphylococcus epidermis (*MRSE)
Community Associated Methicillin resistant Staphylococcus aureus (CA-MSRA) (NRS 123) Genotype USA400
Community Associated Methicillin resistant Staphylococcus aureus (CA-MSRA) (NRS 384) Genotype USA300

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Kills *HIV-1, HBV, and HCV* on pre-cleaned environmental surfaces/objects previously soiled with blood/body fluids in healthcare setting (hospitals, nursing homes) or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood or body fluids and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of Human Immunodeficiency Virus Type 1 (HIV-1) (associated with AIDS), Hepatitis B Virus (HBV) and Hepatitis C Virus (HCV).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 HBV AND HCV ON SURFACES / OBJECTS SOILED WITH BLOOD/BODY FLUIDS:

PERSONAL PROTECTION: When handling items soiled with blood or body fluids use disposable latex gloves, gowns, masks, or eye coverings.

CLEANING PROCEDURES. Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of Conflikt.

CONTACT TIME. Allow surface to remain wet for HBV and HCV **5minutes**, for HIV-1 **1minute**.

DISPOSAL OF INFECTIOUS MATERIALS. Blood and other body fluids should be autoclaved and disposed of according to local regulations for infectious waste disposal.

- OSHA'S BLOOD BORNE PATHOGENS STANDARD -

The current OSHA policy regarding acceptability of disinfectants use for this purpose (decontamination of work surfaces contaminated with blood or OPIM) is stated in the Inspection and Citation Guidelines following paragraph M.d. (1) (b) on page 34 of OSHA Instruction CPL 2-2, 44C, "Enforcement Procedures for Occupational Exposure to Blood borne Pathogens Standard, 29 CFR 1910, 1030." This policy indicates that products registered with the U.S. Environmental Protection Agency (EPA) with claims of tuberculocidal efficacy are considered "appropriate" for purposes of compliance with the standard and would therefore be acceptable for such use."

"OSHA continues to require the use of a tuberculocidal disinfection to clean up blood or body fluids."

Excerpts from OSHA letter: ESchmidt 05-06-94

FUNGICIDAL ACTIVITY. Conflikt is fungicidal against the pathogenic fungus, *Trichophyton mentagrophytes* (Athlete's Foot Fungus) when used as a directed on hard surfaces found in bathrooms, shower stalls, locker rooms, or other clean, non-porous, hard surfaces commonly contacted by bare feet.

MILDEWSTAT. To control mold and mildew on pre-cleaned, hard, non-porous surfaces spray surface to be treated making sure to wet completely. Let air dry. Repeat application at weekly intervals or when mildew growth appears.

- STORAGE AND DISPOSAL -

Do not contaminate water, food, or feed by storage or disposal.

STORAGE. Store in a dry place no lower in temperature than 50°F or higher than 120°F. The shelf life is one year. The expiration date can be found on the product

CONTAINER DISPOSAL. Do not reuse container. Rinse thoroughly and offer for recycling if available. Do not reuse empty spray bottle except with refill bottle.

.

- PRECAUTIONARY STATEMENTS –

KEEP OUT OF REACH OF CHILDREN

CAUTION

Hazards to humans and domestic animals.

Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling. In case of contact, immediately flush eyes or skin with plenty of water for at least 15 minutes. If in eyes, or if swallowed, call a poison control center or doctor immediately for treatment advice. Do not induce vomiting unless told to do so by the poison control center or doctor.

NOTE TO PHYSICIAN. Probable mucosal damage may contraindicate the use of gastric lavage.

- PACKAGING –

16 oz. (475 mL) Spray Pack / 12 per case
32 oz. (950 mL) Trigger Spray / 6 per case
64 oz. (1.9 L) Refill / 6 per case
1 Gallon (3.8 L) Refill / 4 per case

- CATALOG NUMBERS -

Manufactured for:	Item	Cat. No.
Decon Labs, Inc.	**16 oz.**	**4101**
	32 oz.	**4102**
	64 oz.	**4103**
	1 Gal.	**4104**

For Additional Technical Information call
Decon Customer Service
(800) 332-6647, or
See our website at www.deconlabs.com

®Decon Labs, Inc. *Revised 12/12/2012*

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CONTEC

peridox RTU®

Sporicidal Disinfectant and Cleaner for Pharmacy Cleanrooms

HIGHLY EFFECTIVE
EPA-REGISTERED
SPORICIDE, FUNGICIDE,
BACTERICIDE, VIRUCIDE,
AND TUBERCULOCIDE

Broad spectrum EPA-registered one-step, one-application disinfectant and hard surface cleaner*

Combat spores with the industry's fastest sporicidal claim

PeridoxRTU® process eliminates and prevents the spread of spores, as well as *C. difficile*, MRSA, and more than 40 other pathogens, including ESKAPE pathogens – *Enterococcus faecalis* (VRE), *Staphylococcus aureus, Klebsiella pneumoniae, Acinetobacter baumannii, Pseudomonas aeruginosa,* and *Enterobacter aerogenes*). PeridoxRTU® contains no alcohol or bleach, requires no rinsing and leaves no film on surfaces.

This unique hospital grade sporicidal disinfectant and cleaner is ideal for use in pharmacy compounding areas to meet the germicidal detergent requirements of USP<797> and USP <800>. Compatible with stainless steel, PeridoxRTU can be used daily in the ISO Class 5 compounding area, buffer zones, and anterooms. Ideal for hazardous drug removal and decontamination.

According to the Centers for Disease Control and Prevention, EPA-registered disinfectants with a sporicidal claim have been used with success for environmental surface disinfection in patient care areas.
*Follow manufacturer's suggested instructions.

SPORICIDE FUNGICIDE BACTERICIDE VIRUCIDE TUBERCULOCIDE

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Experience the power of PeridoxRTU® Sporicidal Disinfectant and Cleaner.

Power that lasts

Patented, hyperactive chemistry provides fast results. With its shorter kill times and powerful wetting agents PeridoxRTU® stays wet and works faster. The result; assured efficacy against hard-to-kill spores and other dangerous pathogens every time you clean and disinfect.

Cost-effective non-bleach cleaner and disinfectant

PeridoxRTU® provides maximum effectiveness without the risks of bleach, which include damage to stainless steel, LCD screens, pharmacy equipment, clothing, carpet and other surfaces; handling and mixing of bleach by pharmacy staff. PeridoxRTU's proprietary formulation contains surfactants for cleaning efficiency along with corrosion inhibitors for surface protection. In addition, one-step, one-application PeridoxRTU® saves time and labor cost compared to bleach, which requires a rinsery and drying of surfaces.

Personal Protective Equipment (PPE)

Wear appropriate gloves and eye protection. Additional PPE may be required based on engineering controls/environment, method of application, and use protocols.

Ideal for hazardous drug decontamination on stainless steel surfaces* *Third party lab verified amongst common hazardous drugs.

PRODUCT SPECIFICATIONS

Odor	Vinegar
Wetting Ability	Excellent
Freeze/Thaw	Stable
EPA-Registered*	Yes
% Hydrogen Peroxide	4.40%
% Peroxyacetic Acid	0.23%
Detergency	Excellent
Density	1.02 g/mL,
	8.51 lbs./gal.
pH	1.9-2.2 at 20°C
RTU Shelf Life (opened or unopened)	2 years
HMIS Hazard Rating	
Health	2
Flammability	0
Reactivity	0
Personal Protection**	X

PeridoxRTU® Sporicidal Disinfectant and Cleaner in two convenient sizes:

PART #	SIZE	CASE PK.	WT.
HC85335	32 oz. Bottle	6/cs*	15 lbs.
HC85336	1 gal. Bottle	4/cs	37 lbs.

*Includes 6 push/pull caps. All bottles are sealed in plastic.

Complete efficacy data available for download at www.contechealthcare.com.
**EPA #8383-13*
***See SDS for more detailed information.*

SPORICIDE FUNGICIDE BACTERICIDE VIRUCIDE TUBERCULOCIDE www.contechealthcare.com

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peridox RTU®

Efficacy Data

Fungicidal/Mold Killing	Contact Time
Aspergillus niger (hard surface)	1 min.
Aspergillus niger (porous surface)	10 min.
Candida albicans (hard surface)	1 min.
Trichophyton mentagrophytes (athlete's foot fungus) (hard surface)	1 min.

Sporicidal	Contact Time
Clostridium difficile spores	3 min.

Viricidal	Contact Time
Avian influenza virus A (H3N2)	2 min.
Human coronavirus	2 min.
Adenovirus, Type 2	2 min.
Avian influenza virus H5N1	2 min.
Canine Parvovirus	3 min.
Hantavirus (Prospect Hill virus)	2 min.
Hepatitis C virus	2 min.
Herpes simplex virus, Type 1	2 min.
Herpes simplex virus, Type 2	2 min.
Human immunodeficiency virus, Type 1 (HIV-1)	2 min.
Influenza A virus (H1N1)	2 min.
Influenza virus, Type A	2 min.
Influenza virus, Type B	2 min.
Minute virus of mice	2 min.
Murine Norovirus (Strain MNV-1. CW1)	2 min.
Norovirus (F. calicivirus)	2 min.
Poliovirus, Type 1	2 min.
Reovirus	2 min.
Respiratory syncytial virus (RSV)	2 min.
Rhinovirus	2 min.
Rotavirus (Strain WA)	2 min.
Hepatitis B virus	2 min.

Tuberculocidal	Contact Time
Mycobacterium bovis	5 min.

Bactericidal	Contact Time
Enterobacter aerogenes	2 min.
Listeria monocytogenes	2 min.
Pseudomonas aeruginosa	2 min.
Salmonella typhimurium	2 min.
Staphylococcus aureus	2 min.
Vibrio cholerae	2 min.
Salmonella enterica	2 min.
Acinetobacter baumannii	2 min.
Campylobacter jejuni	2 min.
E. coli 0157:H7	2 min.
E. coli ESBL	2 min.
Enterococcus faecalis Vancomycin Resistant (VRE)	2 min.
Enterococcus hirae	2 min.
Haemophilus influenzae	2 min.
Klebsiella pneumoniae	2 min.
Legionella pneumophila	2 min.
Proteus vulgaris	2 min.
Serratia marcescens	2 min.
Shigella sonnei	2 min.
Methicillin Resistant - *Staphylococcus aureus* (MRSA)	2 min.
Community Acquired Methicillin Resistant - *Staphylococcus aureus* (CA-MRSA)	2 min.
Streptococcus Pneumoniae Penicillin Resistant - (PRSP)	2 min.
Streptococcus pyogenes	2 min.
Corynebacterium bovis	2 min.
Bordetella bronchiseptica	2 min.

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Peridox® Sporicidal Disinfectant and Cleaner Material Compatibility

PeridoxRTU® and Peridox® Concentrate kill bacteria, spores, fungi, TB, and viruses on hard, non-porous surfaces. Peridox utilizes a patent-pending chemistry that exhibits supreme antimicrobial efficacy, yet it is mild on surfaces with its blend of corrosion inhibitors.

PeridoxRTU's proprietary formulation contains surfactants for cleaning efficiency along with corrosion inhibitors for surface protection. Peridox products can be used to clean and disinfect surfaces without damage or loss of functionality. Under normal cleaning conditions, Peridox can be used on environmental surfaces, including difficult to clean and disinfect items such as medical equipment, electrical enclosures, and LCD screens. It is the ideal sporicidal disinfectant for use in life science manufacturing facilities, health care facilities and compounding pharmacies.

PeridoxRTU and Peridox Concentrate:

- Has over 40 registered EPA claims.
- Has fast kill times.
- Does not contain alcohol, bleach, quaternary amines, or silver.
- Leaves no persistent, harmful, or corrosive residues or undesirable film on surfaces.
- Compatible with stainless steel.
- Highly effective EPA-registered Sporicide, Bactericide, Virucide, Tuberculocide, and Fungicide

Compatible Materials:

ABS
Acrylic
Aluminum
Chrome
Computer Casings (external)
Electrical Connection Enclosures
Glass
Laminate Flooring/Counters
LCD Screens
Mattress Covers
Nickel
Epoxy or Alkyl-based Paints
Polycarbonate
Polyethylene
Polypropylene
Polyurethane Finishes
Porcelain
PVC
Resin Countertops
Silicone Rubber
Stainless Steel
Switch Plates (Plastic)
Tygon®

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PREempt® RTU

Ready to Use Multi-Surface One-Step Disinfectant Cleaner formulated with AHP® Patented

Ready to Use

WHY CHOOSE PREempt™?

- **CLEANER** Effective disinfectant as well as a cleaner resulting in added confidence that disinfection can occur.
- **FASTER** Rapid and realistic contact times on a broad spectrum of difficult to kill pathogens.
- **RESPONSIBLE** Designed to be easier on surfaces, staff and occupants. Users are not exposed to VOCs (volatile organic compounds) and PPE** is not required as per health and safety rating.
- **SUSTAINABLE** The active ingredient, Hydrogen Peroxide, breaks down into water and oxygen leaving no active residues which helps to reduce environmental impact.

DIRECTIONS FOR USE

For Use as a One-Step Cleaner/Disinfectant Product:

1. Pre-clean heavily soiled areas.
2. Apply Solution by spray, cloth, disposable wipe or mop to hard, non-porous environmental surfaces.
3. *All surfaces must remain wet for 1 minute.*
   Use a 5 minute contact time for TB† and a 10 minute contact time for fungi.
4. Wipe surfaces dry.

For Use to Clean and Disinfect Life Science Laboratory Surfaces, Instruments, and Glassware:

1. Pre-clean heavily soiled areas.
2. Apply Solution by spray, cloth, disposable wipe or mop to hard, non-porous environmental surfaces or completely immerse pre-cleaned glassware and compatible instruments in the solution.
3. Immerse or allow the surface to remain wet for 1 minute. Use a 5 minute contact time for TB† and a 10 minute contact time for fungi.
4. For glassware/instruments: Rinse surface thoroughly and let air dry before reuse. For surfaces: Wipe surface dry.
5. Change immersion solution after each use.

For use in laboratories, clean rooms and other critical environments that require cleaning and surface disinfection. This includes work stations, fume hoods, laboratory counter tops, equipment and other hard non-porous environmental surfaces.

AVAILABLE PRODUCTS

PREempt™ Ready to Use One-Step Surface Cleaner and Disinfectant

EPA REG. NO. 74559-1

SHELF LIFE: 3 Years

CONCENTRATION OF ACTIVE:
0.5% Hydrogen Peroxide

- **Format Size:** 1 U.S. Quart (32 oz.) Bottle
  Product Code: 21101
  Packaging Specifications: 12x1 Quart (32 oz.)
- **Format Size:** 1 Gallon Bottle
  Product Code: 21105
  Packaging Specifications: 4x1 Gallon
- **Format Size:** 5 Gallon Pail
  Product Code: 21109
  Packaging Specifications: 1x5 Gallon

***PPE - Personal Protective Equipment*
TB† stands for BCG (*Mycobacterium bovis*)

EFFECTIVE AGAINST A BROAD-SPECTRUM OF BACTERIA AND*VIRUSES IN 1 MINUTE!

*Virucidal: 1 Min.

- *Poliovirus Type 1
- *HIV-1 (AIDS Virus)
- *Feline Calicivirus
- *Norovirus (Feline Calicivirus, as the surrogate)
- *Human Coronavirus
- This product has demonstrated effectiveness against Influenza A virus and is expected to inactivate all Influenza A viruses including Pandemic 2009 H1N1 Influenza A virus.

Bactericidal: 1 Min.

- *Pseudomonas aeruginosa*
- *Staphylococcus aureus*
- *Salmonella enterica* (formerly known as *Salmonella choleraesuis*)

Antibiotic-Resistant Bactericidal Activity:

- Methicillin-resistant *Staphylococcus Aureus* (MRSA)
- Vancomycin-resistant *Enterococcus faecalis* (VRE)
- *Escherichia coli* with Extended Spectrum Beta-lactamase resistance (ESBL)

Fungicidal: 10 Min.

- *Trichophyton mentagrophytes*

Tuberculocidal: 5 Min.

- †*Mycobacterium bovis (BCG)*

Broad-Spectrum Non-Food Sanitizing: 30 Sec.

- *Klebsiella pneumoniae*
- *Salmonella enterica* (formerly known as *Salmonella choleraesuis*)
- *Pseudomonas aeruginosa*
- *Staphylococcus aureus*
- *Escherichia coli O157:H7*

Soft Surface₸ Sanitation: 1 Min.

- *Enterobacter aerogenes*
- *Staphlyococcus aureus*

PREempt™ Ready to Use Multi-Surface One-Step Disinfectant Cleaner is designed for use as a daily cleaner and disinfectant which has easy to use formats with no mixing or measuring required.

**Please refer to reference sheet for a complete list of pathogenic organisms, additional features, and claims.*

PREempt™ branded products are manufactured by Virox Technologies Inc.

Accelerated Hydrogen Peroxide®, (AHP®) and PREempt™ are registered trademarks of Virox Technologies Inc.

For more information on this or our other products, visit:

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VIROX® TECHNOLOGIES INC.

Engineering Revolutionary Disinfectants for the War Against Microbes

000120

₸ composed of cotton or polyester

Efficacy Report for Sporicidin® Disinfectant Solution and Sporicidin® Disinfectant Towelettes

Sporicidin Disinfectant Solution is a hospital grade disinfectant registered with the US Environmental Protection Agency (EPA registration number 8383-3). Sporicidin Disinfectant Towelettes are made with the same formulation and registered with the US Environmental Protection Agency, registration number 8383-7. Produced under strict quality control, Contec, Inc. is an ISO 9001:2008 registered company. With more than a quarter century of experience producing products for critical environment products in Asia, Europe and the Americas, Sporicidin products are made in the USA.

US EPA reviewed testing by independent laboratories has proven that Sporicidin Disinfectant Solution is able to kill the following organisms when used in a manner consistent with the label instructions. The efficacy of Sporicidin Disinfectant Solution has been tested and proven effective against each of the following organisms utilizing a proprietary, EPA approved test method in GLP conditions.

Viruses (5 minute contact time for both enveloped and non-enveloped viruses)

- Avian Influenza A virus (H5N1), Strain H5N1-PR8/CDC-RG, CDC#2006719965
- Avian Influenza A virus (H9N2), Turkey/WIS/66
- Cytomegalovirus, ATCC VR-538
- Herpes simplex virus types 1/F and 2/G (oral, ocular and genital)
- HIV-1 (AIDS virus)
- Human Coronavirus
- Influenza A virus (H1N1 Pandemic Flu)
- Influenza A virus (H3N2)
- Norovirus, Feline Calcivirus, Surrogate for Norovirus (ATCC VR-782)
- Parainfluenza type 3 virus, ATCC VR-93
- Polio type 1 virus, Brunhilde, ATCC VR-58
- Vaccinia virus, VR-119

Bacteria (10 minute contact time)

- *Acinetobacter baumannii*, ATCC 19606
- *Escherichia coli* (E. coli), ATCC 35150
- Methicillin-resistant *Staphylococcus aureus* (MRSA), ATCC 33591
- *Pseudomonas aeruginosa*, ATCC 15442
- *Salmonella choleraesuis*, ATCC 10708
- *Salmonella enterica*, ATCC 10708
- *Staphylococcus aureus*, ATCC 6538
- *Streptococcus pyrogenes*, ATCC 19615
- *Streptococcus salivarius*, ATCC 7073
- Tuberculosis (*Mycobacterium Bovis* (BCG)), ATCC 35743
- Vancomycin resistant *Enterococcus faecium* (VRE), ATCC 51559

Fungi (10 minute contact time)

- Aspergillus brasiliensis, ATCC 16404
- Penicillium variabile, ATCC 52262
- Stachybotrys chartarum, ATCC 66239
- Trichophyton mentagrophytes (Athlete's Foot fungus), ATCC 9533

The EPA has also reviewed and approved the following Marketing Claims for Sporicidin Disinfectant Solution:

EPA Approved Mold Remediation Marketing Claims

- This product inhibits the growth of damage and odor-causing bacteria and fungi on treated articles and surfaces, such as construction materials.
- This product is used to protect treated articles from decay, mold or mildew.
- This product inhibits bacterial growth on moist surfaces and deodorizes by killing microorganisms that cause offensive odors.
- This product inhibits the growth of mold and mildew and their odors when used as directed.
- This product kills mold and mildew when used as directed.

EPA Approved Cleaning and Sanitizing Marketing Claims

- This product cleans, deodorizes, and controls the growth of damage and odor-causing organisms.
- This product (maximizes) (improves) labor results by effectively controlling odors.
- This product is a ready-to-use product and can be applied with a cloth, sponge, mop and bucket, trigger sprayer, pressure sprayer, or pump sprayer.
- This product neutralizes musty odors and tough odors from smoke.
- This product is specially formulated to effectively eliminate offensive odors caused by mold and mildew.
    - Eliminates odors caused by bacteria and fungi.
    - For use as a mold preventative or remediation treatment in areas where mold can or has been a problem:
    - Commercial and residential buildings.
    - Hospitals, nursing homes.
    - EMS & fire facilities.
    - Day care centers and nurseries.
    - Life care retirement communities, and home healthcare institutions.
    - Restaurants, bars, cafeterias, institutional kitchens, fast food operations and food storage areas.
    - Supermarkets, convenience stores, retail and wholesale establishments, and laundries.
    - Manufacturing facilities.
    - Food establishments, coffee shops, doughnut shops, bagel stores, pizza parlors, liquor stores, and ice cream parlors

- Police stations, courthouses, correctional facilities, jails, prisons, municipal government buildings, forensic laboratories, animal research and lab facilities.
- Institutional facilities, laboratories, factories, business and office buildings, restrooms, hotels and motels.
- Public restrooms, public facilities, shower rooms, shower stalls, and bathrooms.
- Hotel, motels, and dormitories.
- Kitchens & bathrooms.
- Institutions, schools and colleges, churches, classrooms, community colleges, universities, athletic facilities and locker rooms, exercise rooms, exercise facilities, gyms, and gymnasiums.
- Heath clubs and day spas.
- Recreational facilities, sports arenas, and sports complexes.
- Veterinary clinics, animal life science laboratories, kennels, dog/cat animal kennels, breeding and grooming establishments, pet animal quarters, zoos, and other animal care facilities.
- Boats, ships, and barges, and cruise lines.
- Commercial florist and flower shops.
- Basements, crawl spaces, cellars, bedrooms, attics, and living rooms.
- This product may be used as a cleaner and deodorizer or for water/flood damage clean up, sewage backflow cleaning, and trauma scene cleaning.
- Enameled surfaces, (painted) (finished) woodwork, vinyl and plastic, and upholstery.
- Foundations, stops, plumbing fixtures, finished baseboards and windowsills, washable walls, tables, floors, and cabinets.
- Studs, wallboards, joists, beams, trusses, underlayment, sub-flooring, wood framing, plywood, oriented strand board, ceilings and ceiling tiles.
- Refrigerated storage and display equipment.

Based on the performance of Sporicidin Disinfectant Solution, the EPA has approved the following applications for this disinfectant solution.

- Hospital Disinfectant
- Broad Spectrum Disinfectant
- Mold & Mildewcide
- Mildewstat
- Bactericide
- Bacteriostat
- Fungicide
- Fungistat
- Deodorant and Disinfectant
- Antimicrobial

* Please see product label for the individual Sporicidin products for full organism list

Additional information on these products can be found at www.sporicidin.com

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www.contecinc.com

BLEACH ACTIVITY AND DWELL TIMES:

Broad-Spectrum Efficacy Against 50 Microorganisms

View All

Bacteria

Effective Against:	Kill Time
Acinetobacter baumannii	1 min
Bordetella pertussis	1 min
Campylobacter jejuni	1 min
Clostridium difficile spores	3 min*
Enterobacter aerogenes	1 min
Enterobacter cloacae (NDM-1)	1 min
Vancomycin-Resistant *Enterococcus faecalis* (VRE)	1 min
Multidrug resistant *Enterococcus faecium*	1 min
Vancomycin resistant *Enterococcus faecium* (VRE)	1 min
Enterococcus hirae	1 min
ESBL producing *Escherichia coli*	1 min
Escherichia coli (NDM-1)	1 min
Klebsiella pneumoniae	1 min
ESBL producing *Klebsiella pneumoniae*	1 min
Klebsiella pneumoniae (NDM-1)	1 min
Carbapenum resistant *Klebsiella pneumoniae*	1 min
Proteus mirabilis	1 min
Pseudomonas aeruginosa	1 min

VALITEQ®

ASEPTIC TECHNIQUE VALIDATION SYSTEM

RL-2

ASEPTIC TECHNIQUE VALIDATION KIT INSTRUCTIONS AND CONTENTS

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EXHIBIT #10

EXERCISE 1: RISK LEVEL-1 (RL-1) SIMPLE PROCEDURE, (6-MANIPULATIONS, 3 PER RL-2 KIT)

This exercise requires proper use of a dispensing pin, reconstitution and transfer of a large volume without a dispensing pin, use of a single-dose vial, and an ampule. Perform the following procedures, transferring all components to a 100ml capacity empty evacuated container or IV bag. Reconstitution of VM-20R is to be accomplished using 20ml sterile Water For Injection (WFI).

1.	Vial 1	VM-30, using a dispensing pin, transfer	10ml
2.	Vial 2	VM-20R, without dispensing pin, reconstitute and transfer	20ml
3.	Vial 1	VM-30, second withdrawal, transfer	10ml
4.	Ampule	VM-10A, transfer	10ml
5.	Vial 3	VM-10, without dispensing pin, transfer	10ml
6.	Vial 1	VM-30, third withdrawal, transfer	10ml

EXERCISE 2: RISK LEVEL-2 (RL-2) SIMPLE PROCEDURE, (8-MANIPULATIONS, PLUS FLUID TRANSFER, 3 PER RL-2 KIT)

This exercise requires proper transfer of sterile Water For Injection (WFI), using a compounder, gravity transfer set, or a 60ml syringe, whichever is most representative of institutional procedures, in addition to the manipulations in EXERCISE 1.

1.	WFI	Transfer via pump, gravity, or syringe into a 100ml container	50ml
2.	Vial 1	VM-30, using a dispensing pin, transfer	5ml
3.	Vial 2	VM-20R, without dispensing pin, reconstitute and transfer	5ml
4.	Vial 3	VM-10, without dispensing pin, transfer	10ml
5.	Vial 1	VM-30, second withdrawal, transfer	5ml
6.	Vial 2	VM-20R, second withdrawal, transfer	5ml
7.	Ampule	VM-10A, transfer	10ml
8.	Vial 1	VM-30, third withdrawal, transfer	5ml
9.	Vial 2	VM-20R, third withdrawal, transfer	5ml

EXERCISE 3: RISK LEVEL-2, (RL-2) COMPLEX PROCEDURE[4], (50-MANIPULATIONS, REQUIRES 1 RL-2 KIT PER EXERCISE)

This exercise provides multiple repetitions of all procedures above, plus "Y-set" transfers and syringe preparation. Using 100ml (or larger) empty evacuated containers or bags, prepare a total of 6 bags (bags 1 through 6) as follows:

1.	WFI	Transfer via pump, gravity, or syringe	35ml	X6 Bags
2.	Vial 1	VM-30, using a dispensing pin, transfer	5ml	X6 Bags
3.	Vial 2	VM-20R, without a dispensing pin, reconstitute and transfer	3ml	X6 Bags
4.	Vial 3	VM-10, without dispensing pin, transfer	5ml	X6 Bags
5.	Vial 1	VM-30, second withdrawal, transfer	5ml	X6 Bags
6.	Vial 2	VM-20R, second withdrawal, transfer	3ml	X6 Bags
7.	Vial 1	VM-30, third withdrawal, transfer	5ml	X6 Bags
8.	Vial 2	VM-20R, third withdrawal, transfer	3ml	X6 Bags
9.	Using Y-type transfer sets, transfer bags 1 and 2 into a 250ml (or larger) evacuated container or bag (bag 7).			
10.	Repeat with bags 3 and 4 to make bag 8			
11.	Repeat with bags 5 and 6 to make bag 9.			
12.	Ampule	VM-10A, transfer to bag 7	10ml	
13.	Ampule	VM-10A, transfer to bag 8	10ml	
14.	Ampule	VM-10A, transfer to bag 9	10ml	

From each bag 7 through 9, prepare 2 each 20ml syringes (6 total), and 2 each 10ml syringes (6 total). Incubate all syringes and bags 7 through 9. (Additional syringes may be prepared from the bags to increase the number of manipulations.)

MEDICAL TECHNOLOGY ASSOCIATES

Medical Technology Associates, Inc.
6840 Cross Bayou Drive
Largo, FL 33777
Voice: 727-548-8600 Fax: 727-548-8622

Quotation

Date Created 8/30/2017
Quote # QT35528

Good Thru 12/28/2017
Sales Rep Kevin Humble
Terms Net 30

Quoted To:
Axelacare Davie
15951 SW 41st Street, Suite # 500
Davie FL 33331
United States

Ship To:
Axelacare Davie
15951 SW 41st Street, Suite # 500
Davie FL 33331
United States

Quantity	Part Number	Description	Rate	Amount
1	Scope: Pharmacy & ...	MTA is pleased to provide you with this proposal for your review. SCOPE OF WORK: Re sample TSA surface on IV Room Cart. This proposal and terms are hereby accepted. You are authorized to proceed with service(s) described herein. Signature:_____ Print Name: _____ Date: _____ PO#: _____	0.00	0.00
1	Surface Sampling	Surface Sampling (Bacterial & Fungal)	0.00	0.00
2	TSA Surface	TSA (Bacterial) Surface Sample	55.00	110.00
4	Travel Svc Chrg PhL...	Travel Service Charge, Pharmacy & Lab Services	85.00	340.00
1	Freight, NDA Viables	Overnight shipping cost of Viable Media Samples	80.00	80.00
1	Lab Analysis & Ident...	Additional Lab Fees apply if the Lab finds mold/bacteria on the testing plate after incubation. Cost determined by quantity of Isolates identified and determined after incubation of Plates.	0.00	0.00

This Quote Does Not Include Freight Charges.
Cancellation and restocking fees may apply.

Remit To: Medical Technology Associates, Inc.
6840 Cross Bayou Drive
Largo, FL 33777
Fax: 727-548-8622

Subtotal	530.00
Sales Tax	6.60
Total	$536.60

EXHIBIT #11

"CONFIDENTIAL INFORMATION"

ISU LABELED/SEALED CD

RECORDS SEALED*

Patient records which identify patient by name are sealed pursuant to Section 456.057(9)(a), Florida Statutes.

CASES NO.: PH 2017-15122 & 2017-15123_ _____

SUBJECT: AMBIENT HEALTHCARE & ENRIQUE HERNANDEZ, R Ph_____

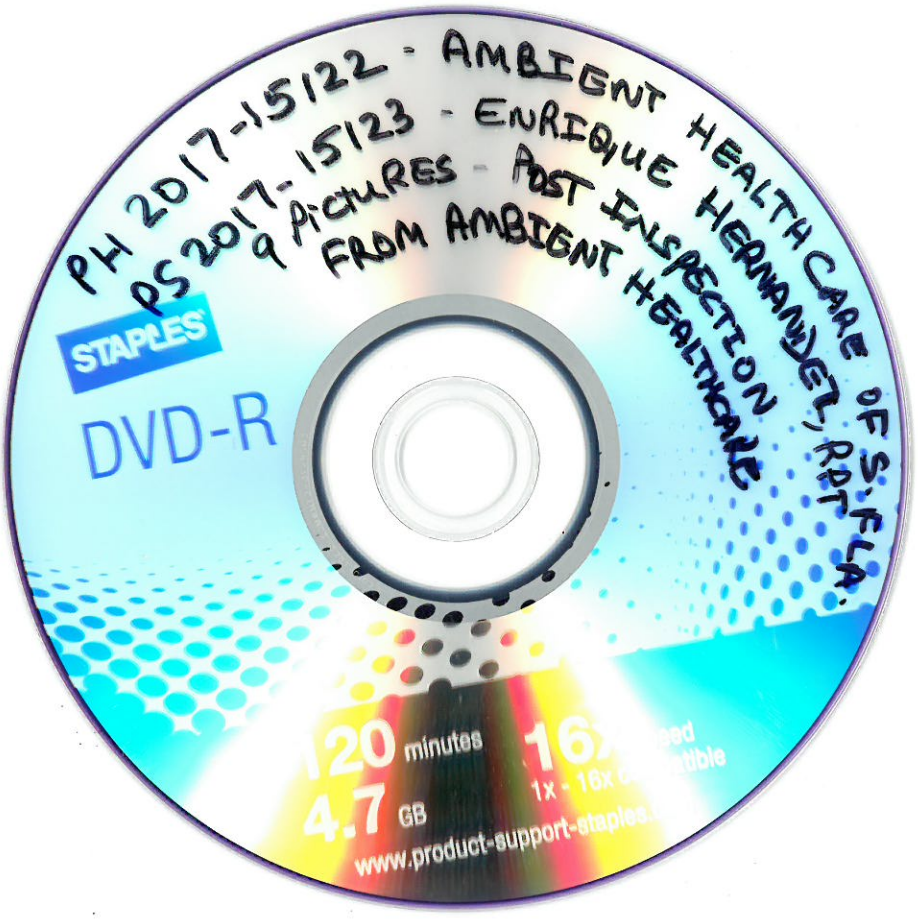
INVESTIGATOR: SYLMA STINSON_____

EXHIBIT : # – One (1) CD containing Nine (9) post-inspection pictures received via email from AMBIENT HEALTHCARE/ENRIQUE HERNANDEZ.

THE CD WILL BE FORWARDED IN A SEPARATE PACKAGE TO PSU, VIA FEDERAL EXPRESS.

PAGES:

*See (1) CD in Exhibit #


PH 2017-15122 - AMBIENT HEALTH CARE OF S. FLA.
PS 2017-15123 - ENRIQUE HERNANDEZ, RAT FLA.
9 PICTURES - POST INSPECTION
FROM AMBIENT HEALTHCARE
STAPLES
DVD-R
120 minutes
4.7 GB
www.product-support-staples

LF-Series
LF-Series
Pharma-Hol
Sterile 70%
Isopropyl Alcohol
Baxter
Baxter
BD Sharps Collector

ULINE
LIFT TO ADJUST
SEAT HEIGHT

LAMINAR AIRFLOW
WORK STATION

LONGARM
Honeywell
Honeywell

SODIUM
CHLORIDE 100 ML

SODIUM
CHLORIDE 30ML

CALCIUM GLUCONATE
100ML

CALCIUM
GLUCONATE 10 ML

SODIUM
ACETATE

SODIUM
ACETATE

COPPER

MAGNESIUM SULFATE

MULTITRACE 5

TPN CLAMPS SMALL

TPN CLAMPS LARGE

ALCOHOL PADS

1 ML SYRINGE
ULINE

Gloved Fingertip Sampling (GFS) Log

Davie - 28
Branch

Michelle Fleischer
Employee Name

5-4-17
Date Initiated

Nutrient Agar: Tryptic Soy Agar w/ Lecithin

LOT/EXP: 1005532190 8/2/17

	Date Observed	Date 5/5/17 GFS 1	Date 5/6/17 GFS 2	Date 5/7/17 GFS 3	If Positive: # of CFU's	Micro-organism identified	Initials	Comments
RH	1 5/4/17	—	—	—				
LH	2 5/4/17	—	—	—				
LH	3 5/5/17		—	—				
RH	4 5/5/17		—	—				
	5							
	6							
	7							
	8							
	9							
	10							
	11							
	12							
	13							
	14							

Note: 3 GFS's required for new employee (initial competency); 1 GFS required annual / semi-annual competence. GFSs are to be observed for 72 hours at manufacturer's recommended temperature. See policy 9710

PASS

FAIL

If fail - repeat test; 2nd fail - Retrain & Document; repeat initial 3 GFS process must pass prior to compounding resumption

Michelle Fleischer RPh/Tech

Signature of Compounder

5/4/17
Date

RPh/Tech

Signature of Reviewer (PIC or designee)

5/7/17
Date

Gloved Fingertip Sampling (GFS) Log

Davie
Branch

Michelle Fleischer
Employee Name

5/9/17
Date Initiated

Nutrient Agar: Tryptic Soy Agar w/ Lecithin and P80

LOT/EXP: 1005532190 8/2/17

	Date Observed		Date 6/10/17 GFS 1	Date 5/11/17 GFS 2	Date 5/12/17 GFS 3	If Positive: # of CFU's	Micro-organism identified	Initials	Comments
RH	1	5/9/17	—	—	—				
LH	2	5/9/17	—	—	—				
	3								
	4								
	5								
	6								
	7								
	8								
	9								
	10								
	11								
	12								
	13								
	14								

Note: 3 GFS's required for new employee (initial competency); 1 GFS required annual / semi-annual competence. GFSs are to be observed for 72 hours at manufacturer's recommended temperature. See policy 9710

PASS

FAIL

If fail - repeat test; 2nd fail - Retrain & Document; repeat initial 3 GFS process must pass prior to compounding resumption

Signature of Compounder — RPh/Tech — 5/12/17 Date

Signature of Reviewer (PIC or designee) — RPh/Tech — 5/12/17 Date

9710.F6

REV: 2/2017

Assessment of Cleaning and Disinfection Practices

Davie -28
Branch:

Michelle Fleischer
Employee Name

5/12/17
Date:

PROCEDURE	SCORE YES	SCORE NO	COMMENTS AND RECOMMENDATIONS
Daily Tasks:			
Prepares correct concentration of disinfectant solution according to manufacturer's instructions – Use RTU solution when available	✓		
Uses appropriately labeled container for the type of surface to be cleaned (floor, wall, production bins, etc.)	✓		
Documents disinfectant solution	✓		
Follows proper garbing procedure when performing any cleaning activities	✓		
At the beginning of the day, cleans all ISO Class 5 PEC's prior to compounding in the following order: side surfaces, IV bar, automated compounder, work surfaces	✓		
Uses a lint free wipe soaked in sterile 70% IPA or other approved disinfectant solution and allows to dry completely	✓		
Removes compounder components that may have been left from the previous day	✓		
Discards all partially used vials and containers that may have been left from the previous day	✓		
Cleans all counters and easily cleanable work surfaces	✓		
Mops floors, using the dedicated clean room mop, starting at the wall opposite the room entry door; mops floor surface in even strokes toward the operator. Moves carts as needed to clean entire floor surface. Use of a microfiber cleaning system is an acceptable alternative to mops	✓		
In the ante area, cleans sink and all contact surfaces; cleans floor with a disinfection solution and clean room dedicated mop or microfiber cleaning system	✓		
Monthly Tasks: Weekly for California			
Performs monthly (weekly) cleaning on designated day. Prepares disinfectant solution as stated in daily tasks that is appropriate for the surfaces to be cleaned	✓		
Cleans buffer area ceiling, walls and storage shelving with a disinfectant solution and a mop or uses a microfiber cleaning system then repeats process in ante area	✓		
Once ISO Class 5 area is clean, cleans compounding room ceiling, followed by walls and ending with the floor. Uses appropriate labeled mops or microfiber cleaning system	✓		
Cleans all buffer area totes and storage shelves by; removing contents, use of germicidal detergent on lint free wipe. Cleans inside surfaces and then entire exterior surface of tote. Allows to air dry. Prior to replacing contents, wipes tote with sterile 70% IPA to remove disinfectant residue. Uses new wipes as needed.	✓		
Cleans buffer area chairs, the interior and exterior of trash bins, and storage bins using disinfectant solution soaked lint free wipe	✓		
Documents all cleaning activities as to who performed such activities with date and time noted	✓		

100% compliance required

Michelle Fleischer — RPh/Tech — Date: 5/12/17
Signature of Compounder

Katrina Phillips — RPh/Tech — Date: 5/12/17
Signature of Reviewer (PIC or designee)

Assessment of Aseptic Technique and Related Practices

Michelle Fleischer
Employee Name

Davie 28
Branch

5/12/17
Date

PROCEDURE	SCORE YES	SCORE NO	COMMENTS AND RECOMMENDATIONS
Performs proper hand hygiene, garbing and gowning according to PP	✓		
Disinfects ISO Class 5 PEC surfaces with an appropriate agent	✓		
Disinfects components/vials with an appropriate agent prior to placing into ISO Class 5 work area	✓		
Introduces only essential materials in a proper arrangement in the ISO Class 5 work area	✓		
Does not interrupt, impede or divert flow of first-air to critical sites	✓		
Performs manipulations only in the appropriate direct compounding area of the ISO Class 5 work area	✓		
Does not expose critical sites to contact contamination or worse than ISO Class 5 air	✓		
Disinfects stoppers, injection ports and ampule necks by wiping with sterile 70% IPA and allows sufficient time to dry	✓		
Affixes needles to syringe without contact contamination	✓		
Punctures vial stoppers and spikes infusion ports without contact contamination	✓		
Disinfects sterile gloves routinely by wiping with sterile 70% IPA during prolonged compounding manipulations or after touching items or surfaces that may contaminate gloves	✓		
Disinfects sterile gloves with sterile 70% IPA when leaving the ISO 5 area and prior to re-entering the ISO 5 area	✓		
Cleans, sets up and calibrates automated compounding devices (e.g. TPN compounder, syringe filling pump) according to manufacturer's instructions	✓		
Filters used per policy and when appropriate (e.g. glass ampules)	✓		
Every completed admixture inspected for thorough mix of contents, presence of particulate matter, evidence of incompatibility, container closure integrity	✓		
Compounding accuracy checks performed per policy when technicians compounding, including use of compounding device(s)	✓		
Completion of compounding sheets per policy by pharmacists and technicians (lot numbers {verified}, signatures, dates, times, drug wastage)	✓		
Disposes of sharps and waste according to policy or recognized guidelines	✓		

100% compliance required

Michelle Fleischer — RPh/Tech — 5/12/17
Signature of Compounder — Date

Katrina Phillips — RPh/Tech — 5/12/17
Signature of Reviewer (PIC or designee) — Date

Assessment of Hand Hygiene & Garbing Practices

Davie-28

Michelle Fleischer

Employee Name:

Branch:

5/12/17

Date:

PROCEDURE	SCORE YES	SCORE NO	COMMENTS AND RECOMMENDATIONS
Presents in clean, appropriate attire and manner	✓		
Wears no cosmetics or jewelry upon entry into the ante area	✓		
Brings no food or drink into the sterile products complex (SPC)	✓		
Dons shoe covers, wears only in SPC	✓		
Dons beard cover if necessary	N/A		
Dons head cover assuring that all hair is covered, wears only in SPC	✓		
Dons face mask to cover bridge of nose down to include chin	✓		
Performs hand hygiene procedure by wetting hands and forearms and washing using soap and warm water. Thoroughly washes hands for at least 30 seconds per P&P 9516	✓		
Dries hands and forearms using lint-free towel or hand dryer.	✓		
If sink is not hands free, shuts off water using towel (used in hand drying above) or elbows such that the bare hands are not used to shut off the water	✓		use towels to close the sink
Selects the appropriate sized gown examining for any holes, tears or other defects	✓		
Dons gown and ensures full closure. Wears only in SPC.	✓		
Enters the buffer area ensuring to not touch door handle	✓		
In the buffer area, disinfects hands utilizing waterless alcohol-based surgical hand gel/foam; allows hands to dry thoroughly prior to donning sterile gloves	✓		
Prior to compounding, in the buffer area dons sterile gloves utilizing appropriate technique; ensures a tight fit with no excess glove material at the fingertips	✓		
Examines gloves ensuring that there are no defects, holes or tears	✓		
While engaging in sterile compounding activities, routinely disinfects gloves with sterile 70% IPA prior to work in the direct compounding area and after touching items or surfaces that may contaminate gloves	✓		
Removes PPE in the ante area	✓		
Removes gloves and performs hand hygiene	✓		
Removes gown and discards it or hangs it on hook if it is to be reused within the same work shift	✓		
Removes and discards mask, head cover and beard cover (if used)	✓		
Removes shoe covers upon exiting the SPC.	✓		

100% compliance required

michelle fleischer — RPh/Tech — 5/12/17

Signature of Compounder — Date

Katrina Phillips — RPh/Tech — 5/12/17

Signature of Reviewer (PIC or designee) — Date

. Beyond-use time does not exceed 6 hours for closure sealed single-dose containers in ISO Class 5 or cleaner air after initial opening or entry, unless specified otherwise by the manufacturer. [SINGLE-DOSE AND MULTIPLE-DOSE CONTAINERS] *Multiple single use SWI were in the PEC's with no puncture date or time.* **e ill reeducate all compoundin Personnel and document any discrepancies to our policies to clearly mar Puncture date and time on all ial or containers open or compoundin**	No
Beyond-use time does not exceed 1 hour for closure sealed single-dose containers after being opened or entered in worse than ISO Class 5 air. [SINGLE-DOSE AND MULTIPLE-DOSE CONTAINERS] *Entered pharmacy bulk package of vancoymycin Lot # 772953A in refrigerator with no time or date of puncture.* **This as a patient that as mixed that mornin ith a particular dose o ancomycin and lab here recei ed a ter compoundin had occurred hich indicated a need to chan e the compounded dose a counter ill Technician mista enly placed this medication ba bac into the Re ri erator to a ait the chan e in dose order e ill reeducate all compoundin Personnel and document any discrepancies to our policies to clearly mar Puncture date and time on all ial or containers open or compoundin**	No

AC T D S GN AND C RT CAT N

Certification and testing of primary (LAFWs, BSCs, CAIs and CACIs) and secondary engineering controls (buffer and ante areas) have been performed by a qualified individual no less than every six months and whenever the device or room is relocated, altered, or major service to the facility is performed. Corrective action for deficiencies are documented. Certification procedures such as those outlined in the CETA Certification Guide for Sterile Compoundin g Facilities (CAG-003-2006) are conducted under dynamic conditions. [ENVIRONMENTAL QUALITY AND CONTROL : Environmental Nonviable Particle Testing Program] *MTA 7-14-17 tested PECs and SECs ; ante room did not pass with the required 20 ACPH - room had 15 THIS IS YOUR SECOND ADVISORY ;* **Se eral endors that can repair or replace air handler in Ante or u er Room ha e been contacted e ill select and contract a ender ithin days or less ith a detail or order that ill correct the de iciencies in the ACP readin to acceptable le els that ill meet the re uirements** *there are 4 X ISO 5 HLF hoods ; Hood # 2298 HEPA filter failed on this date with multiple leaks; a new HEPA filter was shipped on 7-27 and replaced on 8-7-17 and the PEC was recertified on this date. Per PDM HH, facility continued to compound in the PEC after filter failure and before new filter was replaced (7-14 thru 8-7).* **The our S hoods are located inside the mixin room hich is a certi ied class sterile en ironment ne o the our hood ailed the PA ilter inte rity test This same hood did pass Air elocity ni ormity and Smo e test The only de iciency as in the PA ilter hich as ound to ha e lea s concentrated only in the lo er le t uadrant o the ilter sur ace The upper and entire ri ht side o the PA hood ilter did not contain any lea s as demonstrated on Section # o the TA report dated Please see attached Doc. " TA report Q need section hood testin ailure"** **e established a line o demarcation ith a Red laminated tape and did not use or conduct any compoundin in the entire le t side o this hood hile aitin or PA ilter to arri e** **The PA ilter as ordered immediately by TA and they ere contracted to chan e ilter and recerti y hood as soon as it arri es rom the manu acture n the uture this occurrence here to present a ain e ill turn o hood and uarantine until recerti ication is established**	No
The primary engineering controls are placed within a buffer area in such a manner as to avoid conditions that could adversely affect their operation. The PEC is placed out of the traffic flow and in a manner to avoid disruption from the HVAC system and room cross drafts. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls] *The door from the IV room to ante room is a double swing door . When the ante room door opens, the clean room swing doors open;* **ne o the clean room doors has a return sprin hin e that is de ecti e e ha e contacted a ospital door ender " Med Work Services" and they came in on and ill be i in us an estimate on replacin the Clean room doors ith a metal ramed sin le door hich ill be hands ree operational and ill automatically close at all time e ill supply a copy o the or order hen this ender " Med Work Services" i e us there estimate or your records and ill commence or on this replacement ithin days** **e ha e immediately installed a loc in latch on the inside o these double doors hich ill hold the de ecti e door in place so it ill not s in open hich ill maintain pressure di erential o inch ater column bet een the cleanroom and ante room and rom the ante room to the eneral en ironment outside the compoundin area pharmacy prep stora e area please see attached picture "Clean room Door with ne pass loc installed"**	

During inspection, employees were exiting and entering clean room into the ante room while the ante room door was left open, letting dirty air enter through the main pharmacy into the ante room and IV room. **The Ante Room door ill be ept close at all time hile the Clean Room door is bein open All ixin Personal ha e been educated and in ormed e ha e also added as part o the scope o or that ill be conducted by the abo e mentioned ospital door ender an automatic return arm hin e to be installed on the Ante Room door so it ill automatically return to its closed position and remain close at all times hich ill maintain pressure di erential o inch ater column bet een the cleanroom and ante room and rom the ante room to the eneral en ironment outside the compoundin area pharmacy prep stora e area**	

AC T D S GN AND C RT CAT N Secondary n ineerin Controls

. Only the furniture, equipment, supplies, and other material required for the compounding activities to be performed are brought into the buffer room. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls] *Clean room is cluttered with multiple half empty bins, storage containers and an empty plastic tray stored under cart;* **e attempted to explain to the inspector that e only eep the essential e uipment and supplies necessary or daily compounded acti ities in the Clean room area No more stoc items then hat is needed or that days compoundin acti ities e urther explained that hen she had arri ed to do her inspection early in the mornin this is the time o day hen most o our re illin o stoc acti ities are bein per ormed and the reason hy she had obser ed so many empty or hal empty supply bins in the clean room This can also demonstrate that e eep only minimum stoc supplies in the clean room or daily mixin acti ities due to the act that so many empty stoc bins here empty at this time o the day ur Clean room is inspected and recerti ied e ery months and e ha e not had a report that has demonstrated any type o obstruction o lo or turbulences to interrupt S conditions Please see attached picture "Inside Clean Room area"** *a radio is stored under a hood* **This Radio as located under the hood not bloc in any unctional inte rity o the S ood The radio has been remo ed rom the Clean room and sta has been reeducated on the importance o only eepin the essential e uipment and supplies necessary or daily compoundin acti ities in the Clean room area**	No
. Surfaces and essential furniture in buffer rooms or zones and clean rooms are nonporous, smooth, non-shedding, impermeable, cleanable, and resistant to disinfectants. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls] *There are three chairs in the clean room that are dirty;* **All items in the clean room are iped and clean daily ith their respecti e cleanin solutions these older Chairs had orn do n mar s on sur aces They ha e been replaced ith ne ly purchased chairs as demonstrated in be ore and a ter attached pictures o "Chairs in clean room"** *the door on the inside of the clean room is filthy.* **n the bottom o the clean room door no ic plate is in place so the appearance o scu mar s are present as personnel use their le s to push open door oth doors ha e been resur aced and painted As demonstrated in attachment " nside picture o resur aced and painted Clean Room Doors"**	No
The surfaces of ceilings, walls, floors, fixtures, shelving, counters, and cabinets in the buffer area are smooth, impervious, free from cracks and crevices, and non-shedding, thereby promoting cleanability, and minimizing spaces in which microorganisms and other contaminants may accumulate. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls] *The inside door of the clean room has remnants of sticky material stuck onto glass window;* **n one o the Clean Room doors in the inside lass o the ie in indo on this door there as t o pieces o le t o er clear tape This has been remo ed oth doors ha e been resur aced and painted As demonstrated in attachment " nside picture o resur aced and painted Clean Room Doors"**	No

The buffer area does not contain sources of water (sinks) or floor drains. Work surfaces are constructed of smooth, impervious materials, such as stainless steel or molded plastic, so that they are easily cleaned and disinfected. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls] *The wheel attachments on PEC is showing signs of rust.* **The mentioned heel has been remo ed treated or rust on sur ace disin ected and replaced as demonstrated in attached picture "*wheel attachments on PEC***	

Storage shelving, counters, cabinets and carts/casters in the buffer area are smooth, impervious, free from cracks and crevices, non-shedding, non-porous, cleanable, and disinfectable. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls] *Bins containing sterile drug vials are dirty and have sticky material on the outside;* **All medication Bins have been replaced with new ones as demonstrated in picture attached "New IV Meds Bins replaced old"**	No

. An appropriate environmental sampling plan has been developed for airborne viable particles based on a risk assessment of compounding activities performed. Volumetric air sampling is conducted every six months and sites include locations within each ISO Class 5 environment and in the ISO Class 7 and 8 areas, and the areas at greatest risk of contamination (e.g., work areas near the ISO Class 5 environment, counters near doors, pass-through boxes). The plan includes sample locations, method of collection, frequency of sampling, volume of air sampled, and time of day as related to activity in the compounding area and action levels. [ENVIRONMENTAL QUALITY AND CONTROL : Environmental Viable Airborne Particle Testing Program—Sampling Plan] *Your viable sampling plan states that PASSIVE air sampling must be conducted monthly and does not mention USP<797> requirements of VOLUMETRIC air sampling and the volume of air to be sampled in each ISO classified area; Surface sampling policy does not state that ss shall be conducted at the conclusion of compounding, rather at the end of cleaning - also, plates must contain polysorbate 80 and lechitin to deactivate disinfectants and cleaning agents - include this in your policy* **The policy that is related to this recommendation has been re ie ed and re ised by or corporate o ice Clinical team Please see re ised policy # attached e ill reeducate all compoundin Personnel and document any discrepancies to our policies chan es**	No
The number of discrete colonies of microorganisms is counted and reported as colony-forming units (cfu) and documented on an environmental monitoring form. Counts from air monitoring are transformed into cfu/cubic meter of air and evaluated for adverse trends. [ENVIRONMENTAL QUALITY AND CONTROL : Incubation Period] **An n ironmental onitorin orm ill be created to tac by mappin out and monitor any past TA reports o colony ormin unit e ill supply documentation o this orm ith in days or less**	No
. Surface sampling is accomplished in all ISO classified areas on a periodic basis using TSA contact plates with lecithin and polysorbate 80 and/or swabs and is done at the conclusion of compounding. [ENVIRONMENTAL QUALITY AND CONTROL : Surface Cleaning and Disinfection Sampling and Assessment] *Facility conducts monthly surface sampling in addition to semi annually through certification company; Company policy is to conduct surface sampling after cleaning and does not mention that it shall be done at the conclusion of compounding.* **The policy that is related to this recommendation has been re ie ed and re ised by or corporate o ice Clinical team Please see re ised policy # attached e ill reeducate all compoundin Personnel and document any discrepancies to our policies chan es**	No

Competent microbiology personnel are consulted if an environmental sampling consistently shows elevated levels of microbial growth. If any mold, yeast, coagulase positive staphylococcus, or gram negative rods are detected immediate remediation and investigation into the cause and source was conducted. [ENVIRONMENTAL QUALITY AND CONTROL : Action Levels, Documentation and Data Evaluation] *MTA surface sampling on 7-14 in the clean room revealed chrysosporium sp. which is a fungus. The resampling was done on a TSA plate that is not fungal specific.* **1. MTA has been contacted to schedule a retesting with a fugal specific TSA plate. Please see attached document "Quote Axelacare Davie - TSA Surf. Resample"**	
Cleaning and disinfecting agents and methods of application are in accordance with written SOPs and followed by custodial and/or compounding personnel. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas] *. Your policy states you should be using RTU agents however MF RPT informed inspector that a capful of Lph se is mixed with a bucket of water.* **The policy that is related to this recommendation has been re ie ed and re ised by or corporate o ice Clinical team Please see re ised policy # attached e ill reeducate all compoundin Personnel and document any discrepancies to our policies chan es**	No
. Cleaning materials, such as wipes, sponges, and mops, are non-shedding, preferably composed of synthetic micro fibers, and dedicated to use in the buffer area, ante-area, and segregated compounding areas and are not removed from these areas except for disposal. If cleaning materials are reused (e.g., mops), there are procedures based on manufacturer recommendations that ensure that the effectiveness of the cleaning device is maintained and repeated use does not add to the bioburden of the area being cleaned. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas] *dedicated mops are stored in ante room with mop head in direct contact with floor and are not mounted.* **A han in rac has been installed in Ante Room and all dedicated mops are stored o the loor as demonstrated in attached picture " Mop rack in Ante Room"**	No
. Supplies and equipment removed from shipping cartons are wiped with a suitable disinfecting agent (e.g., sterile 70% IPA). [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas] *.Technician placed a dirty pair of scissors on direct compounding area without wiping down with sterile alcohol.* **The pair o scissors mentioned in this report are dele ated to the Clean Room " They do not leave the room at any time". A ne pair o scissors ha e been introduced e ill reeducate all compoundin personnel and document any discrepancies to our policies on Cleanin and Disin ectin Sterile Compoundin Areas**	No

Q A T AND C NTR Secondary n ineerin Controls

. Shelving, walls, and ceilings in ante-areas and buffer areas are cleaned and disinfected at least monthly. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas] *Monthly cleaning records show walls , ceilings and outside of hoods were not cleaned; ceilings were not cleaned in may ;* *.April records show there was no monthly cleaning* **e ha e identi ied the personnel that or ot to document the monthly cleanin acti ities or the month in uestion e ill reeducate all compoundin personnel and document any discrepancies to our policies on Cleanin and Disin ectin Sterile Compoundin Areas**	No

. Compounding personnel remove personal outer garments; cosmetics; artificial nails; hand, wrist, and body jewelry that can interfere with the fit of gowns and gloves; and visible body piercing above the neck. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing] *Technician GT was observed wearing a large necklace , earrings, make up and false eyelashes.* **Technician GT is a recently hired Technician less than t o ee s As part o her initial trainin she as in the Clean room obser in procedures but as not per ormin any compoundin acti ity and as reeducatin Personnel and document any discrepancies to our policies chan es** *Technician FS has a heavy beard and was compounding sterile products without donning a beard cover* **Technician S does not ha e a beard or any acial hair ut e ill reeducate all compoundin personnel and document any discrepancies to our policies on Personnel Cleansin and Garbin**	No
Facility has adequate supplies to meet PPE requirements of USP<797>. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing] *Male technician RS has a beard and was compounding without beard covered; No beard covers available at facility* **Technician RS did ha e a beard at the time o inspection he has remo ed all acial hair since e do supply eard co ers and e ill reeducate all compoundin personnel and document any discrepancies to our policies on Personnel Cleansin and Garbin**	
Low/Medium Risk media-fill tests that closely simulate the most challenging or stressful conditions encountered during compounding are completed at least annually by compounding personnel. Media-filled vials are appropriately incubated for 14 days. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Medium-Risk Level CSPs] *compoudning records show morphine sulfate / NS 4mg/4ml RX #280177040 requires 64 entries into a IV bag however media fill conducted by facility uses only 6 manipulations.* **e are currently usin alite R alidation it n this it there are three exercises each exercise contain a di erent amount o manipulation xercise one has manipulation xercise t o has manipulation xercise three has manipulation This ma es a total o manipulation This should comply ith the media ill tests that closely simulate the most challen in or stressful conditions. Please see attached Doc. " allite Q R 2"**	No
Documentation indicates compounding personnel have successfully completed didactic training, passed written competency assessments, undergone skill assessment using observational audit tools (hand hygiene, garbing, aseptic technique) and media-fill testing annually or semiannually (high risk) and before any compounding personnel begin to prepare CSPs . [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures] *THIS IS YOUR SECOND ADVISORY. See #98* **All Technicians alidation ill be undated ithin days or less and Documentation to con irm ill be supplied ithin the time period mentioned**	No
Compounding personnel and other personnel responsible for cleaning routinely undergo performance evaluation of proper hand hygiene, garbing, and all applicable cleaning and disinfecting procedures conducted by a qualified aseptic compounding expert. Visual observation of hand hygiene, garbing and cleaning is documented and maintained to provide a permanent record and long-term assessment of personnel competency. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures] *All compounding technicians are overdue on all observational assessments ; employee folders have blank checklists dated for 2016 that have not been completed. Last observational assessments for aseptic technique, cleaning and disinfecting and hand hygiene and garbing were completed in 2015* **All Technicians alidation ill be undated ithin days or less and Documentation to con irm ill be supplied ithin the time period mentioned**	No

. Immediately after the compounder completes the hand hygiene and garbing procedure, the evaluator collects a gloved fingertip and thumb sample from both hands of the compounder onto appropriate agar plates. The plates are incubated at 30-35° for 2–3 days. All compounding personnel have successfully completed an initial competency evaluation and gloved fingertip/thumb sampling procedure (0 cfu) no less than three times before initially being allowed to compound CSPs for human use. [ENVIRONMENTAL QUALITY AND CONTROL : Gloved Fingertip Sampling] *GT Rpt informed inspector she did not complete any GFT and yet she was observed compounding in the IV room during the time of this inspection.* **Technician GT is a recently hired Technician less than one ee As part o her initial trainin she as in the Clean room obser in procedures but as not per ormin any compoundin acti ity The inspector said that she sa her hand o er a unopened ial o medication to the Technician that as settin up a compoundin ot** **e attempted to explain to the inspector that she as there or obser ational purpose only and did not enter the Compoundin ood or manipulated any syrin es ials or needles to pre orm any type o compoundin acti ity** **e urther spo e to both Technicians GT and RS to in uire about the obser ed acti ity o the inspector and both Technicians GT and RS con irmed that there as no compoundin acti ity bein per ormed by GT** *MF RPT was hired in 4-2017 and documentation shows only 1 GFT was completed.* **RPT has complete her initial trainin o G T The documentation as not in the binder at the time o the inspection Please see attached Doc " RPT Completed initial trainin "**	No
. Re-evaluation of glove fingertip testing onto appropriate agar plates (Trypticase soy agar (TSA) with lecithin and polysorbate 80) for all compounding personnel occurs at least annually for low- and medium-risk level CSPs and semiannually for high-risk level CSPs before being allowed to continue compounding CSPs. Gloves shall not be disinfected with sterile 70% IPA prior to testing. The cfu action level is based on the total number of cfu on both gloves and not per hand. [ENVIRONMENTAL QUALITY AND CONTROL : Gloved Fingertip Sampling] *Per PDM HH, all Rphs are validated for Sterile compounding however their documentation was not available at the time of this inspection;* **PD con irms that all Pharmacist alidation ill be undated ithin days or less and Documentation to con irm ill be supplied ithin the time period mentioned** *All technicians are overdue for their GFT with the exception of KP Rpt.* **all Technicians alidation ill be undated ithin days or less and Documentation to con irm ill be supplied ithin the time period mentioned**	No

. Written procedures detail cleaning and disinfecting the sterile compounding areas including cleansers, disinfectants, and non-shedding wipe and mop materials. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas] *Cleaning policy is vague and does not detail method of cleaning buffer room or PEC's; In addition, your policy references USP <797> for cleaning agents rather than including specific agents in your policy. Include agents, method of application, dwell time and mixing procedures in your cleaning policy so that anyone reading this policy will be able to clean all areas without question.* **The policy that is related to this recommendation has been re ie ed and re ised by or corporate o ice Clinical team Please see re ised policy # # A # attached e ill reeducate all compoundin Personnel and document any discrepancies to our policies chan es**	No
. A written procedure is in place for cleaning and disinfecting the Direct Compounding Areas. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas] *Policy should be easily understood so anyone that reads policy would understand.* **The policy that is related to this recommendation has been re ie ed and re ised by or corporate o ice Clinical team Please see re ised policy # attached e ill reeducate all compoundin Personnel and document any discrepancies to our policies chan es**	No

Stinson, Sylma

From: Hernandez, Enrique J <ejhernandez@briovarxinfusion.com>
Sent: Friday, September 1, 2017 5:38 PM
To: Stinson, Sylma
Cc: Desaules, Beverly A; Hayes, Dan B
Subject: FW: Notification Letter email #1
Attachments: BOP INSECTION 8.24.17 Corrective Action.docx; MTA report 7.14.17 Q51 need section3 hood testing failure.pdf

From: Hernandez, Enrique J
Sent: Friday, September 01, 2017 5:32 PM
To: 'Stinson, Sylma'
Cc: Hayes, Dan B; Desaules, Beverly A
Subject: RE: Notification Letter

Ms. Sylma
Please see attached response to the Notification Letter you sent on 8.29.17
Please call or email me with any question you may have of this document
I will send you several separate email due to the size of the document attached.
Thank you Sincerely.

Enrique (Henry) Hernandez | BriovaRx Infusion Services
Director of Pharmacy
15951 S.W. 41st Street Suite 500, Davie, Florida 33331, USA
T 1-954-389-1126
F 1-954-389-1129
1-800-670-6922 ejHernandez@**briovarxinfusion.com**

From: Stinson, Sylma [mailto:Sylma.Stinson@flhealth.gov]
Sent: Tuesday, August 29, 2017 3:02 PM
To: Hernandez, Enrique J
Cc: Hayes, Dan B
Subject: RE: Notification Letter

Thank you for verifying receipt of the letters. It was a pleasure speaking with you earlier. I look forward to hearing from you &/or Mr. Hayes. If you have any question or concerns, please do not hesitate to contact me.

Regards,

Sylma C. Stinson

Medical Quality Assurance Investigator
Florida Department of Health I Division of Medical Quality Assurance I Bureau of Enforcement I Investigative Services Unit
North Broward Regional Building
1400 West Commercial Boulevard, Ste. 130-J
Ft. Lauderdale, FL 33309
(954) 267-4511 (Desk)
(954) 213-9527 (Cell)
(954) 202-3254 (Fax)

Florida HEALTH
Medical Quality Assurance

Mission: To protect, promote and improve the health of all people in Florida through integrated state, county and community efforts.

http://survey.doh.state.fl.us/survey/entry.jsp?id=1282149360105
How am I Communicating? Contact my Supervisor

NOTE: Florida has a very broad public records law. Most written communications to or from state officials regarding state business are public records available to the public and media upon request. Your e-mail communications may therefore be subject to public disclosure.

There have been changes to the license renewal process. Please visit www.CEAtRenewal.com to learn more.

From: Hernandez, Enrique J [mailto:ejhernandez@briovarxinfusion.com]
Sent: Tuesday, August 29, 2017 2:56 PM
To: Stinson, Sylma <Sylma.Stinson@flhealth.gov>
Cc: Hayes, Dan B <dhayes@briovarxinfusion.com>
Subject: RE: Notification Letter

Hayes, Dan B dhayes@briovarxinfusion.com

From: Stinson, Sylma [mailto:Sylma.Stinson@flhealth.gov]
Sent: Tuesday, August 29, 2017 2:49 PM
To: Hernandez, Enrique J
Subject: Notification Letter

Good Afternoon,

I am forwarding the a letter and attachments for review by Mr. Dan Haase, as stated. Kindly confirm receipt. Thank you.

Regards,

Sylma C. Stinson
Medical Quality Assurance Investigator
Florida Department of Health I Division of Medical Quality Assurance I Bureau of Enforcement I Investigative Services Unit
North Broward Regional Building
1400 West Commercial Boulevard, Ste. 130-J
Ft. Lauderdale, FL 33309

STATE OF FLORIDA
BOARD OF PHARMACY

CASE NUMBER:	2017-23347
DATE OF COMPLAINT:	December 28, 2017
COMPLAINT MADE BY:	DOH/ISU
SUBJECT:	Hybrid Pharma, LLC Permit No. PH29374 1015 W. Newport Court Drive, #106-A Deerfield Beach, Florida 33442
SUBJECT ATTORNEY:	Steven G. Goerke, Esq. 5300 W. Atlantic Avenue, Suite 412 Delray Beach, Florida 33484
REVIEWED BY:	Andrew Pietrylo Assistant General Counsel
RECOMMENDATION:	Dismiss (4097) Reconsideration

CLOSING ORDER

THE COMPLAINT: The Administrative Complaint alleges that Respondent violated section 465.023(1)(c), Florida Statutes (2017), through a violation of rule 64B16-27.797(1)(a), Florida Administrative Code, which governs the minimum practice standards for sterile compounding.

THE FACTS: On or about December 19, 2017, the Department conducted a sterile compounding inspection of Respondent, which found that Respondent failed to conduct endotoxin testing on a lot of testosterone cypionate, a high-risk level compounded sterile preparation ("CSP"). On January 9, 2020, the Department filed an Administrative Complaint alleging that Respondent violated USP Chapter 797, based on this conduct. Respondent disputed the allegations and requested a formal hearing.

Respondent's counsel submitted a written response to the allegations in the Administrative Complaint, which explained in detail that Respondent was not required to perform endotoxin testing on batches of testosterone cypionate because USP Chapters 797 and 85, and the official monograph for testosterone cypionate, do not provide an endotoxin limit or any suitable method for performing testing on oil-based CSPs.

USP Chapter 797 provides, in pertinent part, that:

> **Bacterial Endotoxin (Pyrogen) Testing**
> All high-risk level CSPs, except those for inhalation and ophthalmic administration, that are prepared in groups of more than 25 identical individual single-dose packages . . . shall be tested to ensure that they do not contain excessive bacterial endotoxins (see *Bacterial Endotoxins Test* ⟨85⟩ and *Pyrogen Test* ⟨151⟩). In the absence of a bacterial endotoxins limit in the official monograph or other CSP formula source, the CSP shall not exceed the amount of USP Endotoxin Units (per hour per kilogram of body weight or square meters of body surface area) specified in *Bacterial Endotoxins Test* ⟨85⟩ referenced above for the appropriate route of administration.

The official monograph for testosterone cypionate does not contain a bacterial endotoxin limit. USP Chapter 85 provides a formula for calculating the endotoxin limit for a CSP based on the route of administration, drug, and body weight/surface area.

In describing how endotoxin tests are performed, USP Chapter 85, provides that that *sample solutions* of drugs to be tested are prepared by dissolving or diluting drugs using sterile water or another aqueous solution. However, as explained by Respondent's counsel, this method is not suitable for oil-based CSPs, as they cannot be dissolved in water, and therefore the results of the test would not be accurate. Because the USP does not offer a suitable method for performing endotoxin testing on this particular class of CSPs, Respondent's counsel argues that such testing is not required under USP Chapter 797.

Respondent's counsel also explains that Respondent has attempted to use third-party test methods to extract endotoxins from a sample for testing, but no such method has been validated or incorporated into the USP. Following the Department's inspection, Respondent agreed to perform such third-party testing on testosterone cypionate going forward, but in the absence of an officially validated method, there is no way for Respondent to verify that such test results are accurate. To date, Respondent is still performing these tests until further guidance regarding an appropriate test method is available.

Because USP Chapter 85 does not contain a suitable endotoxin testing method for testosterone cypionate, and no alternative method has been validated or adopted by the USP, the Department will likely not be able to meet its burden of proof by clear and convincing evidence that Respondent violated rule 64B16-27.797(1)(a), by failing to comply with the requirements of USP Chapter 797. Additionally, Respondent has been permitted as a special sterile compounding pharmacy since September 2015, with no history of discipline, and no patient harm has been reported in relation to this CSP.

THE LAW: Although there was sufficient evidence to support a finding of probable cause at the time of the filing of the Administrative Complaint in this case, in light of the circumstances set forth above, the Department recommends that the previous finding of probable cause be reconsidered and this case be dismissed without further prosecution.

Based on the foregoing facts and findings, and pursuant to section 456.073(4), Florida Statutes, the Probable Cause Panel dismisses this case with no further action to be taken.

It is, therefore, ORDERED that this matter should be and the same is hereby DISMISSED.

DONE and ORDERED this _____ day of _____, 2020.

_____
CHAIRPERSON, PROBABLE CAUSE PANEL
BOARD OF PHARMACY

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v. **CASE NO. 2017-23347**

HYBRID PHARMA, LLC,

RESPONDENT.
_____/

ADMINISTRATIVE COMPLAINT

COMES NOW, Petitioner, Department of Health, by and through its undersigned counsel, and files this Administrative Complaint before the Board of Pharmacy against Respondent, Hybrid Pharma, LLC, and in support thereof alleges:

1. Petitioner is the state agency charged with regulating the practice of pharmacy pursuant to section 20.43, Florida Statutes; chapter 456, Florida Statutes; and chapter 465, Florida Statutes.

2. At all times material to this Administrative Complaint, Respondent was a permitted special sterile compounding pharmacy within the state of Florida, having been issued permit number PH 29374.

3. Respondent's address of record is 1015 West Newport Court Drive, #106-A, Deerfield Beach, Florida 33442.

4. At all times material to this Administrative Complaint, Respondent was engaged in sterile compounding.

5. On or about December 19, 2017, the Department conducted a sterile compounding inspection of Respondent.

6. During the Department's inspection, the following deficiency was found:

a. No endotoxin testing conducted on testosterone cypionate, a high-risk level compounded sterile preparation (CSP), not for inhalation or ophthalmic administration, prepared in batches of more than 25 identical containers, or exposed longer than 12 hours at 2° to 8° and 6 hours at warmer than 8° before being sterilized

7. Section 465.023(1)(c), Florida Statutes (2017), provides violating any of the requirements of Chapter 465 or any of the rules of the Board of Pharmacy constitutes grounds for discipline.

8. Rule 64B16-27.797(1)(a), Florida Administrative Code, provides, in relevant part, that all sterile compounding shall be performed in

accordance with the minimum practice and quality standards of the following chapters of the United States Pharmacopeia ("USP"), 36th revision, Second Supplement, incorporated and adopted by reference with the effective chapter dates of December 1, 2013: Chapter 797, Pharmaceutical Compounding-Sterile Preparations.

9. USP Chapter 797 provides bacterial endotoxin testing shall be conducted for all high-risk level CSPs, excluding those for inhalation and ophthalmic administration, prepared in batches of more than 25 identical containers, or exposed longer than 12 hours at 2° to 8° and 6 hours at warmer than 8° before being sterilized.

10. As set forth above, Respondent violated a provision of USP Chapter 797 through the deficiency identified during the Department's inspection conducted on or about December 19, 2017.

11. Based on the foregoing, Respondent has violated section 465.023(1)(c), Florida Statutes, through a violation of rule 64B16-27.797(1)(a), Florida Administrative Code.

[*Remainder of page intentionally left blank.*]

WHEREFORE, the Petitioner respectfully requests that the Board of Pharmacy enter an order imposing one or more of the following penalties: permanent revocation or suspension of Respondent's license, restriction of practice, imposition of an administrative fine, issuance of a reprimand, placement of the Respondent on probation, corrective action, refund of fees billed or collected, remedial education and/or any other relief that the Board deems appropriate.

SIGNED this 10th day of January, 2020.

Scott A. Rivkees, MD
State Surgeon General

/s/ Anthony Brian Coniglio
ANTHONY BRIAN CONIGLIO
Assistant General Counsel
Fla. Bar No. 1002943
DOH Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65
Tallahassee, FL 32399-3265
Telephone: (850) 558-9870
Facsimile: (850) 245-4662
Email: anthony.coniglio@flhealth.gov

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK Angel Sanders
DATE JAN 10 2020

PCP Meeting: January 9, 2020
PCP Members: Montgomery & Bisaillon

NOTICE OF RIGHTS

Respondent has the right to request a hearing to be conducted in accordance with Section 120.569 and 120.57, Florida Statutes, to be represented by counsel or other qualified representative, to present evidence and argument, to call and cross-examine witnesses and to have subpoena and subpoena duces tecum issued on his or her behalf if a hearing is requested.

A request or petition for an administrative hearing must be in writing and must be received by the Department within 21 days from the day Respondent received the Administrative Complaint, pursuant to Rule 28-106.111(2), Florida Administrative Code. If Respondent fails to request a hearing within 21 days of receipt of this Administrative Complaint, Respondent waives the right to request a hearing on the facts alleged in this Administrative Complaint pursuant to Rule 28-106.111(4), Florida Administrative Code. Any request for an administrative proceeding to challenge or contest the material facts or charges contained in the Administrative Complaint must conform to Rule 28-106.2015(5), Florida Administrative Code.

Please note that mediation under Section 120.573, Florida Statutes, is not available to resolve this Administrative Complaint.

NOTICE REGARDING ASSESSMENT OF COSTS

Respondent is placed on notice that Petitioner has incurred costs related to the investigation and prosecution of this matter. Pursuant to Section 456.072(4), Florida Statutes, the Board shall assess costs related to the investigation and prosecution of a disciplinary matter, which may include attorney hours and costs, on the Respondent in addition to any other discipline imposed.

Attorneys At Law
MCRAE LAW OFFICES, P.A.
5300 West Atlantic Avenue, Suite 412
Delray Beach, Florida 33484
Phone: 561-638-6600
Fax: 888-308-6020

Mitchell T. McRae
Steven G. Goerke *

* Board Certified Civil Trial Lawyer

Via email to Andrew.Pietrylo@flhealth.gov

August 19, 2020

Andrew J. Pietrylo, Jr.
Assistant General Counsel
Office of the General Counsel
Prosecution Services Unit
Florida Department of Health
4052 Bald Cypress Way, Bin #C-65
Tallahassee, FL 32399-3265

Re: DOH v. Hybrid Pharma, LLC, Case No. 2017-23347

Dear Mr. Pietrylo:

Please accept this writing as a supplemental response on behalf of respondent, Hybrid Pharma, LLC. On behalf of Hybrid Pharma, LLC request is made that this matter be dismissed. In the event this matter is not dismissed, Hybrid Pharma, LLC requests a timely hearing before an Administrative Judge. It is my belief that Hybrid Pharma's prior written responses which are incorporated herein, as supplemented by this writing, demonstrate both legal and factual grounds for the dismissal of this claim.

The documents forwarded to me by your office confirm that the inspection report was prepared reflecting that the Date of Inspection was **December 19, 2017**. Despite the date of the written inspection report, an Administrative Complaint was not filed until **January 10, 2020**, more than two years after the inspection report. The extensive delay in filing the Administrative Complaint has caused prejudice to Hybrid Pharma as this claim hinders its ability to obtain licensure in at least one other state. Hybrid Pharma requests that the Administrative Complaint be dismissed as untimely under Florida Statute §456.073(2).

Hybrid Pharma also disputes the accuracy of the probable cause meeting information contained in the Administrative Complaint. The Administrative Complaint reflects a Probable Cause Panel meeting date of January 9, 2020, although there appears to be no public information supporting

that a PCP meeting was held on this date. Additionally, the PCP Members listed are Mr. Montgomery and Mr. Bisaillon. It is my client's belief that Mr. Bisaillon resigned from the Board of Pharmacy in advance of this date. Consequently, my client is of the opinion that if the PCP information in the Administrative Complaint is incorrect, the Administrative Complaint should be dismissed as inaccurate and/or untimely.

The Administrative Complaint should also be dismissed as it contradicts the inspection report upon which the violation is purportedly based. Paragraph 32 of the inspection report affirmatively states that "*Testosterone lot #171006a 2000 ml has not been tested for endotoxins.*" Despite the inspector's specific reference that lot #171006a was "Testosterone", the Administrative Complaint contradicts the inspector's finding and instead alleges that "During the Department's Inspection, the following deficiency was found: a) No endotoxin testing was conducted on testosterone cypionate …." It is elementary that Testosterone and Testosterone Cypionate and different chemicals. Nowhere within the inspection report does the inspector make any reference to Testosterone Cypionate. Consequently, the violation alleged in the Administrative Complaint is not found within the Department's own inspection report.

It is noteworthy that the Department conducted its inspection of Hybrid Pharma simultaneously with the FDA as Hybrid Pharma is FDA approved. The FDA, which also uses the U.S. Pharmacopeia as its reference guide, did not find any violation relating to lot #171006a as the lot contained Testosterone Cypionate and not Testosterone. I have attached as Exhibit A information relating to lot #171006a confirming that the proper chemical compound in the lot was Testosterone Cypionate.

The USP Official Monographs also reflect the difference in the chemical compounds. The USP Official Monograph for Testosterone Injectable Suspension, a copy of which is attached as Exhibit B, contains specific information addressing "Bacterial endotoxins" as well as "pH". The USP Official Monograph for Testosterone Cypionate Injection, a copy of which is attached as Exhibit C, does not make any reference to bacterial endotoxins or pH. From a scientific standpoint, the lack of mention of bacterial endotoxins and/or pH relating to the Testosterone Cypionate Injection is completely logical. The Testosterone Cypionate injection uses a "suitable vegetable oil" instead of water. Vegetable oil is anaerobic and, therefore, cannot support bacterial or fungal growth. In the absence of such growth, there would be no endotoxins within the oil. Further, vegetable oil has no pH.

The difference in water-based and oil-based injectable vehicles is also evidenced in USP <1>. USP <1> provides in part: "**Aqueous Vehicles** – The vehicles for aqueous Injections meet the requirements of the *Pyrogen Test <151> or the Bacterial Endotoxins Test <85>,* whichever is specified." The paragraph following "aqueous vehicles" in USP <1> provides in part: "**Other Vehicles** – Fixed oils used as vehicles for nonaqueous Injections are of vegetable origin, are odorless or nearly so, and have not odor suggesting rancidity." **Nowhere within the section on "Other Vehicles" is there any reference to need to meet the requirements of the Pyrogen**

Test <151> or the Bacterial Endotoxins Test <85>. The complete absence of reference to the Bacterial Endotoxin Test <85> in that portion of USP <1> relating to "Other Vehicles" confirms that Hybrid Pharma did not violate the USP as it relates to its Testosterone Cypionate testing.

The inapplicability of USP <85> to oil-based compounds if further supported in the wording of USP <85>. Particularly, that portion of USP <85> entitled "Preparation of Solutions" provides in part as follows" "Sample Solutions - Prepare the *Sample Solutions* by dissolving or diluting drugs using *Water for BET*. Some substances or preparations may be more appropriately dissolved, or diluted in other aqueous solutions. If necessary, adjust the pH of the solution to be examined (or dilution thereof) so that the pH of the mixture of the lysate and *Sample Solution* falls within the pH range specified by the lysate manufacturer, usually 6.0–8.0. The pH may be adjusted by use of an acid, base, or suitable buffer …." It is elementary that oil and water do not mix rendering the use of water to determine endotoxin levels in oil-based compounds untested, unproven, unreported and unreliable.

Hybrid Pharma is aware that USP <797> provides that if the official monograph does not contain a bacterial endotoxin limit, such as is the case with the Official Monograph for Testosterone Cypionate Injection, "the CSP shall not exceed the amount of USP Endotoxin Units (per hour per kilogram of body weight or square meters of body surface area) specified in *Bacterial Endotoxins Test* <85> referenced above for the appropriate route of administration." However, for the reasons set forth above, testing pursuant to USP <85> is not conducive to oil-based Injections.

Of great importance is the fact that the inspection report reflects that the Department's inspector answered "Yes" to Item 33 "Endotoxin testing process indicates that it is compliant with USP <85> [BACTERIAL ENDOTOXINS TEST USP<85>]." The Department's inspector also answered "Yes" to Item 34: "High Risk CSP's are within allowable limits for bacterial endotoxins. [FINISHED PREPARATION RELEASE CHECKS AND TESTS: Bacterial Endotoxin (Pyrogen) Testing]. These answers confirm that Hybrid Pharma was in fact compliant at the time of the inspection.

Hybrid Pharma has tried to follow unwritten approaches to test endotoxin levels suggested by third parties in adding water to its oil-based compounds for testing, but the results cannot be truly verified as the various factors such as ingredients, water volume, etc., have not be properly established by nor incorporated into the USP. Hybrid Pharma references the American Pharmaceutical Review article attached hereto as Exhibit D, in support of its position.

The USP does not address or is not clear on what testing endotoxin testing is applicable to oil-based Injections. More importantly, the inspection report (Items 33 and 34) completed by the Department confirm that Hybrid Pharma was compliant with its bacterial endotoxin testing. As such, Hybrid Pharma cannot be held to have committed a knowing violation of Section 465.023(1)(c), Florida Statues, or a knowing violation of rule 64B16-27.797(1)(a), Florida

Administrative Code. Accordingly, Hybrid Pharma respectfully requests that this matter be dismissed. Alternatively, Hybrid Pharma requests that this matter be timely scheduled for an Administrative Hearing.

The Department's decision to dismiss a parallel claim against Jeff Goldrich, Hybrid Pharma's former pharmacist, confounds my client. If Mr. Goldrich as the pharmacist was facing identical claims for the same allege violation, why was the claim against him dismissed. While I recognize the Department is free to determine what claims to pursue against which persons/ entities, this action leads Dr. Rajalingam to believe a prejudice exists against him personally.

Thank you for considering the above. My client and I would appreciate the opportunity to discuss this matter with you directly at your earliest convenience.

Very truly yours,

McRAE LAW OFFICES, P.A.

By: _____
Steven Goerke

Cc: Hybrid Pharma

TESTOSTERONE CYPIONATE 200MG
LOT 171006A BUD 04/16/18
MFG 10/06/17

EXHIBIT A

Hybrid Pharma LLC
NDC 26436-5074-10
TESTOSTERONE CYPIONATE
Injection
200MG/ML
IM Use Only
10ML

Each ml Contains:
Testosterone Cypionate 200mg/mL
Benzyl Alcohol 0.9%
Grapeseed Oil qs.
Store at controlled room temperture 20-25° C (68°-77°F)
This is a compounded Drug Rx Only
OFFICE USE ONLY

Not For Resale

Report adverse events to www.fda.gov/medwatch or 1-800-FDA-1088

Hybrid Pharma LLC
1815 W Newport Center Dr 108A
Deerfield Beach, FL 33442
(954) 788-2771

LOT 171006A BUD 04/16/18

HYBRID PHARMA PRODUCTION SHEET TESTOSTERONE CYPIONATE 200MG/ML INJECTABLE NDC 26436-5074 -10

TESTOSTERONE CYPIONATE 200MG/ML INJECTABLE		ISO 7 Buffer Room	
PREPARATION DATE	10/6/17	Temperature F [Range 68 -77F]	71F
BATCH SIZE	2000 ML	Humidity % [Range 30 -65%]	36%
LOT#/ BATCH#	171006A	Pressure Gauge -[>0.02]"w.c	-0.03"
BEYOND USE DATE /Maximum BUD*	4/6/18	Biological safety cabinet, ISO 5	✓
RPH INITIALS			
RPT INITIALS			

*** Labelled BUD may be less than the Maximum BUD**

MATERIALS REQUIRED:

CALIBRATED BALANCE	WEIGH BOATS/ WEIGHING PAPERS/SPATULAS
MAGNETIC STIR PLATE, STIR BAR, 2-3"	OVERHEAD STIRRER, STIR ROD
BEAKERS WITH MARK IN IT OR SUITABLE GLASSWARE	DEPYROGENATE ALL THE GLASSWARES AND STERILIZE THE TUBES AND ACCESSORIES
STERILE 0.2MICRON MEMBRANE FILTERS	OR STERILE CAPSULE FILTER
BUBBLE POINT TESTER/FILTER INTEGRITY TESTER	
CALIBRATED TRANSFER PUMP/DISPENSER PUMP	STERILE TRANSFER TUBES
STERILE DEPYROGENATED VIALS	CAPS ,CAPPER
STERILE AND DRY RUBBER STOPPERS	RINSE WITH 2% DISODIUM EDETATE SOLUTION, RINSING WITH DISTILLED WATER. AUTOCLAVE STOPPERS.

TESTOSTERONE CYPIONATE 200MG
LOT 171006A BUD 04/16/18
MFG 10/06/17

Batch #

Warm the oil, Benzyl benzoate and benzyl alcohol to 90 -110 ^{0}F and add the powder to the oil solution. Stir the solution at this temperature for about 10 minutes to make the solution clear and pre-filter through 0.45 micron filter.
Weigh and transfer the powder inside the Powder hood.

WEIGHING	TESTOSTERONE CYPIONATE 200MG/MLINJECTABLE							
	FORM	**MEASURE**	**UNITS**	**MANUFACTURER/ WHOLESALER/ NDC**	**LOT NUMBER**	**EXPIRY DATE**	**WEIGHT TAKEN**	
TOTAL QUANTITY MADE	LIQUID	**100**	**mL**				**2000**	mL
Testosterone Cypionate	POWDER	**20**	**gm**	**API 58597-0078-8**	**032117A-1** ✓	**01/21/2019** ✓	**400.00**	**gm**
Benzyl Benzoate	LIQUID	**22.4**	**gm**	**Medisca/3877910311**	**140026A**	**08/30/2018** ✓	**450.00**	**gm** → 500
Benzyl alcohol	LIQUID	**0.945**	**mL**	**Medisca 38779102984**	**140195C** ✓	**11/30/2018** ✓	**19**	**mL**
Grapeseed oil	LIQUID	**64**	**gm**	**Medisca/3877920891**	**143150A** ✓	**3/31/2019** ✓	**1280.00**	**gm** 1330.
Mixing Speed rpm		Minutes					2000ml	qs

350 · 94F in 15 minute clear. Total time 350rpm 45 min

Stage 1 filtration

TESTOSTERONE CYPIONATE 200MG
LOT 171006A BUD 04/06/18
MFG 10/06/17

COMPOUNDING/ PRODUCTION DIRECTIONS:

1. MEASURE AND/OR WEIGH ACCURATELY THE REQUIRED QUANTITY FOR THE TOTAL AMOUNT TO BE PREPARED.
2. INCORPORATE THE SOLID INTO OIL, WARM THE SOLUTION, STIR AND ALLOW COMPLETE DISSOLUTION FOR ABOUT 45 MINUTES.
3. ALLOW IT TO COOL DOWN TO ROOM TEMPERATURE.

MEMBRANE FILTRATION:

4. Stage1: 0.45 MICRON FILTER FOR PARTICLES.
5. Stage 2: STERILE 0.22MICRON FILTER AND RECORD THE DETAILS BELOW IN THE TABLES

ISO 7 Buffer Room	Temperature F [Range 68 -77F] 71 F
Pressure Gauge - [>0.02]" w.c -0.03"	Humidity % [Range 30 -65%] 36%
ISO 5 HOOD Biological Safety cabinet	✓

6.

DETAILS OF 0.2 MICRON FILTER (0.45 MICRON +0.2 MICRON)	MANFACTURER/ LOT #	MDI Capsule filter Sterile DTL-S DT3786E 2021-07	BUBBLE POINT /FILTER INTEGRITY AFTER FILTRATION, PSI	57 psi Pass

DISPENSING/ DOSING INTO VIALS:

7. DISPENSE 10ML INTO DEPYROGENATED 10ML AMBER TYPE I VIALS
8. USE STOPPERS PREVIOUSLY STERILIZED IN AN AUTOCLAVE TO STOPPER THE VIALS.
9. STERILE FILL AND STOPPER WITHIN ISO 5 DESIGNATED HOOD UNDER HEPA FILTER AND THE PREPARATION SHOULD BE PREPARED USING STRICT ASEPTIC TECHNIQUES.
10. AT THE FINISH OF COMPOUNDING, TAKE GLOVED FINGERTIP SAMPLING AND GOWN SAMPLING OF THE COMPOUNDING PERSONNEL AND SUBMIT FOR QC TESTING.
11. RECORD THE NUMBER OF VIALS MADE.

TESTOSTERONE CYPIONATE 200MG
LOT 1719006A BUD 04/16/18
MFG 10/06/17

DATE			DATE
GLASSWARES, TUBES & ACCESSORIES: AUTOCLAVED / DEPYROGENATED	✓	MEMBRANE FILTRATION /TRANSFER	0.2 µm
WEIGHING IN MINUTES	~ 15 min	DISPENSING INTO VIALS; volume	10 ML ± 5 ml
MIXING TIME IN MINUTES	~ 45 min	STOPPERING	~ 3 hrs
FILTER INTEGRITY TESTING, HOLD PRESSURE Bubble Point	57 psi	CAPPING	
LABEL PRINTING		LABELLING IN THE VIALS	
QUALITY CONTROL -STERILITY TEST PREPARATION	24 x 5ml	QUALITY CONTROL- STERILITY TEST BATCH RELEASING	
TOTAL NUMBER OF FINISHED VIALS	192 X10ML	REJECTED SAMPLES	@50ml; 1x5ml Broken
NUMBER OF VIALS SUBMITTED FOR STERILITY TESTING	10 X10ML	NUMBER OF VIALS SUBMITTED FOR ASSAY	
RETAINED SAMPLES AT 20 -25 ^{0}C[68-77 ^{0}F]	10 X10ML	STERILITY TEST	Pass /Fail 10/23
QC RELEASED DATE AND NUMBER OF VIALS IN INVENTORY FOR SALES/DISPENSING	X10ML	ASSAY LIMIT [90 -110%] 93.9%	Pass /Fail

23 x 5ml
172 x 10ml

TESTOSTERONE CYPIONATE 200MG
LOT 170068A BUD 04/2016
MFG 10/05/17

Quality *Control*

Product Specification:	*Compounded*
Drug Form	*Injectable oil*
Sample Lot Number	
Preservative	*YES*
Storage	AT 20 -25 ^{0}C[68-77 ^{0}F]

Test Parameters	***Product Specification***
Appearance of the product:	Liquid
Packing Size & packing appearance	Amber Glass Vial 10ml 5ml ----------ml
Color	
Clarity	Clear
Particulate Matters	None
Leak Proof/Cap Tight	Yes
Quality & Purity: Grade Active Pharmaceutical Ingredients	USP NF
In house / Theoretical Calculated Assay	90 – 110 %
Label /BUD	3months 6 months 12months ----------
Custom Compounding/Drug Shortage/Dosage Form/Strength	----------/Yes/ same/ same
Manufacturer / Literature Reference / In house Testing Assay / Third party Testing	

Testing conducted in accordance with current Good Laboratory Practices.

Signed by Quality Control Date

TESTOSTERONE CYPIONATE 200MG
LOT 17100GA BUD 04/16/18
MFG 10/08/17

ITEMS CHECK LIST	Batch #	DEPYROGENATE OR AUTOCLAVE CYCLE
SPATULA		
MAGNETIC STIR BAR		
3000/4000 ML BEAKER		DP LB136
10 mL graduated CYLINDER		DP LB134
250 ML BEAKER		DP DPLB137
2000ml bottle		DP LB134
0.45 µm PRE FILTER NON STERILE		FOR STAGE 1 FILTRATION
STERILE TRANSFER SET		Sterile Repeater Pump Fluid Transfer Tube set, Universal Spike –Luer Lock , REF: H93811 1193584 2020-01-31
0.2 µm STERILE FILTER		STAGE 2 STERILE FILTRATION MDI Aseptivent TF Capsule filter Sterile DTL-S DT3786E 2021-07
10 ML VIAL Amber		DP LB135 137
FORCEPS/ TWEEZER		
RUBBER STOPPERS		20mm AC
VIAL CAPS		135 137
CRIMPER		
TSA PLATES AIR		W64 Hardy 15 X100mm TSA 26ml USP H17177 2017-10-14
TSA PLATES SURFACE		P34 Hardy TSA w lecithin/Tween 15 x60mm , USP H17205 2017 10 22

TESTOSTERONE CYPIONATE 200MG
LOT 121056A BUD 04/18/19
MFG 10/06/17

CONFIDENTIAL

Label Printing, Tracking & Verification Log

Date:

Batch /Lot: TESTOSTERONE CYPIONATE 200MG/ML LOT 171006A BUD 04/16/18 MFG 10/06/17

Name: Size:

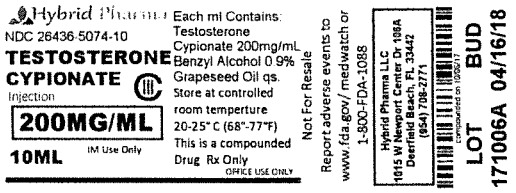
Total Labels Required (YIELD + 5) = 192 +3 25 +3

Pre-Label Design check _____ (Signature)

Label Element	Checked
lot or batch number;	
dosage form and strength;	
quantity or volume	
date compounded;	
expiration date;	
storage and handling instructions;	

Total Labels Printed 211+6 Verified By _____

Complete after labeling operation

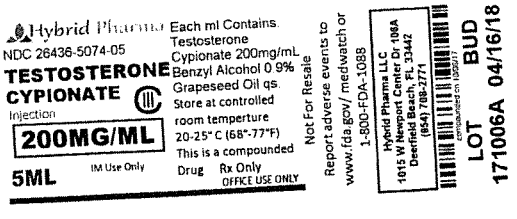


Label audit: Left over or short Labels NO_____ YES_____

If Yes Explain:

Final Inspection by _____

Pass ✓ Fail _____



ASEPTIC MONITORING DURING COMPOUNDING:

Environmental/Personnel monitoring during production as completed and write comments. Form 75a

Batch details, Name of the drug, strength					
Batch size and Vial size	ml, vials				
Details of settle plate TSA, collection time batch, expiry, manufacturer used to collect air in the LAFH W64 Hardy 15 X100mm TSA 26ml USP			H17177 2017-10-14		
During Compounding ISO 5 Hood settle air Plates	Ø Cfu/date	Pass/ Fail		Start date 10/6/17	End Date 10/10/17
Negative control	Ø Cfu/date	Pass/ Fail			
Details of TSA W/LEC &P80 batch, expiry, manufacturer Temp: 30-35^{0}C P34 Hardy TSA w lecithin/Tween 15 x60mm , USP			H17205 2017 10 22		

Post Compounding Gloved fingertip Personnel: J.G.	LEFT 1 Cfu Pass/ Fail	RIGHT 0 Cfu Pass/ Fail	HOOD SURFACE 0 Cfu Pass/ Fail	Start date 10/6/17	End Date 10/10/17
		Sleeve Ø Cfu Pass/ Fail	Negative control 0 Cfu Pass/ Fail		

TESTOSTERONE CYPIONATE 200MG
LOT 1710068 BUD 04/16/18
MFG 10/06/17

HYBRID PHARMA

Sterility Test Inspection Log TSB w/L& T20 20-25^0 C [68-77F] Incubator 1 Form 122A

Indicate X if cloudy. For accelerated early release of the batch, follow it up on Day 1 to Day 14. If it is not monitored these days [holidays or missed] they shall be followed asap.

Testosterone cypionate 200mg/ml

Broth Lot# Broth Expiry Date	U261 17194 2017-11-10	Days of Inspection				Results		
		1	3	7	14	Pass	Fail	
Sample Lot # 171006A						✓		Start Date 10/6/17
Negative Control						✓		Finish Date 10/23/17

Sterility Test Inspection Log FTM 30 - 35^0 C Incubator 2 Form 122B

Broth Lot# Broth Expiry Date	U41 H17156 2017-12-02	Days of Inspection				Results		
		1	3	7	14	Pass	Fail	
Sample Lot # 171006A						✓		Start Date 10/6/17
Negative Control						✓		Finish Date 10/23/17

TESTOSTERONE CYPIONATE 200MG
LOT 171006A BUD 04/16/18
MFG 10/06/17

CONFIDENTIAL

HYBRID PHARMA ON-SITE STERILITY TESTING /MEMBRANE FILTRATION DOCUMENTATION FORM 122C_Rev.2

171006A Testosterone cypionate 200mg/ml

Batch details, Name of the drug, strength, Batch size, number of vials		2000 ml, 10ml vials		vials used in sterility test 10 X 10ml vials	
During Sterility test ISO 5 Hood settle air Plates		Ø Cfu Pass/ Fail		Start date 10/6/17	End Date 10/10/17
Negative Control		Ø Cfu Pass/ Fail			
Post sterility test Personnel Gloved fingertip	LEFT Ø Cfu Pass/ Fail	RIGHT Ø Cfu Pass/ Fail	HOOD SURFACE Ø Cfu Pass/ Fail	Incubation Temp. 30 -35^{0}C	
	Negative Control Ø Cfu Pass/ Fail				
Details of Fluid D, USP	Details of the membrane, batch, expiry, manufacturer	Details of settle plate TSA to collect air in the LAFH		Details of TSA W/LEC &P80	
U110 H17144 2017-11-20	Thermo Scientific CN147-0045 0.45 1192096 12-28-18	H17177 2017-10-14		H171205 2017-10-22	

TESTOSTERONE CYPIONATE 200MG
LOT 171006A BUD 04/16/18
MFG 10/06/17

CONFIDENTIAL

quantity, in mg, of $C_{19}H_{28}O_2$ in the portion of Testoste taken by the formula:

$$10C(A_U / A_S)$$

in which C is the concentration, in mg per mL, of USP Testosterone RS in the *Standard preparation;* and A_U and A_S are the absorbances of the solutions from the *Assay preparation* and the *Standard preparation,* respectively.

Testosterone Injectable Suspension

» Testosterone Injectable Suspension is a sterile suspension of Testosterone in an aqueous medium. It contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of $C_{19}H_{28}O_2$.

Packaging and storage—Preserve in single-dose or multiple-dose containers, preferably of Type I glass.

USP Reference standards ⟨11⟩—
USP Endotoxin RS
USP Testosterone RS

Identification—The testosterone obtained by filtration and washing, as directed in the *Assay,* and dried at 105° to constant weight, meets the requirements for *Identification* tests *A* and *B* under *Testosterone.*

Bacterial endotoxins ⟨85⟩—It contains not more than 3.5 USP Endotoxin Units per mg of testosterone.

Uniformity of dosage units ⟨905⟩: meets the requirements.

pH ⟨791⟩: between 4.0 and 7.5.

Other requirements—It meets the requirements under *Injections* ⟨1⟩.

Assay—Transfer an accurately measured volume of previously well-mixed Injectable Suspension, equivalent to about 100 mg of testosterone, to a fine-porosity, sintered-glass filtering crucible, previously dried at 105° for 1 hour, and filter with suction. If the filtrate is not clear, again pass it through the same filter into a second receiver. Wash the residue in the filter with several 5-mL portions of water until 2 mL of the last washing, when evaporated on a steam bath, leaves a negligible residue. [NOTE—If the Injectable Suspension is passed through the filter twice, rinse the first receiver with the portions of water before passing them through the filter.] Dry the crucible and the collected testosterone at 105° for 1 hour. Completely dissolve the testosterone with five 25-mL portions of methanol, passing each portion through the crucible under gentle suction, and transfer the combined methanol solution to a 200-mL volumetric flask. Rinse the crucible and receiver with two 25-mL portions of methanol, add the rinsings to the main solution, dilute with methanol to volume, and mix. Transfer 5.0 mL of this solution to a 250-mL volumetric flask, dilute with methanol to volume, and mix. Concomitantly determine the absorbances of this solution and a Standard solution of USP Testosterone RS, in the same medium having a known concentration of about 10 µg per mL in 1-cm cells at the wavelength of maximum absorbance at about 241 nm, with a suitable spectrophotometer, using methanol as the blank. Calculate the quantity, in mg, of $C_{19}H_{28}O_2$ in each mL of the Injectable Suspension taken by the formula:

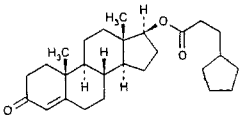
$$(10C / V)(A_U / A_S)$$

in which *C* is the concentration, in µg per mL, of USP Testosterone RS in the Standard solution, *V* is the volume, in mL, of Injectable Suspension taken, and A_U and A_S are the

EXHIBIT B

e Injectable S
ely.

Testosterone Cypionate



$C_{27}H_{40}O_3$ 412.60
Androst-4-en-3-one, 17-(3-cyclopentyl-1-oxopro
(17β)-.
Testosterone cyclopentanepropionate [58-20-8

» Testosterone Cypionate contains not l
97.0 percent and not more than 103.0
$C_{27}H_{40}O_3$, calculated on the dried basis.

Packaging and storage—Preserve in well-clos
sistant containers.

USP Reference standards ⟨11⟩—
USP Cholesteryl Caprylate RS
$C_{35}H_{60}O_2$ 512.86
USP Testosterone Cypionate RS

Identification, *Infrared Absorption* ⟨197K⟩.

Melting range ⟨741⟩: between 98° and 104

Specific rotation ⟨781S⟩: between +85° and

Test solution: 20 mg per mL, in chloroform

Loss on drying ⟨731⟩—Dry it in vacuum over
4 hours: it loses not more than 0.5% of its weig

Residue on ignition ⟨281⟩: not more than

Free cyclopentanepropionic acid—Dissolve
10 mL of alcohol that previously has been neut
faint blue color following the addition of 2 or 3
bromothymol blue TS, and promptly titrate wit
dium hydroxide VS: not more than 0.70 mL of
dium hydroxide is required (0.20% of cyclopen
pionic acid).

Assay—

Internal standard solution—Dissolve 80 mg of
teryl Caprylate RS in a mixture of methanol and
(4:1) in a 100-mL volumetric flask, then add th
vent mixture to volume.

Standard preparation—Weigh accurately abo
USP Testosterone Cypionate RS into a suitable
pipet 10 mL of *Internal standard solution,* and

Assay preparation—Prepare as directed for *St*
aration, using an accurately weighed portion of
10 mg of Testosterone Cypionate instead of the
Standard.

Procedure—Inject 1 µL of the *Assay preparati*
Standard preparation, successively, into a suitab
matograph fitted with a flame-ionization detec
typical conditions, the instrument contains a 3-
glass column packed with 1% (w/w) phase G6
S1AB. The column temperature is maintained a
the helium carrier gas flows at 50 mL per minu
ble chromatogram, the resolution factor, *R* (see
raphy ⟨621⟩), is not less than 3 between the int
dard and testosterone cypionate peaks, and fiv
injections of a single *Standard preparation* show
of variation of not more than 2% in the peak a
testosterone cypionate to internal standard. M
eas under the peaks for testosterone cypionate
teryl caprylate in each chromatogram. Calculat
R_U, of the area of the testosterone cypionate p

USP 36

EXHIBIT C

area of the internal standard peak in the chromatogram from the *Assay preparation*, and similarly calculate the ratio, R_S, in the chromatogram from the *Standard preparation*. Calculate the quantity, in mg, of $C_{27}H_{40}O_3$ in the portion of Testosterone Cypionate taken by the formula:

$$W(R_U / R_S)$$

in which W is the weight, in mg, of USP Testosterone Cypionate RS in the *Standard preparation*, and the other terms are as defined therein.

Testosterone Cypionate Injection

» Testosterone Cypionate Injection is a sterile solution of Testosterone Cypionate in a suitable vegetable oil. It contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of $C_{27}H_{40}O_3$. It may contain a suitable solubilizing agent.

Packaging and storage—Preserve in single-dose or multiple-dose containers, preferably of Type I glass, protected from light.

USP Reference standards ⟨11⟩—
USP Cholesteryl Caprylate RS
$C_{35}H_{60}O_2$ 512.86
USP Testosterone Cypionate RS

Identification—Dilute a suitable volume of Injection with chloroform to obtain a solution having a concentration of about 400 µg of testosterone cypionate per mL. Prepare a 20- × 20-cm thin-layer chromatographic plate (see *Chromatography* ⟨621⟩), coated with a 0.25-mm layer of chromatographic siliceous earth, by placing it in a developing chamber containing and equilibrated with a mixture of chloroform and corn oil (90:10), and allowing the solvent front to move about three-fourths of the length of the plate. Remove the plate, and allow the chloroform to evaporate. Apply 10 µL each of the solution under test and of a solution of USP Testosterone Cypionate RS in chloroform containing about 400 µg per mL on the plate, on a line about 2.5 cm from the bottom edge and about 1.5 cm apart. Place the plate in a developing chamber that contains and has been equilibrated with a mixture of methanol and water (90:10) previously saturated with corn oil. Develop the chromatogram until the solvent front has moved to about 10 cm above the line of application. Remove the plate, and heat in an oven at 105° for a few minutes. Spray the plate with a mixture of alcohol and sulfuric acid (3:1), and heat in an oven at 105° for 1 to 2 minutes. Observe the plate under long-wavelength UV light: the R_F value of the principal spot obtained from the solution under test corresponds to that obtained from the Standard solution.

Other requirements—It meets the requirements under *Injections* ⟨1⟩.

Assay—

Internal standard solution and *Standard preparation*—Prepare as directed in the *Assay* under *Testosterone Cypionate*.

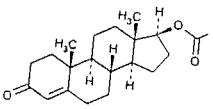
Assay preparation—Transfer 1 mL of Injection, accurately measured, into a glass-stoppered, 50-mL centrifuge tube. Add 30 mL of a mixture of methanol and water (9:1), insert the stopper, and shake for 15 minutes. Centrifuge, remove the dilute methanol layer without disturbing the oil, and transfer it to a 200-mL volumetric flask. Repeat the extraction with three additional 30-mL portions of the dilute methanol, collecting the combined extracts in the volumetric flask. Dilute the combined extracts with the dilute methanol to volume, mix, and chill the contents of the flask to −8°. Remove the flask from the freezer, and immediately filter a portion of the contents. Allow the filtrate to reach room temperature, transfer a portion of it, equivalent to about 3 mg of testosterone cypionate, to a suitable vial, and evaporate to dryness. Add by pipet 3 mL of *Internal standard solution*, and shake vigorously to dissolve the residue.

Procedure—Proceed as directed for *Procedure* in the *Assay* under *Testosterone Cypionate*. Calculate the quantity, in mg, of $C_{27}H_{40}O_3$ in the portion of Injection taken by the formula:

$$600(C / V)(R_U / R_S)$$

in which C is the concentration, in mg per mL, of USP Testosterone Cypionate RS in the *Standard preparation;* and V is the volume, in mL, of the filtrate used in the *Assay preparation*.

Testosterone Enanthate



$C_{26}H_{40}O_3$ 400.59
Androst-4-en-3-one, 17-(1-oxoheptyl)oxy-, (17β)-.
Testosterone heptanoate [315-37-7].

» Testosterone Enanthate contains not less than 97.0 percent and not more than 103.0 percent of $C_{26}H_{40}O_3$.

Packaging and storage—Preserve in well-closed containers, and store in a cool place.

USP Reference standards ⟨11⟩—
USP Testosterone Enanthate RS

Identification—

A: *Infrared Absorption* ⟨197K⟩.

B: *Ultraviolet Absorption* ⟨197U⟩—
Solution: 10 µg per mL.
Medium: alcohol.
Absorptivities at 240 nm, calculated on the anhydrous basis, do not differ by more than 3.0%.

C: Reflux 25 mg with 2 mL of a 1 in 100 solution of potassium hydroxide in methanol for 1 hour. Cool the mixture, add 10 mL of water, filter, and wash the precipitate with water until the last washing is neutral to litmus. Dry the precipitate in vacuum at 60° for 3 hours: the testosterone so obtained melts between 151° and 157°.

Melting range ⟨741⟩: between 34° and 39°, the initial temperature of the bath not exceeding 20°.

Specific rotation ⟨781S⟩: between +77° and +82°.
Test solution: 20 mg per mL, in dioxane.

Water, *Method I* ⟨921⟩: not more than 0.5%.

Free heptanoic acid—Dissolve 500 mg in 10 mL of alcohol that previously has been neutralized to a faint blue color following the addition of 2 or 3 drops of bromothymol blue TS, and promptly titrate with 0.01 N sodium hydroxide *VS*: not more than 0.6 mL of 0.01 N sodium hydroxide is required (0.16% of heptanoic acid).

Ordinary impurities ⟨466⟩—
Test solution: methanol.
Standard solution: methanol.
Eluant: a mixture of cyclohexane and ethyl acetate (2:1).

American Pharmaceutical Review™

EXHIBIT D

Bacterial Endotoxins Testing in Lipid-Based Drug Formulations Using Liquid-Liquid Extraction

Thursday, December 19, 2019 Tweet Facebook

Christopher W. Lester
J. Timothy Ramsey
Jonathon S. Salsbury

Abstract

Lipid-based drug products present complications for bacterial endotoxins testing because the Limulus-based detection system functions only in an aqueous environment. By taking advantage of the amphipathic nature of lipopolysaccharides, an oil-water extraction process may be used to separate endotoxins from oily drug formulations. This article presents the results of an endotoxin spiking study that demonstrates the effectiveness of this method, with consideration of the testing parameters that can affect endotoxin recovery.

Introduction

Bacterial Endotoxins Testing (BET) is critically important for demonstrating the safety and purity of parenteral drug products. The test detects and quantifies endotoxins from Gram-negative bacteria using Limulus Amoebocyte Lysate (LAL), an enzymatic detection system derived from the horseshoe crab, Limulus polyphemus.[1] Like all biological systems, the LAL enzyme complex has evolved to operate in an aqueous environment. This presents technical challenges for BET when the test article to be examined is insoluble in water.[2] Insolubility of the test article can be considered a form of physical interference, which prevents the LAL enzymes from making contact with endotoxins in the sample.

Endotoxins consist chiefly of lipopolysaccharide (LPS), a component of the outer plasma membrane in Gram-negative bacteria. LPS is an amphipathic molecule, consisting of polar saccharide chains and a polysaccharide core, attached to a highly-conserved lipid component known as lipid A.[3] Due to its amphipathic nature, LPS forms micelles in every solvent, both aqueous and organic, and its lipid A component allows it to bind to nonpolar materials.[4]

Because the polysaccharide chains comprise the majority of the chemical structure of LPS, endotoxins are more soluble in water than in nonpolar solvents. It is therefore possible to extract endotoxins from nonpolar liquids by means of liquid-liquid extraction. It has been demonstrated that endotoxins spiked into ultrapure paraffin oil could be extracted into an equal volume of water, with recoveries of 94.2% to 111%.[2] BET analysis of nonpolar test articles is

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Endotoxin Detection and Tes

Endotoxin Detection and Tes

therefore possible, provided that the endotoxins can be extracted efficiently into an aqueous solution.

We set out to determine the feasibility of performing BET on a lipid-based drug product and placebo, using liquid-liquid extraction to separate endotoxins from the test articles.

Method Feasibility

The product under examination is a sterile solution of active drug substance in triglycerides, currently in Phase 1 clinical trial. A method was desired that could be used to perform BET on both the active drug product and the placebo, which consists only of the triglyceride vehicle. In order to conserve sample material, initial feasibility testing was performed using unflavored, fractionated coconut oil as a mock sample.

USP <85> states that when samples are subjected to a treatment in order to overcome interference, standard endotoxin must be added to a sample prior to treatment in order to demonstrate that the interference can be overcome without loss of endotoxins.[1] In order to be considered free of interference, the measured concentration of endotoxin must be within 50-200% of the known added endotoxin concentration, after subtraction of any endotoxin detected in the solution without added endotoxin. However, because control standard endotoxin (CSE) is typically reconstituted in water, this presented a problem for the validity of such a study: if the added endotoxin remained associated with the water in which it had been reconstituted, then a true extraction event would not have taken place; the endotoxin would not have been in the oil to begin with.

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This technical obstacle was overcome by reconstituting CSE in dimethyl sulfoxide (DMSO), as described by Schlösser.[5] DMSO is a polar aprotic solvent that is fully miscible in both oil and water. A vial containing 500 ng of CSE was reconstituted with 5.0 mL DMSO, yielding a solution of 100 ng CSE/mL. 10.0 µL of this CSE solution was then added to 990 µL of oil, for a final endotoxin concentration of 1 ng CSE/mL.

The pre-extraction endotoxin content of the CSE/oil solutions, in endotoxin units per mL (EU/mL), could not be directly determined, because the activity of this 500 ng/vial CSE had not been quantified with the turbidimetric LAL that would be used in the assay. To account for this, an extraction control solution was prepared by adding 10.0 µL of CSE solution to 990 µL of lysate reagent water (LRW). The endotoxin activity of the oil samples was therefore assessed in a relative manner, as a percentage of the activity observed in the extraction control (% extraction efficiency). A sample negative control, to which no endotoxin had been added, was also subjected to the extraction procedure. To ensure homogeneity, all samples were vortexed for 30 seconds prior to use.

To perform the extraction, 0.5 mL of each sample replicate was added to 4.5 mL LRW in separate 15-mL, pyrogen-free centrifuge tubes; this constituted a 1:10 sample dilution. The four CSE/oil tubes were capped and vortexed for 5, 15, 30, and 50 minutes. The water sample (extraction control) and negative control were both vortexed for 50 minutes. After vortexing, the oil samples showed an extensive emulsion at the lipidaqueous boundary. This emulsion did not disperse after one hour of rest time, so all tubes were centrifuged for 10 minutes at relative centrifugal force (RCF) = 2900 g, which forced the complete separation of the lipid and aqueous layers.

Initially, vortexing was performed with depyrogenated glass beads to ensure thorough homogenization; however, this resulted in the formation of a solid white precipitate upon vortexing. It was concluded that this solid matter was produced by friction between the glass beads and the walls of the centrifuge tube. Subsequent attempts omitted the beads, and no further precipitate formation was observed.

For each sample, 200 µL of the aqueous phase was withdrawn from the tube and added to 1.8 mL LRW for a 1:100 sample dilution, which was vortexed for 30 seconds prior to use. All 1:100 sample dilutions were tested via the USP <85> kinetic turbidimetric technique, using four unspiked sample wells and four wells spiked to contain 0.5 EU/mL as a positive product control (PPC). The purpose of the PPC was to demonstrate that no interfering substances from the original test article remained in the 1:100 test solution. Per USP <85>, the accepted range for PPC recovery is 50-200%. Testing also was attempted at the 1:10 dilution, but small amounts of residual oil were transferred to the microplate in each sample well, and PPC recovery was low (43-65%), so further testing at this dilution was discontinued.

Table 1. Method feasibility test for oil-water extraction of endotoxins (1:100 sample dilution)

Sample (Vortex Time)	Endotoxin Value (EU/mL)	PPC Recovery (%)	Extraction Efficiency (%)
CSE/oil (50 min)	12.4	107%	69.2%
CSE/oil (30 min)	6.7	106%	37.5%
CSE/oil (15 min)	9.9	106%	55.3%
CSE/oil (5 min)	< 0.5	99%	0%
CSE/water Extraction Control (50 min)	17.8	118%	N/A
Sample NC (50 min)	< 0.5	124%	N/A

The initial feasibility test demonstrated that endotoxins could be recovered from an oily test article (Table 1). The 1:100 sample dilution did not interfere with the assay, as evidenced by PPC recovery values near 100% for all samples. Extraction efficiency was acceptable with 50 minutes of vortexing, but was markedly lower with only 30 minutes of extraction, and fell to undetectable levels with only 5 minutes of extraction.

Feasibility testing also demonstrated that the endotoxin activity of CSE reconstituted in DMSO declined sharply over time, from 25.1 EU/mL on the day of reconstitution to 17.8 EU/mL after 1 day of storage at 2–8°C. (DMSO has a freezing point of 19°C, so CSE was vortexed for 5 minutes to resuspend after thawing.) Because of this, subsequent testing used CSE in DMSO that had been freshly prepared on the day of use.

Product-Specific Method Verification

Method verification for drug product and placebo formulations proceeded along the same general approach described for method feasibility. For each formulation, the oil-water extraction was performed on an unspiked sample (sample A), a sample spiked with CSE in DMSO to contain 1 ng CSE/mL (sample B), and an equivalent volume of LRW spiked to contain 1 ng CSE/mL (sample C). To improve the accuracy of the CSE spike, the volume was increased to 50.0 µL of CSE in DMSO, added to 4.95 mL of sample.

As in the feasibility test, 0.5 mL of sample was added to 4.5 mL LRW for a 1:10 dilution, vortexed at high speed for 50 minutes, then centrifuged at RCF = 2900 g for 10 minutes to separate the oil and water phases. After centrifugation, the lipid phase of each sample A and sample B was drawn off with an automatic pipette, and the aqueous phase of all samples was vortexed 30 seconds to re-homogenize the endotoxin.

A test dilution of 1:100 was prepared from the aqueous phase, as described for the feasibility test. Additionally, a higher "pass point" dilution of 1:400 was prepared from the 1:100 dilution, in order to establish a validated range of dilutions at which the method could be performed. The use of higher dilutions of 1:800 and 1:1000 was attempted, but

results were inconsistent at these dilutions because of high variability in the amount of endotoxin recovered from samples B and C, and these eff orts were discontinued. Dilutions higher than 1:1000 were not tested, because the estimated activity of the spiked CSE in DMSO would fall below the limit of detection (0.005 EU/mL).

All samples were tested by the USP <85> kinetic turbidimetric technique. Equivalent dilutions of samples A, B, and C were tested on the same microplate to ensure comparability of results. The test was performed independently by three analysts to demonstrate intermediate precision.

Table 2. Endotoxin Extraction Efficiency from Drug Product and Placebo

Formulation	Dilution	Extraction Efficiency*		
		Analyst 1	Analyst 2	Analyst 3
Drug Product	1:100	89%	88%	79%
	1:400	51%	72%	80%
Placebo	1:100	104%	94%	111%
	1:400	65%	75%	104%

*Extraction Efficiency = (Endotoxin Value of Spiked Sample B) ÷ (Endotoxin Value of Spiked Sample C) × 100%.

All analysts obtained extraction effi ciencies in the range of 50-200% required by USP <85> (Table 2). The measured endotoxin activity of the spiked water control (sample C) was uniformly lower than in the feasibility test, ranging from 5.7 to 8.3 EU/mL; this is attributable to the use of a new lot of LAL reagent during the method verification. Endotoxin content in the unspiked sample (sample A) was below the limit of detection for all analysts.

None of the tested sample dilutions exhibited interference with the positive product controls. Across all dilutions and trials, PPC recovery ranged from 100% to 138% for drug product, and from 101% to 127% for placebo.

Conclusion

The results of the method verification demonstrate that endotoxins can be successfully recovered from a lipid sample matrix by liquidliquid extraction. CSE reconstituted in DMSO can be effectively and homogeneously dissolved into lipid samples, and this spiked endotoxin migrates efficiently into the aqueous phase when diluted 1:10 with water. This extraction process can be performed simply by vortexing at high speeds, but time is a critical factor; consistent recovery was not observed for vortex times below 50 minutes.

This study highlights a number of additional technical challenges that must be considered when validating the endotoxin extraction procedure for a new product. Unlike natural endotoxins, CSE settles out of solution over time, so the lipid and aqueous layers must be separated after extraction so that CSE can be resuspended. Emulsion of the layers can be quickly overcome through centrifugation, provided that the aqueous layer is then vortexed to re-homogenize the CSE.

After extraction, direct testing of the aqueous layer proved inadvisable, as enough residual oil remained to interfere with the assay. A ten-fold dilution from this layer, for a 1:100 overall dilution, proved effective in preventing this interference; however, subsequent serial dilutions introduced wide variability in results. The most likely explanation for

this is that the CSE adhered to the pipettes that were used in these subsequent dilution steps. This suggests that studies with spiked high-potency CSE should involve as few serial dilutions as possible. Any dilutions that are necessary should be performed in borosilicate glass pipettes, rather than with automatic pipettors, because the lipid A portion of the LPS molecule has a high affinity for nonpolar plastic pipette tips.

USP <85> allows for samples to be tested at dilutions up to the maximum valid dilution (MVD), which is a function of the endotoxin limit for the test article in question. When validating an extraction method such as this one, however, the dilution range is further constrained by the need to quantify the recovered endotoxin. Different lots of CSE vary in their activity, and different lots of LAL vary in their responsiveness to different lots of CSE; and even when CSE activity has been quantified for a given lot pairing, it is done with CSE reconstituted in water, not in DMSO. Because of all these factors, the exact activity of endotoxin being spiked into a sample will not be known until the test is run. The use of an extraction control, in which an equal amount of CSE is spiked into water and tested alongside the lipid samples, ensures a more accurate determination of extraction effi ciency than assuming a theoretical value of EU/mL that has been introduced into the sample. A maximum dilution can then be determined based on the level of endotoxin activity observed.

References

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4. Millipore Sigma. Lipopolysaccharides technical document. Available at https://www.sigmaaldrich.com/technical-documents/protocols/biology/lipopolysaccharides.html. Accessed October 8, 2019.
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Author Biographies

Christopher Lester is a senior scientist specializing in bacterial endotoxins testing within microbiology testing services at the PPD® Laboratories GMP lab in Middleton, Wisconsin. Chris and his team perform bacterial endotoxins testing, which includes method development, verification and stability testing for a wide variety of drug formulations. Chris has been performing GxP testing in the contract research industry since 2014.

Timothy Ramsey is the lab manager of microbiology testing services at the PPD® Laboratories GMP lab in Middleton. Tim has more than 20 years of experience in managing microbiology operations in contract laboratory and pharmaceutical manufacturing environments.

Jonathon Salsbury is the associate director of microbiology and physical testing services at the PPD® Laboratories GMP lab in Middleton. Jonathon has been involved with pharmaceutical sciences for more than 20 years, including over 15 years in the contract research industry.

Comments

Pietrylo, Andrew

From: Steven Goerke <sgoerke@mcraelawfirm.com>
Sent: Monday, September 21, 2020 3:49 PM
To: Pietrylo, Andrew
Subject: DOH v. Hybrid Pharma, Case No. Case No. 2017-23347 - Corrected
Attachments: Endosafe Test Record.pdf

Mr. Pietrylo:

My client requested a rewording in one sentence. I am therefore resending this email with a rewording of the last paragraph.

Thank you for your email. I wanted to confirm that after receipt of the December 19, 2017 inspection report, Hybrid Pharma's principal made great effort to try to try to determine what kind of endotoxin testing could be undertake on Testosterone Cypionate despite Hybrid Pharma's firm belief that the USP does not spell out an appropriate BET. Despite the holiday season, the Dr. Rajalingam contacted multiple individuals in the scientific community. Based on conversations with others in the scientific community, Hybrid started a new test on January 4, 2018 on the very Testosterone Cypionate lot citied by the DOH inspector. A copy of the Test Record slip on the cited lot is attached. The lot in question passed the test that was implemented. Hybrid Pharma continues to run this same test on Testosterone Cypionate to this date.

Dr. Ponswany Rajalingam has a Master of Science in Chemistry and a Ph.D in Physical Organic Chemistry. Dr. Ponswamy Rajalingam has decades of experience as a research chemist. His wife, Dr. Umarani Rajalingam, has a Ph.D. in Organic/Medicinal Chemistry. Dr. Umarani Rajalingam worked in University of Texas at Arlington, Queens University in Kingston, Canada, University of Weston Ontario, Canada. She was a Visiting Faculty in University of Lille, France. Teaching Faculty in South University, West Palm Beach and Palm Beach State College. She is a registered technician for Hybrid. Dr. Umarani Rajalingam has over thirty years' experience in quality control in the pharmaceutical industry. Hybrid Pharma uses highly educated and experienced individuals well versed in science.

Please note that I need to make a correction regarding my correspondence to you of August 19, 2020. I inadvertently stated that the 2017 inspection was a joint inspection with the FDA. This statement was in error. The joint inspection occurred at a later date. Please disregard my reference to a joint inspection.

Hybrid Pharma is FDA registered. Hybrid continues to search of an effective BET for Testosterone Cypionate and has discussed the issue with numerous persons in the scientific community. As recently as today, representatives of Hybrid participated in an FDA presentation in which the presenters confirmed that as a 503B facility Hybrid **SHOULD NOT** follow USP <797> as the inspection method for Testosterone Cypionate. The FDA presenter stated that Hybrid should follow the GMP (Good Manufacturing Practice) protocols as it states in the USP monograph. Based on the position of the FDA that USP <797> is not a proper production and inspection technique for the Testosterone Cypionate and that Good Manufacturing Practice is the proper method as described in the USP monograph. Accordingly, the Administrative Complaint against Hybrid Pharma should not stand as Good Manufacturing Practice was at all times followed.

Regards,

Steve Goerke

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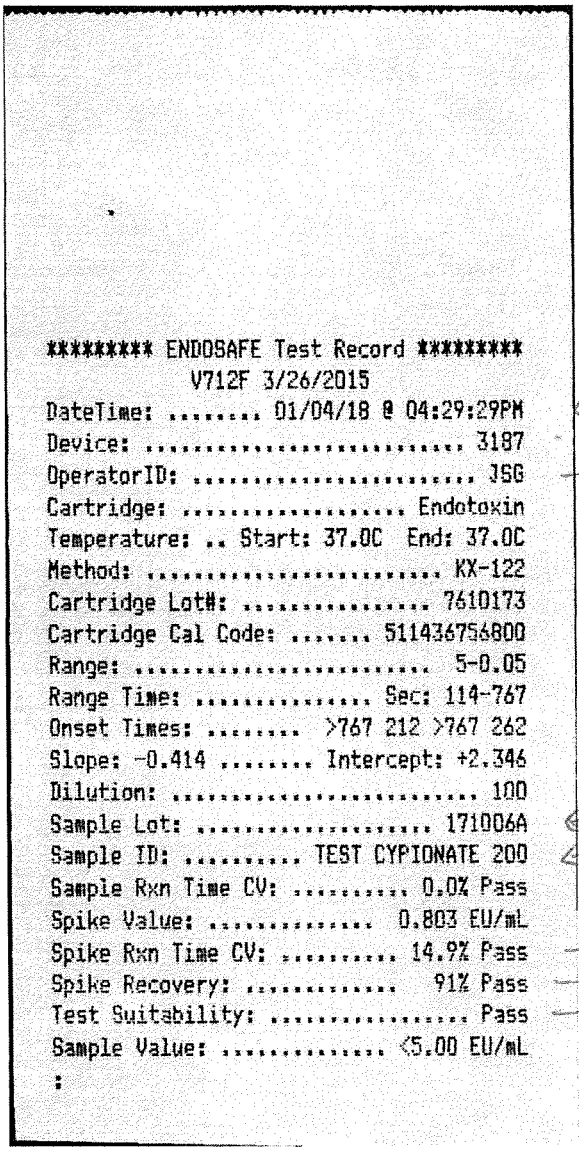
Endotoxin Studies of Testosterone cypionate

171006A



```
********* ENDOSAFE Test Record *********
            V712F 3/26/2015
DateTime: ........ 01/04/18 @ 04:29:29PM
Device: ............................ 3187
OperatorID: ......................... JSG
Cartridge: ..................... Endotoxin
Temperature: .. Start: 37.0C  End: 37.0C
Method: ........................... KX-122
Cartridge Lot#: ................. 7610173
Cartridge Cal Code: ....... 511436756800
Range: ........................... 5-0.05
Range Time: ................ Sec: 114-767
Onset Times: ........  >767 212 >767 262
Slope: -0.414 ........ Intercept: +2.346
Dilution: ............................ 100
Sample Lot: ..................... 171006A
Sample ID: ........... TEST CYPIONATE 200
Sample Rxn Time CV: ........... 0.0% Pass
Spike Value: ..............  0.803 EU/mL
Spike Rxn Time CV: ........... 14.9% Pass
Spike Recovery: .............  91% Pass
Test Suitability: ................. Pass
Sample Value: ............... <5.00 EU/mL
:
```

Response to DOH Inspection Report, dated December 19, 2017

Inspection Report item in underline

DOH Inspector's comments in italics

9. A 0.2-µm certified sterilizing membrane filter is used that is chemically and physically compatible with the CSP. Filtration is completed rapidly without filter replacement. Sterilization method is verified to achieve sterility for the quantity and type of containers. [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Sterilization of High-Risk Level CSPs by Filtration]

Compounding record for Zinc sulfate 10mg/ml final volume of 300 ml was sterilized by filtration with a Baxter Supor 32 mm syringe filter. Manufacturer recommended volume for this filter is less than 150 ml.

RESPONSE: While the manufacturer lists 150 ml as a recommended volume for this filter, it does not give a maximum recommended volume. The manufacturer also fails to mention the conditions or criteria used to determine the "recommended" volume.

The volume any given filter can process and still maintain its integrity is based upon many factors including substrate viscosity, solubility, structure, pressure, purity, and size to name a few. The validation test performed at the end of every batch (known as bubble point or pressure holding test) is the determining factor when assessing a filters failure point.

We have not had any premature failure of the Supor 0.2 micron filter after processing 300ml of Zinc Sulfate.

Action Plan: Although no official maximum filtered volume is given for this filter, we will use 150ml as the maximum allowed volume going forward.

15. Dry heat depyrogenation is used to render glassware or containers, such as vials free from pyrogens as well as viable microbes. The description of the dry heat depyrogenation cycle and duration for specific load items is included in written documentation in the compounding facility. The effectiveness of the dry heat depyrogenation cycle is verified using endotoxin challenge vials (ECVs). [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY: Depyrogenation by Dry Heat]

Firm is using distilled water to rinse glassware not sterile water; SECOND ADVISORY.

Response to June 14, 2017 DOH Inspection Report:

All the non-sterile glassware is washed with tap water to remove any suspended particles, and then washed with distilled water in the cleaning process. Next, it is **rinsed with sterile water for injection.** We explained the cleaning procedure to the inspectors. We have many cases of sterile water for injection (Baxter product) in the inventory room within the pharmacy. We only take from inventory the necessary amount to use during the sterilization process.

Response to December 19, 2017 DOH Inspection Report:

The inspector claims again that we are using distilled water for the final rinse of glassware. **This is incorrect.** Distilled water is used in the cleaning process but not in the final rinse stage. Sterile water is transported from the storage room after being removed from its cardboard shipping containers. We do not store sterile water in the prep room. See on the next page the SOP regarding the procedure to wash glassware and vials prior to depyrogenation.

32. Endotoxin testing is conducted for High-risk level CSP's that are prepared in batches of more than 25 identical containers, or exposed longer than 12 hours at 2° to 8°, and 6 hours at warmer than 8°, before being sterilized or in multidose containers for administration to multiple patients. (excluding those for inhalation and ophthalmic administration) [FINISHED PREPARATION RELEASE CHECKS AND TESTS: Bacterial Endotoxin (Pyrogen) Testing]

Testosterone lot #171006a 2000 ml has not been tested for endotoxins.

Response:

The USP monograph for Testosterone Cypionate does not reference any endotoxin value requirement for this product.

The USP contains maximum allowable endotoxin levels for all official **water soluble** injectable products. The USP describes the methods used to determine these values. The USP does not list any method to test **oil soluble** products. The USP fails to list the maximum allowable endotoxin level for oil based injectable drugs, most notably *TESTOSTERONE CYPIONATE*.

While doing research into this we found some labs were doing endotoxin testing on Testosterone Cypionate utilizing their own unofficial methods. These methods all involve adding water to the oil and extracting solution from the water based layer after shaking. The hope is that the endotoxin will be drawn into the water layer and the extracted water layer would be free from oil contamination.

No validation of this method exists and is most likely the reason it is not mentioned in the USP <797>, <71>,<85> or any of the other references listed below.

The test methods refer to dilution with LAL Reagent Water. These methods work fine with water soluble drugs.

The USP gives **no guidance, methods or procedures** to determine endotoxin levels involving oil based preparations which can interfere with the gel clotting and photometric methods.

We do endotoxin testing for all water based batches as per USP <85>.

We have tested the Testosterone batch in question (lot# 171006A) using an unofficial water extraction method found common in many testing labs. It shows a sample value of <5.00 EU/mL which calculates into:

$$\frac{< 5.00\ \text{EU/mg}}{200\ \text{EU/ml}} = \textbf{<0.025 EU/mg} \quad \textbf{(PASS)}$$

Suggested limits for unlisted, unofficial drugs is calculated:

*Endotoxin Limit K = 5.0 EU/kg for parenteral drugs. For an average body weight of 70kg the endotoxin limit is 350EU. This value (0.05 EU/mg) is expressed in Endotoxin Units per mg of product. In order to convert this value to an endotoxin unit concentration per ml, multiply it (0.5EU/mg) by the product potency 10mg/ml. 10mg/ml x 0.05 EU/mg=0.5 EU/ml.

Common references which omit Testosterone Cypionate endotoxin information.

https://www.ashp.org/-/media/assets/policy-guidelines/docs/guidelines/compounding-sterile-preparations.ashx

http://www.pharmacopeia.cn/v29240/usp29nf24s0_c85.html

https://www.fda.gov/downloads/drugs/guidances/ucm310098.pdf

http://www.pharmacopeia.cn/v29240/usp29nf24s0_m81190.html

Action Plan: We will perform the water extraction endotoxin values on all future batches even though this method is not documented in any official documents.

Guidance for Industry

Pyrogen and Endotoxins Testing: Questions and Answers

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Center for Veterinary Medicine (CVM)
Center for Devices and Radiological Health (CDRH)
Office of Regulatory Affairs (ORA)

June 2012
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Guidance for Industry

Pyrogen and Endotoxins Testing: Questions and Answers

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http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm

U.S. Department of Health and Human Services
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Contains Nonbinding Recommendations

Guidance for Industry[1] Pyrogen and Endotoxins Testing — Questions and Answers

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

I. INTRODUCTION

This guidance provides recommendations for biological product, drug, and device firms on FDA's current thinking concerning the testing recommendations and acceptance criteria in the *United States Pharmacopeia* (USP) Chapter <85> Bacterial Endotoxins Test,[2] USP Chapter <161> Transfusion and Infusion Assemblies and Similar Medical Devices,[3] and the Association for the Advancement of Medical Instrumentation (AAMI) ST72:2002/R2010, Bacterial Endotoxins—Test Methodologies, Routine Monitoring, and Alternatives to Batch Testing (AAMI ST72).[4,5] These three documents describe the fundamental principles of the gel clot, photometric, and kinetic test methods, and recommend that appropriate components and finished products be tested for the presence of pyrogens and endotoxins.

This guidance does not cover the entire subject of pyrogen and endotoxins testing. Instead, it addresses those issues that may be subject to misinterpretation and are not covered in compendial procedures or in currently available guidance documents. You should already have a thorough understanding of these documents when using this guidance.

---

[1] This guidance has been prepared by the Division of Manufacturing and Product Quality, Office of Compliance, in the Center for Drug Evaluation and Research (CDER) in cooperation with the Center for Biologics Evaluation and Research (CBER), the Center for Veterinary Medicine (CVM), the Center for Devices and Radiological Health (CDRH), and the Office of Regulatory Affairs (ORA) at the Food and Drug Administration.

[2] *United States Pharmacopeia* (USP), 2011, Chapter <85>, Bacterial Endotoxins Test.

[3] USP, 2011, Chapter <161>, Transfusion and Infusion Assemblies and Similar Medical Devices.

[4] Association for the Advancement of Medical Instrumentation (AAMI), 2002/R2010, Bacterial Endotoxins — Test Methodologies, Routine Monitoring, and Alternative to Batch Testing.

[5] Veterinary drug requirements parallel the human drug requirements in safety evaluation for pyrogenicity (21 CFR 514.1(b)(5)(v), and 514.1(b)(5)(vii)(b)).

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. BACKGROUND

For more than 30 years, FDA has accepted the use of a Limulus Amoebocyte Lysate (LAL) test for endotoxins in lieu of the rabbit pyrogens test. In a November 4, 1977, *Federal Register* notice (42 FR 57749), FDA described conditions for using LAL as a finished product test.[6] By 1983, FDA indicated in guidance that an LAL test could be used as a finished product test for endotoxins. These tests were described in a series of draft and final guidance documents. The last guidance document, *Guideline on Validation of the Limulus Amebocyte Lysate Test as an End-Product Endotoxin Test for Human and Animal Parenteral Drugs, Biological Products, and Medical Devices*, was published in 1987 (the 1987 Guidance).

FDA has found that the published USP and AAMI documents describing methods and calculation of pyrogen and endotoxins testing limits[7] provide industry with appropriate information. We also note the continued development of USP Chapters <85> and <161> and FDA guidance documents. The Agency has withdrawn the 1987 Guidance because it no longer reflects the Agency's current thinking on the topic. However, because the compendial chapters and standards do not address certain regulatory perspectives, FDA is providing supplemental information in this guidance to explain our current thinking regarding the submission and maintenance of pyrogen and endotoxins testing for FDA-regulated products.

III. QUESTIONS AND ANSWERS

1. How do I establish a sampling plan for in-process testing and finished product release?

The current good manufacturing practice (CGMP) regulations for finished pharmaceuticals and the medical device quality system regulations require development of controls that include scientifically sound and appropriate sampling plans.[8,9]

---

[6] "Licensing of Limulus Amebocyte Lysate, Use as an Alternative for Rabbit Pyrogen Test" (42 FR 57749, November 4, 1977).

[7] USP, 2011, Chapter <85>, Bacterial Endotoxins Test; USP, 2011, Chapter <161>, Transfusion and Infusion Assemblies and Similar Medical Devices, Association for the Advancement of Medical Instrumentation (AAMI), 2002/R2010, Bacterial Endotoxins—Test Methodologies, Routine Monitoring, and Alternatives to Batch Testing.

[8] See 21 CFR 211.160.

[9] See 21 CFR 820.70, and 21 CFR 820.250.

Sampling plan information is addressed in AAMI ST72, but not USP Chapter <85>. Firms should include a sampling plan as part of their application documentation. In the sampling plan, firms should consider the potential for contamination in raw materials, in-process materials, and the finished product. Specifically, firms should take into account aspects of the manufacturing design, including consistency of a manufacturing process, impact of in-process hold times, endotoxins removal steps, and finished product endotoxins specifications. The sampling plan should be considered dynamic; firms should begin with maximum coverage and adjust their sampling plans as they gain confidence in the prevention of endotoxins in their manufacturing processes. Firms should update their regulatory filings when adjusting sampling plans. For drugs and biological products, in-process changes to sampling plans are annual reportable changes.[10] For devices, a 30-day notice[11] may be appropriate for in-process changes to the sampling plan.[12]

2. When is retesting appropriate?

When conflicting results occur within a test run, firms should consult USP Chapter <85>, Gel Clot Limits Test, Interpretation, for guidance on repeat testing. As specified in Chapter <85>, if the test failure occurred at less than the maximum valid dilution (MVD), the test should be repeated using a greater dilution not exceeding the MVD. A record of this failure should be included in the laboratory results. If a test is performed at the MVD and an out-of-specification (OOS) test result occurs that cannot be attributed to testing error, the lot should be rejected. [13] All testing procedures, including those for retesting within the above limits, should be specified in advance in written standard operating procedures approved by the firm's quality control unit.

3. Is sample storage and handling important?

Yes. The ability to detect endotoxins can be affected by storage and handling. Firms should establish procedures for storing and handling (which includes product mixing) samples for bacterial endotoxins analysis using laboratory data that demonstrate the stability of assayable endotoxins content. Protocols should consider the source of

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[10] See 21 CFR 314.81(b)(2)(iv).

[11] 21 CFR 814.39(f).

[12] For guidance regarding when and how to submit a 30-day notice, please refer to the FDA Guidance for Industry and FDA Staff; *30-Day Notices, 135-Day Premarket Approval (PMA) Supplements, and 75-Day Humanitarian Device Exemption (HDE) Supplements for Manufacturing Method or Process Changes (issued April 13, 2011).* *http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM080194.pdf*.

[13] For guidance regarding how to examine results that are above acceptable limits, please refer to the FDA guidance for industry on *Investigating Out-of-Specification (OOS) Test Results for Pharmaceutical Production*. Although this guidance is not intended to address biological assays, many of the concepts in the guidance are applicable to bacterial endotoxins testing. We update guidance documents periodically. To make sure you have the most recent version of a guidance, check the FDA Drugs guidance Web page at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.

endotoxins used in the study, bearing in mind that purified bacterial endotoxins might react differently from native sources of endotoxins.

4. Can finished product samples for analysis of bacterial endotoxins be pooled into a composite sample prior to analysis?

Yes. With some exceptions (see below), finished drug product units may be pooled into a composite sample and assayed for bacterial endotoxins. The composite sample may be represented by the entire unit or partial aliquots (equal volumes) of finished product containers from one manufactured lot of aqueous-based pharmaceuticals. Pooling would generally be accepted for small-volume parenterals (those with volumes of 100 mL or less) as long as the MVD is adjusted to a proportional, lower value because of the potential for diluting a unit containing harmful levels of endotoxins with other units containing lower, less harmful, levels of endotoxins. This "adjusted MVD" is obtained by dividing the MVD computed for an individual sample by the total number of samples to be pooled. FDA suggests pooling no more than three units per composite in keeping with the concept of testing representative beginning, middle, and end finished product containers. If this reduction in MVD results in an inability to overcome product-related assay interference because of an insufficient dilution, then the samples should be tested individually.

Finished medical devices may also be pooled into a composite sample and assayed for bacterial endotoxins. Testing for medical devices should be conducted using rinsing/eluting and sampling techniques as described in ISO 10993-1[14] and ISO 10993-12,[15] as also used for inhibition/enhancement. Sampling can be adjusted for special situations. After a suitable eluate/extract pool is obtained from a finished production lot, this pooled extract should be kept under conditions appropriate for stability until it is tested in duplicate.

FDA recommends that pooled samples be a composite of aseptically removed aliquots (after at least 30 seconds of vigorous mixing) from each of the product containers.[16] In this way, the original, individual containers will be available for possible retesting in the event the pooled sample displays an OOS result.

Some product types should not be pooled. Two examples are drug products that have an initial low MVD (see discussion above of "adjusted MVD") and products that are manufactured as a suspension, because sample aliquot homogeneity may present significant interference issues. FDA also does not recommend pooling in-process

[14] ISO 10993-1:2009 Biological evaluation of medical devices Part 1: Evaluation and testing in the risk management process.
[15] ISO 10993-12:2007 Biological evaluation of medical devices Part 12: Sample preparation and reference materials.
[16] See 21 CFR 211.84(c)(3).

samples from different in-process stages of the manufacturing process because it may be difficult to ensure the homogeneity of these materials.

5. May a firm use alternative assays to those in the USP for a compendial article?

Yes, firms may use alternative methods and/or procedures if they provide advantages in terms of accuracy, sensitivity, precision, selectivity, or adaptability to automation or computerized data reduction, and in other special circumstances. Such alternative procedures and methods should be validated as described in the USP General Chapter <1225>, Validation of Compendial Procedures,[17,18] and should be shown to achieve equivalent or better results.[19] When a difference appears or in the event of a dispute, the final decision is made based upon the USP compendial gel clot method unless otherwise indicated in the monograph for the product being tested.[20]

Below are two examples of alternative assays.

(1) Recombinant Horseshoe Crab Factor C Assay

If a manufacturer chooses to use a recombinant factor C-based assay, then method validation should be in accordance with the requirements of USP Chapter <85>, Bacterial Endotoxins Test, as described in the section for Photometric Quantitative Techniques, and USP Chapter <1225>, Validation of Compendial Procedures. [21]

(2) Monocyte Activation Type Pyrogen Test

Product-specific validation is necessary to establish whether a particular test substance or material is appropriate for evaluation of the monocyte activation method. The validation should include, but is not limited to, interference testing, accurate detection of pyrogen in individual test samples, and, for devices, ability of test system to provide direct contact to the monocytes.

6. What is the best process for transitioning from one alternate bacterial endotoxins test (BET) method to another?

The transition between tests that measure the same entity (e.g., LAL cascade) can be made by comparing the two tests to verify the equivalence of the new method. [22] The comparison of the limit of detection and inhibition/enhancement is fundamental. The

[17] USP, General Notices 6.30. Alternative and Harmonized Methods and Procedures.
[18] USP, 2011, Chapter <1225>, Validation of Compendial Procedures.
[19] USP, General Notices 6.30. Alternative and Harmonized Methods and Procedures.
[20] USP, 2011, Chapter <85>, Bacterial Endotoxins Test.
[21] USP, 2011, Chapter <1225>, Validation of Compendial Procedures.
[22] USP, 2011, Chapter <1225>, Validation of Compendial Procedures.

sensitivity of the new method can be evaluated on spiked product samples.[23] In addition to using spiked samples, a battery of field samples of product found to be positive may be a good source for comparing results from the methods. The method validation should also attempt to address the variability found in the normal use of the method and the manufacturing environment (e.g., source materials or seasonal changes).[24]

For drug, animal drug, and biological products, the transition to a new method should be submitted in a prior approval supplement (PAS). Alternatively, once a firm has established a general method for making the transition between tests, it may submit the method for review in a PAS—comparability protocol (CP). The CP should describe, in detail, the methods used to transition between assays and the acceptance criteria used to establish the equivalence of the new method. After approval of the CP, results of implementation of the CP may be directed to be reported in a reduced reporting category (Supplement—Changes Being Effected or Annual Report or Special Report (21 CFR 314.80)). The firm should maintain the study protocol, final report, and all data at the facility for FDA review. The firm should confirm the filing process with the appropriate review division before submitting a CP. For Class III devices, the transition to a new assay requires a 30-day notice filed under 21 CFR 814.39(e). See FDA's guidance, *Modifications to Devices Subject to Premarket Approval (PMA) - The PMA Supplement Decision-Making Process,* http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM089360.pdf. Manufacturing changes for Class I and II devices should be in accordance with the quality system regulation, 21 CFR part 820. Design control, production and process control requirements can be found at 21 CFR 820.30, 21 CFR 820.70, 21 CFR 820.72, and 21 CFR 820.75.

For devices, a 30-day notice may be appropriate for changes to quality control testing used on incoming components, raw materials, the in-process device, or the finished device, including performing end-product pyrogen testing on nonsterile samples prior to sterilization.[25] Manufactures of medical devices should demonstrate a sensitivity that is consistent with the route of administration for the device and the type of body contact. Manufacturers may use another endotoxin test after demonstrating a reproducible correlation between methods and the USP reference standard.

7. What happened to the endotoxins limit table in Appendix E of the 1987 Guidance?

The endotoxins limit table is out of date due to the increase in numbers of dosage (regimes) and drug strengths since the publication of the 1987 Guidance. The appropriate

[23] International Conference on Harmonisation (ICH) *Q2(R1) Validation of Analytical Procedures: Text and Methodology* (1994); USP, 2008, Chapter <1225>, Validation of Compendial Procedures.
[24] Thompson, M. et al., 2002, "Harmonized Guidelines for Single-Laboratory Validation of Methods of Analysis: IUPAC Technical Report," *Pure Appl. Chem*., Vol. 74, No. 5, pp. 835-855.
[25] 21 CFR 814.39(f).

way to establish the endotoxins limit is to use the calculation methods provided in the USP or AAMI standards. Monograph limits may also not account for current product strengths or dosage regimes; these should also be checked using the calculations recommended in the standards.

If there are several components in a finished product, then the overall endotoxins limit for parenterally-administered products should not exceed the overall threshold limit specified in the USP <85> Bacterial Endotoxins Test, regardless of an individual component endotoxins limit. Intrathecally-administered products, ophthalmics, or devices (see question 11 for devices) may have endotoxins limit requirements that are not based on the calculation for parenterally administered products. FDA encourages firms to check with the appropriate office or review division about these products.

8. How can Quality by Design concepts support endotoxins limits? [26]

When implementing Quality by Design concepts, the strategy for endotoxins testing should be based upon product and process understanding in combination with risk management to ensure consistent final product quality. The appropriate in-process testing should be used to evaluate the production process areas at risk of endotoxins formation or incursion. Many firms already have programs for monitoring incoming ingredients and components, including the processing water, for endotoxins contamination. The finished product release specification should be considered when determining in-process limits for each phase of manufacturing tested. For purposes of evaluating the relative risk of product contamination, quantitative testing may be preferable to limit testing to facilitate product quality trending and to identify and correct excursions before they exceed the specification and cause product failure. An endotoxins limit should be justified on a case-by-case basis, and will be evaluated as a part of each relevant marketing application or supplement.

9. When is the USP Chapter <151> Pyrogenicity Test (the rabbit pyrogen test) appropriate?

For certain biological products, 21 CFR 610.13(b) requires a rabbit pyrogen test. The requirement in 21 CFR 610.13(b) may be waived if a method equivalent to the rabbit pyrogen test is demonstrated in accordance with 21 CFR 610.9.

For human and animal drugs, some USP monographs still require a rabbit pyrogen test. Even with such monographs, a firm may substitute an endotoxins test or alternative cell-based test if the firm can demonstrate equivalent pyrogen detection. The appropriate FDA review division will consider alternative methods, such as monocyte activation, on a case-by-case basis.

[26] ICH Harmonised Tripartite Guideline, *Q8(R2) Pharmaceutical Development*, Step 4 Version (2009).

For devices and drug materials, firms should assess the risk of the presence of non-endotoxin pyrogens. If the risk assessment indicates that non-endotoxin pyrogens may be present, it may be more appropriate to use the rabbit pyrogen test.

Bacterial endotoxins assays are subject to a variety of interferences related to the physical and chemical properties of the test article. Where such interferences cannot be mitigated through sample dilution (up to the MVD) or other validated means of sample preparation, firms should use the rabbit pyrogen test.

10. How would an appropriate endotoxins limit be determined for a veterinary product that targets multiple species?

For a veterinary product labeled for use in multiple species, the limit should be based on the maximum product dose used on the smallest species. If the label indicates that the product may be used on juvenile and adult animals, the juvenile is considered the worst case. If the weight of the animal is required to calculate the dose, firms should use an average weight for that species. For a listing of some average animal weights, see the FDA draft guidance for industry on *Waivers of In Vivo Demonstration of Bioequivalence of Animal Drugs in Soluble Powder Oral Dosage Form Products and Type A Medicated Articles*. For animal weights not listed in that guidance, please contact FDA's Center for Veterinary Medicine.

11. What are the endotoxins limits for medical devices?

The Center for Devices and Radiological Health (CDRH) has adopted the USP Endotoxin Reference Standard and limits for medical device extracts expressed in EU/mL. USP Chapter <161> Transfusion and Infusion Assemblies and Similar Medical Devices provides the limits for medical devices within its scope. The endotoxins limit for a medical device is dependent on the intended use of the device and what the device contacts (e.g., blood, the cardiovascular system, cerebrospinal fluid, intrathecal routes of administration, permanently implanted devices, and devices implanted subcutaneously).[27]

For medical devices, using the extraction volume recommendations described below, the limit is 0.5 EU/mL or 20 EU/device for products that directly or indirectly contact the cardiovascular system and lymphatic system. For devices in contact with cerebrospinal fluid, the limit is 0.06 EU/mL or 2.15 EU/device. For devices that are in direct or indirect contact with the intraocular environment, a lower endotoxins limit may apply. Please contact the appropriate review division for specific recommendations.

The process of preparing an eluate/extract for testing may vary from device to device. Some medical devices can be flushed, some may have to be immersed, while others may need disassembly. Unless otherwise directed by another compendial standard, our

[27] USP, 2011, Chapter <161>, Transfusion and Infusion Assemblies and Similar Medical Devices.

recommended rinse volumes include the following: (1) each of the 10 test units should be rinsed with 40 mL of non-pyrogenic water; (2) for unusually small or large devices, the surface area of the device that contacts the patient may be used as an adjustment factor in selecting the rinse or extract volume. The endotoxins limit can be adjusted accordingly. In any case, the rinse/extract procedure should not result in a greater dilution of endotoxin than recommended in USP <85>. For inhibition/enhancement testing, both the rinse/extract solution and the device eluate/extract should be tested.

Examples of medical devices with testing or interference challenges include devices that are coated with anticoagulant, contain heavy metals, or that have particulates. In these situations, treatments for interferences can include digestion, dilution, and addition of buffers, centrifugation, or filtration.

During the same surgical procedure or placement in the same surgical site, multiple units of the same device from one manufacturer should generally meet the same endotoxins limit as a single device administered during the procedure. In instances where multiple units of the same device are known or intended for use in a single procedure, manufacturers should justify any deviation from the overall endotoxins limit identified in this guidance.

When a manufacturer of medical devices plans to use LAL testing that deviates significantly from this guidance or recognized standard, a premarket notification (510(k)) under section 510(k) of the Federal Food, Drug, and Cosmetic Act (the Act) or a premarket approval application (PMA) supplement under section 515 of the Act should be submitted. Significant deviations include, but are not necessarily limited to: higher endotoxin concentration release criteria, sampling from fewer than three (3) lots for inhibition/enhancement testing, lesser sensitivity to endotoxins, and a device rinsing protocol resulting in greater dilution of endotoxins than that recommended in this guidance.

12. What is the FDA's expectation for regular screening of therapeutic drug products?

Ideally, the undiluted product should be screened as long as there is no interfering/enhancing property within the LAL test. However, in some product formulations, the ingredients interfere with the LAL test. For such formulations, the USP recommends that the product be diluted to overcome interference or enhancement properties. The calculated MVD is the dilution of a sample at which the endotoxins limit would be detected, but it should not be the regular testing dilution. When product interference is encountered during development, FDA recommends that the firm determine the lowest product dilution that would neutralize the interfering condition.

FDA recommends that firms begin subsequent product screening at a product dilution just above the level that neutralized the interference. For example, if the product has an MVD of 1:100, and the product displays inhibition at the 1:10, but not at the 1:20, it may

be best to screen product at 1:30. If bacterial endotoxins are detected at this level, then the firm should conduct full enumeration with the product to titrate the true amount of endotoxins.

13. Are control standard endotoxins still acceptable for use in running bacterial endotoxins tests?

Control standard endotoxins (CSEs) are endotoxin preparations other than the international or national reference standards that are traceable in their calibration to the international reference endotoxins standard. CSEs may be secondary or tertiary standards and are usually manufactured and certified by an LAL reagent manufacturer for use with a specific lot of reagent under defined assay conditions. CSEs have become an accepted source for preparation of standard curve calibrators and as assay controls, and have provided a cost saving to LAL users and helped to preserve the inventory of primary standards. FDA encourages the continued use of CSEs that are suitably calibrated to the international reference endotoxins standard.

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〈 85 〉 BACTERIAL ENDOTOXINS TEST

✦Portions of this general chapter have been harmonized with the corresponding texts of the European Pharmacopeia and/or the Japanese Pharmacopeia. Those portions that are not harmonized are marked with symbols (✦✦) to specify this fact.✦

This chapter provides a test to detect or quantify bacterial endotoxins that may be present in or on the sample of the article(s) to which the test is applied. It uses Limulus Amebocyte Lysate (LAL) obtained from the aqueous extracts of circulating amebocytes of horseshoe crab (*Limulus polyphemus* or *Tachypleus tridentatus*) which has been prepared and characterized for use as an LAL Reagent.✦[1]✦

There are two types of techniques for this test: the gel-clot techniques, which are based on gel formation, and the photometric techniques. The latter include a turbidimetric method, which is based on the development of turbidity after cleavage of an endogenous substrate, and a chromogenic method, which is based on the development of color after cleavage of a synthetic peptide-chromogen complex. Proceed by any one of these techniques, unless otherwise indicated in the monograph. In case of dispute, the final decision is based on the gel-clot techniques, unless otherwise indicated in the monograph.

In the gel-clot techniques, the reaction endpoint is determined from dilutions of the material under test in direct comparison with parallel dilutions of a reference endotoxin, and quantities of endotoxin are expressed in USP Endotoxin Units (USP-EU). [NOTE—One USP-EU is equal to one IU of endotoxin.]

Because LAL Reagents have been formulated to be used also for turbidimetric or colorimetric tests, such tests may be used to comply with the requirements. These tests require the establishment of a standard regression curve; the endotoxin content of the test material is determined by interpolation from the curve. The procedures include incubation for a preselected time of reacting endotoxin and control solutions with LAL Reagent and reading of the spectrophotometric light absorbance at suitable wavelengths. In the endpoint turbidimetric procedure the reading is made immediately at the end of the incubation period. In the endpoint colorimetric procedure the reaction is arrested at the end of the preselected time by the addition of an enzyme reaction-terminating agent prior to the readings. In the turbidimetric and colorimetric kinetic assays the absorbance is measured throughout the reaction period and rate values are determined from those readings.

APPARATUS AND GLASSWARE

Depyrogenate all glassware and other heat-stable materials in a hot-air oven using a validated process.✦[2]✦ Commonly used minimum time and temperature settings are 30 minutes at 250°. If employing plastic apparatus, such as microplates and pipet tips for automatic pipetters, use only that which has been shown to be free of detectable endotoxin and not to interfere with the test. [NOTE—In this chapter, the term “tube” includes any other receptacle such as a micro-titer well.]

PREPARATION OF THE STANDARD ENDOTOXIN STOCK SOLUTION AND STANDARD SOLUTIONS

The *USP Endotoxin RS* has a defined potency of 10,000 USP Endotoxin Units (EU) per vial. Constitute the entire contents of 1 vial of the RSE with 5 mL of LAL Reagent Water✦[3]✦, mix intermittently for 30 minutes, using a vortex mixer, and use this

concentrate for making appropriate serial dilutions. Preserve the concentrate in a refrigerator for making subsequent dilutions for not more than 14 days. Mix vigorously, using a vortex mixer, for not less than 3 minutes before use. Mix each dilution for not less than 30 seconds before proceeding to make the next dilution. Do not store dilutions, because of loss of activity by adsorption, in the absence of supporting data to the contrary.

Preparatory Testing

Use an LAL Reagent of confirmed label sensitivity.

The validity of test results for bacterial endotoxins requires an adequate demonstration that specimens of the article or of solutions, washings, or extracts thereof to which the test is to be applied do not of themselves inhibit or enhance the reaction or otherwise interfere with the test. Validation is accomplished by performing the inhibition or enhancement test described under each of the three techniques indicated. Appropriate negative controls are included. Validation must be repeated if the LAL Reagent source or the method of manufacture or formulation of the article is changed.

Preparation of Sample Solutions

Prepare sample solutions by dissolving or diluting drugs or extracting medical devices using LAL Reagent Water. Some substances or preparations may be more appropriately dissolved, diluted, or extracted in other aqueous solutions. If necessary, adjust the pH of the solution (or dilution thereof) to be examined so that the pH of the mixture of the LAL Reagent and sample falls within the pH range specified by the LAL Reagent manufacturer. This usually applies to a product with a pH in the range of 6.0 to 8.0. The pH may be adjusted using an acid, base, or suitable buffer as recommended by the LAL Reagent manufacturer. Acids and bases may be prepared from concentrates or solids with LAL Reagent Water in containers free of detectable endotoxin. Buffers must be validated to be free of detectable endotoxin and interfering factors.

DETERMINATION OF MAXIMUM VALID DILUTION (MVD)

The Maximum Valid Dilution is the maximum allowable dilution of a specimen at which the endotoxin limit can be determined. It applies to injections or to solutions for parenteral administration in the form constituted or diluted for administration, or, where applicable, to the amount of drug by weight if the volume of the dosage form for administration could be varied. The general equation to determine MVD is:

$$MVD = (\text{Endotoxin limit} \times \text{Concentration of sample solution}) / (\lambda)$$

where the concentration of sample solution and λ are as defined below. Where the endotoxin limit concentration is specified in the individual monograph in terms of volume (in EU per mL), divide the limit by λ, which is the labeled sensitivity (in EU per mL) of the LAL Reagent, to obtain the MVD factor. Where the endotoxin limit concentration is specified in the individual monograph in terms of weight or Units of active drug (in EU per mg or in EU per Unit), multiply the limit by the concentration (in mg per mL or in Units per mL) of the drug in the solution tested or of the drug constituted according to the label instructions, whichever is applicable, and divide the product of the multiplication by λ, to obtain the MVD factor. The MVD factor so obtained is the limit dilution factor for the preparation for the test to be valid.

ESTABLISHMENT OF ENDOTOXIN LIMITS

The endotoxin limit for parenteral drugs, defined on the basis of dose, is equal to K/M, [4] where K is the threshold human pyrogenic dose of endotoxin per kg of body weight, and M is equal to the maximum recommended human dose of product per kg of body weight in a single hour period.

The endotoxin limit for parenteral drugs is specified in individual monographs in units such as EU/mL, EU/mg, or EU/Unit of biological activity.

GEL-CLOT TECHNIQUES

The gel-clot techniques detect or quantify endotoxins based on clotting of the LAL Reagent in the presence of endotoxin. The concentration of endotoxin required to cause the lysate to clot under standard conditions is the labeled sensitivity of the LAL Reagent. To ensure both the precision and validity of the test, tests for confirming the labeled LAL Reagent sensitivity and for interfering factors are described under *Preparatory Testing for the Gel-Clot Techniques*.

Preparatory Testing for the Gel-Clot Techniques

Test for Confirmation of Labeled LAL Reagent Sensitivity— Confirm the labeled sensitivity using at least 1 vial of the LAL Reagent lot. Prepare a series of two-fold dilutions of the *USP Endotoxin RS* in LAL Reagent Water to give concentrations of 2λ, λ, 0.5λ, and 0.25λ, where λ is as defined above. Perform the test on the four standard concentrations in quadruplicate and include negative controls. The test for confirmation of lysate sensitivity is to be carried out when a new batch of LAL Reagent is used or when there is any change in the experimental conditions that may affect the outcome of the test.

Mix a volume of the LAL Reagent with an equal volume (such as 0.1-mL aliquots) of one of the standard solutions in each test tube. When single test vials or ampuls containing lyophilized LAL Reagent are used, add solutions directly to the vial or ampul. Incubate the reaction mixture for a constant period according to directions of the LAL Reagent manufacturer (usually at 37 ± 1° for 60 ± 2 minutes), avoiding vibration. To test the integrity of the gel, take each tube in turn directly from the incubator and invert it through about 180° in one smooth motion. If a firm gel has formed that remains in place upon inversion, record the result as positive. A result is negative if an intact gel is not formed. The test is not valid unless the lowest concentration of the standard solutions shows a negative result in all replicate tests.

The endpoint is the last positive test in the series of decreasing concentrations of endotoxin. Calculate the mean value of the logarithms of the endpoint concentration and then the antilogarithm of the mean value using the following equation:

$$\text{Geometric Mean Endpoint Concentration} = \text{antilog}\,(\Sigma e / f),$$

where Σe is the sum of the log endpoint concentrations of the dilution series used, and f is the number of replicate test tubes. The geometric mean endpoint concentration is the measured sensitivity of the LAL Reagent (in EU/mL). If this is not less than 0.5λ and not more than 2λ, the labeled sensitivity is confirmed and is used in tests performed with this lysate.

Interfering Factors Test for the Gel-Clot Techniques— Prepare solutions A, B, C, and D as shown in *Table 1*, and perform the inhibition/enhancement test on the sample solutions at a dilution less than the MVD, not containing any detectable endotoxins, following the procedure in the *Test for Confirmation of Labeled LAL Reagent Sensitivity* above. The geometric mean endpoint concentrations of solutions B and C are determined using the equation in that test.

Table 1. Preparation of Solutions for the Inhibition/Enhancement Test for Gel-Clot Techniques

Solution	Endotoxin Concentration/Solution to which Endotoxin is Added	Diluent	Dilution Factor	Initial Endotoxin Concentration	Number of Replicates
A[a]	none/sample solution	—	—	—	4
B[b]	2λ/sample solution	sample solution	1	2λ	4
			2	1λ	4
			4	0.5λ	4
			8	0.25λ	4

[a] Solution A: a sample solution of the preparation under test that is free of detectable endotoxins.

[b] Solution B: test for interference.

[c] Solution C: control for labeled LAL Reagent sensitivity.

[d] Solution D: negative control of LAL Reagent Water.

Solution	Endotoxin Concentration/Solution to which Endotoxin is Added	Diluent	Dilution Factor	Initial Endotoxin Concentration	Number of Replicates
C[c]	2λ/water for BET	LAL Reagent Water	1	2λ	2
			2	1λ	2
			4	0.5λ	2
			8	0.25λ	
D[d]	none/LAL Reagent Water	—	—	—	2

a Solution A: a sample solution of the preparation under test that is free of detectable endotoxins.

b Solution B: test for interference.

c Solution C: control for labeled LAL Reagent sensitivity.

d Solution D: negative control of LAL Reagent Water.

This test must be repeated when any condition that is likely to influence the test results changes. The test is not valid unless Solutions A and D show no reaction and the result of Solution C confirms the labeled sensitivity.

If the sensitivity of the lysate determined in the presence of the sample solution under test of Solution B is not less than 0.5λ and not greater than 2λ, the sample solution does not contain factors which interfere under the experimental conditions used. Otherwise, the sample solution to be examined interferes with the test.

If the sample under test does not comply with the test at a dilution less than the MVD, repeat the test using a greater dilution, not exceeding the MVD. The use of a more sensitive lysate permits a greater dilution of the sample to be examined and this may contribute to the elimination of interference.

Interference may be overcome by suitable treatment, such as filtration, neutralization, dialysis, or heating. To establish that the chosen treatment effectively eliminates interference without loss of endotoxins, perform the assay described below using the preparation to be examined to which *USP Endotoxin RS* has been added and which has been subjected to the selected treatment.

Gel-Clot Limit Test

This test is used when a monograph contains a requirement for endotoxin limits.

Procedure— Prepare Solutions A, B, C, and D as shown in *Table 2*, and perform the test on these solutions following the procedure in the *Test for Confirmation of Labeled LAL Reagent Sensitivity* under *Preparatory Testing for the Gel-Clot Techniques.*

Table 2. Preparation of Solutions for the Gel-Clot Limit Test

Solution*	Endotoxin Concentration/Solution to which Endotoxin is Added	Number of Replicates
A	none/diluted sample solution	2
B	2λ/diluted sample solution	2
C	2λ/LAL Reagent Water	2
D	none/LAL Reagent Water	2

* Prepare Solution A and positive product control Solution B using a dilution not greater than the MVD and treatments as directed in the *Interfering Factors Test for the Gel-Clot Techniques* under *Preparatory Testing for the Gel-Clot Techniques.* Positive control Solutions B and C contain the standard endotoxin preparation at a concentration corresponding to twice the labeled LAL Reagent sensitivity. The negative control Solution D is LAL Reagent Water.

Interpretation— The test is not valid unless both replicates of positive control Solutions B and C are positive and those of negative control Solution D are negative. The preparation under test complies with the test when a negative result is found for both tubes containing Solution A. The preparation under test does not comply with the test when a positive result is found for both tubes containing Solution A.

Repeat the test when a positive result is found for 1 tube containing Solution A and a negative result for the other one. The preparation under test complies with the test when a negative result is found for both tubes containing Solution A in the repeat result. If the test is positive for the preparation under test at a dilution less than the MVD, the test may be repeated at a dilution not greater than the MVD.

Gel-Clot Assay

This assay quantifies bacterial endotoxins in sample solutions by titration to an endpoint.

Procedure— Prepare Solutions A, B, C, and D as shown in *Table 3*, and test these solutions by following the procedure in the *Test for Confirmation of Labeled LAL Reagent Sensitivity* under *Preparatory Testing for the Gel-Clot Techniques.*

Table 3. Preparation of Solutions for the Gel-Clot Assay

Solution	Endotoxin Concentration/ Solution to which Endotoxin is Added	Diluent	Dilution Factor	Initial Endotoxin Concentration	Number of Replicates
A[a]	none/sample solution	LAL Reagent Water	1	—	2
			2	—	2
			4	—	2
			8	—	2
B[b]	2λ/sample solution	—	1	2λ	2
C[c]	2λ/LAL Reagent Water	LAL Reagent Water	1	2λ	2
			2	1λ	2
			4	0.5λ	2
			8	0.25λ	2
D[d]	none/LAL Reagent Water	—	—	—	2

[a] Solution A: a sample solution under test at the dilution, not to exceed the MVD, with which the *Interfering Factors Test for the Gel-Clot Techniques* was completed. Subsequent dilution of the sample solution must not exceed the MVD. Use LAL Reagent Water to make dilution series of four tubes containing the sample solution under test at concentrations of 1, ½, ¼, and 1/8 relative to the dilution with which the *Interfering Factors Test for the Gel-Clot Techniques* was completed. Other dilutions may be used as appropriate.

[b] Solution B: Solution A containing standard endotoxin at a concentration of 2λ (positive product control).

[c] Solution C: two series of 4 tubes of LAL Reagent Water containing the standard endotoxin at a concentration of 2λ, λ, 0.5λ, and 0.25λ, respectively.

[d] Solution D: LAL Reagent Water (negative control).

Calculation and Interpretation— The test is not valid unless the following conditions are met: (1) both replicates of negative control Solution D are negative; (2) both replicates of positive product control Solution B are positive; and (3) the geometric mean endpoint concentration of Solution C is in the range of 0.5λ to 2λ.

To determine the endotoxin concentration of Solution A, calculate the endpoint concentration for each replicate series of dilutions by multiplying each endpoint dilution factor by λ. The endotoxin concentration in the sample is the geometric mean endpoint concentration of the replicates (see the formula given in the *Test for Confirmation of Labeled LAL Reagent*

Sensitivity under *Preparatory Testing for the Gel-Clot Techniques*). If the test is conducted with a diluted sample solution, calculate the concentration of endotoxin in the original sample solution by multiplying by the dilution factor. If none of the dilutions of the sample solution is positive in a valid assay, report the endotoxin concentration as less than λ (if the diluted sample was tested, less than λ times the lowest dilution factor of the sample.) If all dilutions are positive, the endotoxin concentration is reported as equal to or greater than the greatest dilution factor multiplied by λ (e.g., initial dilution factor times 8 times λ in *Table 3*).

The article meets the requirements of the test if the concentration of endotoxin is less than that specified in the individual monograph.

PHOTOMETRIC TECHNIQUES

The turbidimetric method measures increases in turbidity. Depending on the test principle used, this technique is classified as either endpoint-turbidimetric or kinetic-turbidimetric. The endpoint-turbidimetric technique is based on the quantitative relationship between the concentration of endotoxins and the turbidity (absorbance or transmission) of the reaction mixture at the end of an incubation period. The kinetic-turbidimetric technique is a method to measure either the onset time needed to reach a predetermined absorbance of the reaction mixture or the rate of turbidity development.

The chromogenic method measures the chromophore released from a suitable chromogenic peptide by the reaction of endotoxins with the LAL Reagent. Depending on the test principle employed, this technique is classified as either endpoint-chromogenic or kinetic-chromogenic. The endpoint-chromogenic technique is based on the quantitative relationship between the concentration of endotoxins and the release of chromophore at the end of an incubation period. The kinetic-chromogenic technique is a method to measure either the onset time needed to reach a predetermined absorbance of the reaction mixture or the rate of color development.

All photometric tests are carried out at the incubation temperature recommended by the LAL Reagent manufacturer, which is usually 37 ± 1°.

Preparatory Testing for the Photometric Techniques

To assure the precision or validity of the turbidimetric and chromogenic techniques, preparatory tests are conducted to verify that the criteria for the standard curve are valid and that the sample solution does not inhibit or enhance the reaction. Revalidation for the test method is required when conditions that are likely to influence the test result change.

Verification of Criteria for the Standard Curve— Using the Standard Endotoxin Solution, prepare at least three endotoxin concentrations to generate the standard curve. Perform the test using at least three replicates of each standard endotoxin concentration according to the manufacturer's instructions for the LAL Reagent (with regard to volume ratios, incubation time, temperature, pH, etc.). If the desired range in the kinetic methods is greater than two logs, additional standards should be included to bracket each log increase within the range of the standard curve. The absolute value of the correlation coefficient, $|r|$, must be greater than or equal to 0.980 for the range of endotoxin concentrations indicated by the manufacturer of the LAL Reagent.

Interfering Factors Test for the Photometric Techniques— Select an endotoxin concentration at or near the middle of the endotoxin standard curve. Prepare Solutions A, B, C, and D as shown in *Table 4*. Perform the test on Solutions A, B, C, and D at least in duplicate following the instructions for the LAL Reagent used (with regard to volume of sample and LAL Reagent, volume ratio of sample to LAL Reagent, incubation time, etc.).

Table 4. Preparation of Solutions for the Inhibition/Enhancement Test for Photometric Techniques

Solution	Endotoxin Concentration	Solution to which Endotoxin is Added	Number of Replicates

Solution	Endotoxin Concentration	Solution to which Endotoxin is Added	Number of Replicates
A[a]	none	sample solution	not less than 2
B[b]	middle concentration of the standard curve	sample solution	not less than 2
C[c]	at least 3 concentrations (lowest concentration is designated λ)	LAL Reagent Water	each not less than 2
D[d]	none	LAL Reagent Water	not less than 2

a Solution A: the sample solution may be diluted not to exceed MVD.

b Solution B: the preparation under test at the same dilution as Solution A, containing added endotoxin at a concentration equal to or near the middle of the standard curve.

c Solution C: the standard endotoxin at the concentrations used in the validation of the method described in *Verification of Criteria for the Standard Curve* under *Preparatory Testing for the Photometric Techniques* (positive control series).

d Solution D: LAL Reagent Water (negative control).

Calculate the mean recovery of the added endotoxin by subtracting the mean endotoxin concentration in the solution (if any) from that containing the added endotoxin. In order to be considered free of interfering factors under the conditions of the test, the measured concentration of the endotoxin added to the sample solution must be within 50% to 200% of the known added endotoxin concentration after subtraction of any endotoxin detected in the solution without added endotoxin.

When the endotoxin recovery is out of the specified ranges, the interfering factors must be removed as described in the *Interfering Factors Test for the Gel-Clot Techniques* under *Preparatory Testing for the Gel-Clot Techniques.* Repeating the *Interfering Factors Test for the Gel-Clot Techniques* validates the treatment.

Procedure for the Photometric Techniques

Follow the procedure described in the *Interfering Factors Test for the Photometric Techniques* under *Preparatory Testing for the Photometric Techniques.*

Calculation for the Photometric Techniques

Calculate the endotoxin concentration of each of the replicates of test Solution A using the standard curve generated by positive control series C. The test is not valid unless the following conditions are met: (1) the results of control series C comply with the requirements for validation defined under *Verification of Criteria for the Standard Curve* under *Preparatory Testing for the Photometric Techniques;* (2) the endotoxin recovery, calculated from the concentration found in Solution B after subtracting the endotoxin concentration found in Solution A is within 50 to 200%; and (3) the result of negative control series D does not exceed the limit of the blank value required in the description of the LAL Reagent used.

Interpretation of Results from the Photometric Techniques

In photometric assays, the preparation under test complies with the test if the mean endotoxin concentration of the replicates of Solution A, after correction for dilution and concentration, is less than the endotoxin limit for the product.

✦1 LAL Reagent reacts with some β-glucans in addition to endotoxins. Some preparations that are treated will not react with β-glucans and must be used for samples that contain glucans.✦

✦2 For a validity test of the procedure for inactivating endotoxins, see *Dry-Heat Sterilization* under *Sterilization and Sterility Assurance of Compendial Articles* ⟨ 1211 ⟩. Use an LAL Reagent having a sensitivity of not less than 0.15 Endotoxin Unit per mL.✦

[3] *Sterile Water for Injection* or other water that shows no reaction with the specific LAL Reagent with which it is to be used, at the limit of sensitivity of such reagent.

[4] *K* is 5 USP-EU/kg for any route of administration other than intrathecal (for which *K* is 0.2 USP-EU/kg body weight). For radiopharmaceutical products not administered intrathecally the endotoxin limit is calculated as 175/*V*, where *V* is the maximum recommended dose in mL. For intrathecally administered radiopharmaceuticals, the endotoxin limit is obtained by the formula 14/*V*. For formulations (usually anticancer products) administered on a per square meter of body surface, the formula is *K*/*M*, where *K* = 5 EU/kg and *M* is the (maximum dose/m^2/hour × 1.80 m^2)/70 Kg.

Auxiliary Information— *Staff Liaison* : Radhakrishna S Tirumalai, Scientist
Expert Committee : (MSA05) Microbiology and Sterility Assurance
USP29–NF24 Page 2521
Phone Number : 1-301-816-8339

U.S. PHARMACOPEIA

Search USP29 Go

Testosterone Cypionate Injection

» Testosterone Cypionate Injection is a sterile solution of Testosterone Cypionate in a suitable vegetable oil. It contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of $C_{27}H_{40}O_3$. It may contain a suitable solubilizing agent.

Packaging and storage— Preserve in single-dose or multiple-dose containers, preferably of Type I glass, protected from light.

USP Reference standards ⟨ 11 ⟩ **—** *USP Cholesteryl Caprylate RS*. *USP Testosterone Cypionate RS*.

Identification— Dilute a suitable volume of Injection with chloroform to obtain a solution having a concentration of about 400 µg of testosterone cypionate per mL. Prepare a 20- × 20-cm thin-layer chromatographic plate (see *Chromatography* ⟨ 621 ⟩), coated with a 0.25-mm layer of chromatographic siliceous earth, by placing it in a developing chamber containing and equilibrated with a mixture of chloroform and corn oil (90:10), and allowing the solvent front to move about three-fourths of the length of the plate. Remove the plate, and allow the chloroform to evaporate. Apply 10 µL each of the solution under test and of a solution of *USP Testosterone Cypionate RS* in chloroform containing about 400 µg per mL on the plate, on a line about 2.5 cm from the bottom edge and about 1.5 cm apart. Place the plate in a developing chamber that contains and has been equilibrated with a mixture of methanol and water (90:10) previously saturated with corn oil. Develop the chromatogram until the solvent front has moved to about 10 cm above the line of application. Remove the plate, and heat in an oven at 105° for a few minutes. Spray the plate with a mixture of alcohol and sulfuric acid (3:1), and heat in an oven at 105° for 1 to 2 minutes. Observe the plate under long-wavelength UV light: the R_F value of the principal spot obtained from the solution under test corresponds to that obtained from the Standard solution.

Residual solvents ⟨ 467 ⟩ **:** meets the requirements.
(Official January 1, 2007)

Other requirements— It meets the requirements under *Injections* ⟨ 1 ⟩ .

Assay—

Internal standard solution and *Standard preparation*—Prepare as directed in the *Assay* under *Testosterone Cypionate.*

Assay preparation— Transfer 1 mL of Injection, accurately measured, into a glass-stoppered, 50-mL centrifuge tube. Add 30 mL of a mixture of methanol and water (9:1), insert the stopper, and shake for 15 minutes. Centrifuge, remove the dilute methanol layer without disturbing the oil, and transfer it to a 200-mL volumetric flask. Repeat the extraction with three additional 30-mL portions of the dilute methanol, collecting the combined extracts in the volumetric flask. Dilute the combined extracts with the dilute methanol to volume, mix, and chill the contents of the flask to −8°. Remove the flask from the freezer, and immediately filter a portion of the contents. Allow the filtrate to reach room temperature, transfer a portion of it, equivalent to about 3 mg of testosterone cypionate, to a suitable vial, and evaporate to dryness. Add by pipet 3 mL of *Internal standard solution*, and shake vigorously to dissolve the residue.

Procedure— Proceed as directed for *Procedure* in the *Assay* under *Testosterone Cypionate.* Calculate the quantity, in mg, of $C_{27}H_{40}O_3$ in the portion of Injection taken by the formula:

$$600(C / V)(R_U / R_S),$$

in which *C* is the concentration, in mg per mL, of *USP Testosterone Cypionate RS* in the *Standard preparation;* and *V* is the volume, in mL, of the filtrate used in the *Assay preparation.*

Auxiliary Information— *Staff Liaison* : Daniel K. Bempong, Ph.D., Scientist
Expert Committee : (MDPS05) Monograph Development-Pulmonary and Steroids
USP29–NF24 Page 2088
Phone Number : 1-301-816-8143

********* ENDOSAFE Test Record *********
V712F 3/26/2015
DateTime: ..... 01/04/18 @ 04:29:29PM
Device: 3187
OperatorID: ..... JSG
Cartridge: ..... Endotoxin
Temperature: .. Start: 37.0C End: 37.0C
Method: KX-122
Cartridge Lot#: 7610173
Cartridge Cal Code: 511436756800
Range: 5-0.05
Range Time: ..... Sec: 114-767
Onset Times: ..... >767 212 >767 262
Slope: -0.414 ..... Intercept: +2.346
Dilution: 100
Sample Lot: 171006A
Sample ID: ..... TEST CYPIONATE 200
Sample Rxn Time CV: ..... 0.0% Pass
Spike Value: ..... 0.803 EU/mL
Spike Rxn Time CV: ..... 14.9% Pass
Spike Recovery: ..... 91% Pass
Test Suitability: ..... Pass
Sample Value: ..... <5.00 EU/mL
:

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v.

HYBRID PHARMA, LLC,

RESPONDENT.

_____/

CASE NO. 2017-23347

STIPULATION FOR THE SUBSTITUTION OF COUNSEL FOR RESPONDENT, HYBRID PHARMA, LLC

IT IS HEREBY STIPULATED AND AGREED that the law firm of McRae Law Offices, P.A., is hereby substituted in place of Panza Maurer & Maynard, P.A., as counsel of record for Respondent, Hybrid Pharma, LLC. Panza Maurer & Maynard, P.A., and Thomas F. Panza, Esq. and Jennifer K. Graner, Esq. of the firm, shall have no further responsibilities or representation in this case. All future correspondence, pleadings, and motions shall be directed to Steven Goerke, Esq., and Mitchell T. McRae, Esq. of McRae Law Offices, P.A.

PANZA MAURER & MAYNARD, P.A.
2400 E. Commercial Boulevard, Suite 905
Ft. Lauderdale, FL 33301
Tel: (954)-390-0100; Fax: (954) 390-7991

By: _____
Thomas F. Panza, Esq.
Fla. Bar No.: 138551
tpanza@panzamaurer.com
Jennifer K. Graner, Esq.
Fla. Bar No.: 907091
jgraner@panzamaurer.com

McRAE LAW OFFICES, P.A.
5300 W. Atlantic Ave, Suite 412
Delray Beach, FL 33484
Tel. (561) 638-6600, Fax (888) 308-6020

By: _____
Steven Goerke, Esq.
Fla. Bar No: 494135
sgoerke@mcraelawfirm.com
Mitchell T. McRae, Esq.
Fla. Bar No. 441759
mmcrae@mcraelawfirm.com

CONSENT OF CLIENT

I, Dr. Ponswamy Rajalingam, as Managing Member of Hybrid Pharma, LLC hereby consent to the substitution of counsel as set forth above.

HYBRID PHARMA, LLC

By: Dr. Ponswamy Rajalingam, Managing Member

Dated: 7/24/2020

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing was filed with the Department of Health, Agency Clerk, via fax (850) 413-8743 and a copy sent via e-mail this 28th day of July 2020, to:

Andrew J. Pietrylo, Jr.
Assistant General Counsel
DOH Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65
Tallahassee, FL 32399-3265
Andrew.Pietrylo@flhealth.gov

McRAE LAW OFFICES, P.A.
5300 W. Atlantic Ave, Suite 412
Delray Beach, FL 33484
Phone: (561) 638-6600
Fax: (888) 308-6020

By: _____
Steven Goerke, Esq.
Fla. Bar No. 494135
sgoerke@mcraelawfirm.com

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v.

HYBRID PHARMA, LLC,

RESPONDENT.
_____/

CASE NO. 2017-23347

2020 JUL 28 PM 2:17

NOTICE OF APPEARANCE AS COUNSEL FOR FOR RESPONDENT, HYBRID PHARMA, LLC

PLEASE NOTE the appearance of undersigned counsel as counsel of record for Respondent, Hybrid Pharma, LLC, in the above-captioned matter.

McRAE LAW OFFICES, P.A.
5300 W. Atlantic Ave, Suite 412
Delray Beach, FL 33484
Phone: (561) 638-6600
Fax: (888) 308-6020

By: _____
Steven Goerke, Esq.
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sgoerke@mcraelawfirm.com
Mitchell T. McRae, Esq.
Fla. Bar No. 441759
mmcrae@mcraelawfirm.com

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing was filed with the Department of Health, Agency Clerk, via fax (850) 413-8743 and a copy sent via e-mail this 28th day of July 2020, to:

Andrew J. Pietrylo, Jr.
Assistant General Counsel
DOH Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65
Tallahassee, FL 32399-3265
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STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v.

HYBRID PHARMA, LLC,

RESPONDENT.

_____/

CASE NO. 2017-23347

STIPULATION FOR THE SUBSTITUTION OF COUNSEL FOR RESPONDENT, HYBRID PHARMA, LLC

IT IS HEREBY STIPULATED AND AGREED that the law firm of Panza Maurer & Maynard, P.A. is here by substituted in place of Grossman, Furlow, & Bayó, as counsel of record for Respondent, Hybrid Pharma, LLC. Grossman, Furlow & Bayó shall have no further responsibilities or representation in this case. All future correspondence, pleadings, and motions shall be directed to Thomas F. Panza, Esq. and Jennifer K. Graner, Esq. of the law firm Panza Maurer & Maynard, P.A.

Grossman, Furlow, & Bayó
2022-2 Raymond Diehl Road
Tallahassee, FL 32308

By: _____
Edwin A. Bayó, Esq.
Florida Bar No.: 327727

Panza Maurer & Maynard, P.A.
2400 E. Commercial Boulevard, Suite 905
Ft. Lauderdale, FL 33331

By: _____
Thomas F. Panza, Esq.
Florida Bar No.: 138551

CONSENT OF CLIENT

I Ponswamy RAJALINGAM, as President, of Hybrid Pharma, LLC hereby consent to the substitution of counsel as set forth above.

HYBRID PHARMA, LLC

Dr. Ponswamy Rajalingam

Dated: 6/5/2020

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing was filed with the Department of Health, Agency Clerk, via fax (850) 413-8743 and a copy sent via e-mail this 8th day of June, 2020, to:

Anthony Brian Coniglio
Assistant General Counsel
DOH Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65
Tallahassee, FL 32399-3265
Anthony.coniglio@flhealth.gov

Respectfully submitted,

PANZA MAURER & MAYNARD, P.A.
2400 E. Commercial Boulevard, Suite 905
Ft. Lauderdale, FL 33301
Tel: (954)-390-0100; Fax: (954) 390-7991

By: _____
Thomas F. Panza, Esq.
Fla. Bar No.: 138551
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Jennifer K. Graner, Esq.
Fla. Bar No.: 907091
jgraner@panzamaurer.com

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,
BOARD OF PHARMACY
Petitioner,

v. CASE NO. 2017-23347

HYBRID PHARMA, LLC
Respondent.
_____/

PETITION FOR HEARING INVOLVING DISPUTED ISSUES OF MATERIAL FACT

Respondent, HYBRID PHARMA, LLC, by and through the undersigned attorney and pursuant to Sections 120.569 and 120.57, Florida Statute, files herewith this Petition for Administrative Hearing Involving Disputed Issues of Material Fact, and as grounds therefore would state the following:

1. The agency affected is the Board of Pharmacy, 4052 Bald Cypress Way, Tallahassee, FL 32399 (hereinafter "Board" or "Petitioner") .

2. Respondent is HYBRID PHARMA, LLC. For purposes of this proceeding, Respondents' address and phone number will be that of the undersigned counsel.

3. On January 17, 2020, by U.S. Certified Mail, Respondent and Counsel received an Administrative Complaint from agents of the Board of Pharmacy.

4. Respondent's substantial interests will be adversely affected by disciplinary action against its special sterile compounding pharmacy permit in Florida.

5. Respondent is a "small business party" as that term is defined by section 57.111, Fla. Stat.

6. Respondent asserts the existence of disputed issues of material fact, and requests an evidentiary hearing for determination and ruling on the disputed issues of material fact. The

disputed facts include, but are not limited to, whether Respondent violated Section 456.023(1)(c), Fla. Stat., through a violation of Rule 64B16-27.797(1)(a), F.A.C.

7. Respondent submits as ultimate facts that it did not violate Section 456.023(1)(c), Fla. Stat., through a violation of Rule 64B16-27.797(1)(a), F.A.C.

8. This Petition is filed less than 21 days from receipt of the Administrative Complaint.

WHEREFORE, Respondent requests that they first be granted the opportunity for negotiating a suitable disposition with Petitioner, and hereby requests that this matter not be forwarded to the Division of Administrative Hearings pending such negotiation. Respondent waives any time limits applicable.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing has been furnished by E-MAIL and U.S. Mail to Anthony Brian Coniglio, Assistant General Counsel, Department of Health, 4052 Bald Cypress way, Bin C-65, Tallahassee, FL 32399-3265 this 17 day of January, 2020.

Respectfully Submitted,

Edwin A. Bayó
Fla. Bar No. 327727
Paul P. Drake
Fla. Bar No. 115451
Grossman, Furlow, and Bayó, LLC
2022-2 Raymond Diehl Road
Tallahassee, FL 32308
Phone: (850)385-1314
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Email: e.bayo@gfblawfirm.com
Email: p.drake@gfblawfirm.com
Counsel for Respondent

Grossman, Furlow
& Bayó, LLC
ATTORNEYS AT LAW

October 30, 2019

2019 NOV -6 PM 3:42
LEGAL

Anthony Brian Coniglio, Asst. Gen. Counsel
Florida Department of Health
Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65
Tallahassee, FL 32399-3265

Re: Hybrid Pharma, LLC, Case No. 2017-23347

Dear Mr. Coniglio:

We are in receipt of the investigative file for the above captioned case. Please consider this letter as our response to same.

As you know, this case (and the companion case 2017-23346) were opened as a result of a sterile compounding pharmacy inspection on December 19, 2017. Our client's response to this inspection clearly shows that all alleged deficiencies were corrected.

After this case was opened, Hybrid Pharma was jointly inspected by the Florida Department of Health and the FDA between May 20, 2019 and June 20, 2019. As a result of this inspection, the Florida Department of Health issued a notice of investigative report to the facility on July 2, 2019, and the FDA issued a 483 form on June 24, 2019. Our client responded to the FDA483 on July 17, 2019. That response and attachments are contained on the enclosed CD.

In order to ensure compliance with all relevant statutes and rules, and to ensure that each deficiency in the 503b facility inspection report and FDA483 had been corrected, our client enlisted pharmacy consultant David S. Joseph, R. Ph., who performed a mock sterile compounding inspection and gap analysis for the pharmacy. Mr. Joseph's report regarding his findings are contained as **Exhibit 1** on the enclosed CD.

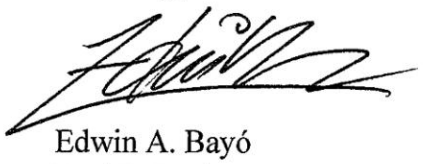
In Mr. Joseph's report, several documents are mentioned that would be available upon completion. They are enclosed and are as follows:

- Observation A: Upgraded Drug Recall Procedure SOP – **Exhibit 2**
- Observation A: Sterility Test Early Release SOP – **Exhibit 3**
- Observation E: Pictures of Cleanroom Wall and Floor – **Exhibit 4**
- Observation F: Laminar Flow Test Report – **Exhibit 5**
- Observation F: Leak Testing of HEPA filters – **Exhibit 6**
- Observation G: Laminar Flow Test Report – Exhibit 5
- Observation J: Media Fill Testing 2019 – **Exhibit 7**

- Observation K: Sterility Test Early Release SOP – Exhibit 3
- Observation K: HPLC Performance Qualification – **Exhibit 8**
- Observation P & Q: Gowning in Cleanroom and ISO Rooms SOP - **Exhibit 9**
- Observation P & Q: Garbing and Cleaning SOP – **Exhibit 10**
- Observation P & Q: Biannual Observation Audit – **Exhibit 11**

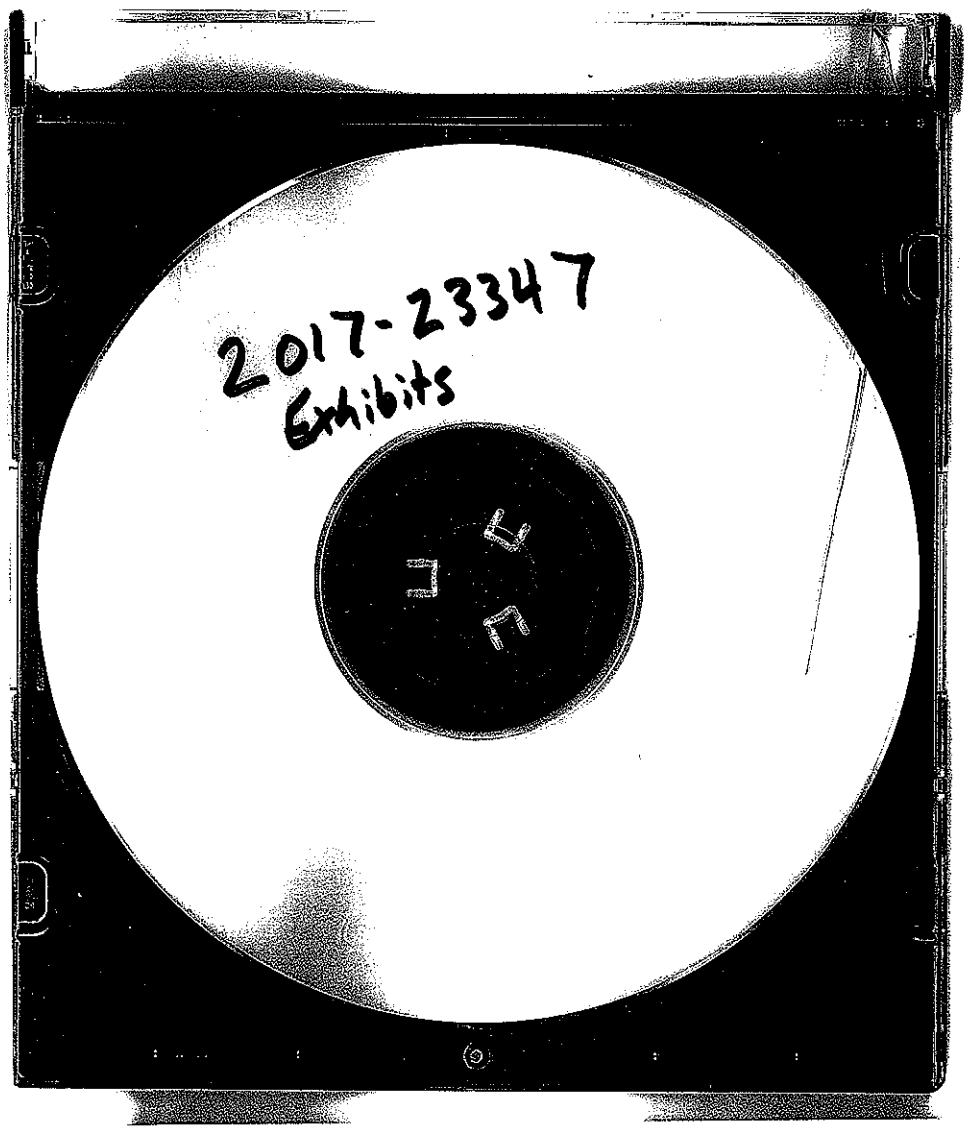
As can be seen from the response to the FDA483, as well as the mock inspection and our client's response to same, our client is operating in accordance with all relevant pharmacy compounding regulations. Please let me know if you or the panel have any questions.

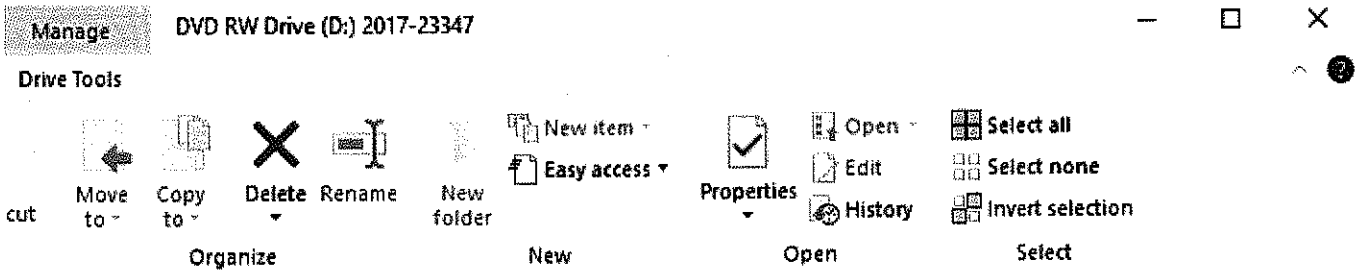
Sincerely,



Edwin A. Bayó
Paul P. Drake

cc: Hybrid Pharma, LLC


2017-23347
Exhibits



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Name	Date modified	Type	Size
Files Currently on the Disc (11)			
Exh 1 - Hybrid Pharma Gap Analysis 7-19...	8/22/2019 8:10 AM	Adobe Acrobat D...	263 KB
Exh 2 - Obsv A - Recall_SOP_revised	8/7/2019 8:43 AM	Adobe Acrobat D...	1,779 KB
Exh 3 - Obsv A and K - Sterility test_early ...	8/7/2019 8:43 AM	Adobe Acrobat D...	1,814 KB
Exh 4 - Obsv E -CLEANROOM_WALL_FLO...	8/12/2019 11:52 AM	Adobe Acrobat D...	1,167 KB
Exh 5 - Obsv F & G - Laminar Flow Test R...	8/16/2019 9:34 AM	Adobe Acrobat D...	333 KB
Exh 6 - Obsv F - HEPA Filter Leak Testing ...	8/21/2019 10:44 AM	Adobe Acrobat D...	273 KB
Exh 7 - Obsv J - Media Fill Testing 2019	8/12/2019 11:52 AM	Adobe Acrobat D...	2,770 KB
Exh 8 - Obsv K - PerkinElmer_200 HPLC_P...	8/12/2019 11:52 AM	Adobe Acrobat D...	5,040 KB
Exh 9 - Obsv P & Q - SOP Garbing and Cl...	8/12/2019 12:06 PM	Adobe Acrobat D...	9,172 KB
Exh 10 - Obsv P & Q - SOP Gowning in Cl...	8/12/2019 12:02 PM	Adobe Acrobat D...	2,005 KB
Exh 11 - Obvs P & Q - BIANNUAL_OBSER...	8/12/2019 11:52 AM	Adobe Acrobat D...	2,174 KB

DAVID S. JOSEPH, RPH

DAVID JOSEPH PHARMACY PRACTICE CONSULTING, LLC

Hybrid Pharma Mock inspection/Gap Analysis

This report is being submitted in response to a joint inspection of Hybrid Pharma by The Florida Department of Health and the FDA, which was conducted between May 20, 2019 and June 20, 2019. As a result of this inspection, the Florida Department of Health issued a notice of investigative report to the facility on July 2, 2019, and the FDA issued a 483 form on June 24, 2019.

The purpose of this report is to provide observations and resolutions based on the comments in the above-mentioned reports with the goal of full regulatory compliance.

This report with be divided into several sections:

1. General Comments
2. Observation/Resolution to the Florida Department of Health Items
3. Observation/Resolution to the FDA 483 items
4. Additional Observation/Resolution not mentioned in reports.

1.General Comments:

Hybrid Pharma, located at 1015 W. Newport Center Dr. Ste 106A, Deerfield Beach, Florida is licensed under several permits; 503B by the FDA, Special Sterile Compounding Permit by the Florida Department of Health, Community Pharmacy Permit by the Florida Department of Health, and a Wholesale Permit from the Florida Department of Health. The emphasis of this report will be focused on the Special Sterile Compounding Permit and the FDA 503B permit.

The facility is located in an office park complex. The general pharmacy area has become inadequate for the needs of the operation and management is considering a move to a larger space. The area is cramped and full of boxes and items for storage. The sterile compounding area, however, has been kept separate and is free of clutter that might cause contamination.

2. Observation/Resolution to the Florida Department of Health Items:

A. Department of Health Observation:

"Failure to allow completion of sterility tests before releasing product to the market.:"
"*Required 14-day USP Chapter <71> incubation for batch of high risk CSP's was not completed"
"*Dispensing records indicated lot was released to the public BEFORE assuring high risk CSP's were free from bacteria and fungi."

- Resolution:
    - This was an isolated incident involving one or two batches. USP<71> allows "early release" of compounded preparations under two (2) qualifiers, (1) the product being tested for sterility is being monitored daily for signs and turbidity and not released before 3 days, and (2) that the facility has a complete SOP for recall of CSP's in the case of a sterility failure after release.
    - Hybrid Pharma has met both of these criteria with data showing daily observations of the growth plates and an upgraded recall procedure (available upon request).

B. Department of Health Observation:

"Failure to appropriately confirm high risk CSP's are sterilized"
"*Some CSP's primary sterilization method is through steam sterilization,"
"The autoclave cycles have not been validated using biological indicators to ensure spores and microorganisms are eliminated from final product."
"Established time and temperature for each CSP that is autoclaved has not been proven."
"Condensation and water observed inside autoclave."

- Resolution:
    - Several CSP's prepared by hybrid pharmacy are first sterilized via filtration and then re-"sterilized" in the autoclave. This is an unnecessary step with no specific parameters for the processing of the end product. Recommendation: eliminate this duplicate step for those CSP's.
    - The balance of the CSP's which are terminally sterilized have data indicating that biological indicators are used in processing and that cycles are validated. Data available upon request.
    - Water is never present in the autoclave during processing. On occasion, water may be present during shut down of the unit.

C. Department of Health Observation:

"Failure to ensure non-sterile ingredients used in high risk CSP's are within expiry"
"*High risk batch assigned BUD (beyond use date) of 5/19/19 but THREE non-sterile active ingredients expired 7/21/18, 4/15/19 and 5/5/19."
"*Injectable high-risk batch assigned BUD of 6/30/2019, API expires 6/15/2019."
"*Injectable high-risk batch assigned BUD of 5/11/18, API expires 4/30/2019." (DOH error?)

- Resolution:
    - This situation was a result of inattention to detail when creating a compounding record. Hybrid Pharma creates "manual" compounding records which demands that Pharmacist's checking these records pay very close attention to all data entered. In these cases, the appropriately dated API was used, but the compounding sheet was not updated to reflect this.

- Recommendation: Better Pharmacist oversight of compounding records, and to purchase an electronic compounding data system such a PK which would eliminate this issue.

- Response from Hybrid Pharma: Hybrid Pharma is planning on purchasing RS software, as this is less expensive and they can store the data in their location, rather than controlled by PK in cloud.

D. Department of Health Observation"

"*Failure to document filter integrity test was performed for high risk CSP sterilized through membrane filtration."

- Resolution:
    - This is an "attention to detail" item that must be confirmed by Pharmacist oversight. Although the records I observed did show proper bubble point information, the management and PDM must assure that this date is being properly entered.

E. Department of Health Observation:

"Failure to maintain cleanable work surfaces in critical compounding areas"
"HEPA filters located in LAFW in CR1 has wet, brown discoloration."
"Gum like substance affixed on CR2 wall above door."
"Floors inside cleanrooms are not smooth, allowing microbes to harbor."
"Loose ceiling room tiles located in both cleanrooms (CR #1 and CR#2) allowing dirty, unclassified air into compounding rooms."

- Resolution:
    - The manufacturer of the LAFW in CR1 has validated that the brown substance is attached to the HEPA filter and in no way causing critical issues. (data available).
    - The "gum like" substance is a patch put on the wall by the vendor after drilling an incorrectly located hole. The vendor will correct this. (photo to be made available upon completion).
    - The owner has made arrangements to install a smooth, epoxy floor in all compounding areas. (photo to be made available upon completion).
    - All cleanroom ceiling tiles are now sealed.

F. Department of Health Observation:

"Failure to ensure certification of cleanrooms and hoods is conducted by a qualified entity; BOTH cleanrooms were certified despite testing HEPA filters for leaks."
"*PEC's were certified under STATIC conditions: NO simulation of compounding. Filling machines used to filter (sterilize) product into containers were not present and operational during certification (July 2018, January 2019)."

- Resolution:
    - Certificates in the pharmacy indicates leak testing of hoods occurred in ISO 5 and ISO 7 areas. Anteroom HEPA filters were not leak tested. Hybrid Pharma is rectifying this. Results available when completed.
    - PEC's were certified under DYNAMIC conditions. The pharmacist checking the report did not notice that it was incorrect. The vendor will correct the report. Pharmacists advised to be more diligent.

G. Department of Health Observation:

"Failure to prove compounding zones and hoods provide HEPA filtered air that is critical in the compounding process."
"*LAFW smoke studies performed outside of the hood."
"*Full length of compounding area not demonstrated to have sweeping laminar, unidirectional air to prevent backwash into "sterile" final container."
"*Membrane filtered (sterilized), partially stoppered CSP formulations that require transfer from PEC to lyophilizer travel through non-ISO 5 zone, putting sterilized solution at high risk for contamination.

- Resolution:
  - A new certifier will be contracted to perform the proper smoke studies regarding the LAFW. Results available upon completion.
  - Hybrid Pharma currently does not have a lyophilizer contained inside of the negative-pressure buffer room. This makes the transfer of sterile, partially stoppered product into the lyophilizer in ISO 5 conditions difficult to achieve.
  - The options for the operation to solve this situation are:
    - Discontinue these types of lyophilizer operations at this time.
    - Move the lyophilizer into the negative pressure room and create an ISO 5 unidirectional flow zone.
    - Ask the board for a variance to allow movement of product to lyophilizer in an ISO certified container. (Success not assured).

- Response from Hybrid Pharma:
  - Discontinuing is not an option currently, as we are selling few other products for the same customers as we may lose that orders also. Moving into the negative pressure room and re certifying the lyophilizer and the room is possible and will be a large task and the other possibility will be:
    - We did two times the Media fill test by stimulating the exact conditions and we did not observe any failure.
    - We are monitoring the non-viable particle before and after the transfer of the vials showing the particle count meets ISO 5 environment even though the partially stoppered vials not exposed to the open atmosphere.
    - We are monitoring viable particles by having settling plates in multiple locations and that meets more than ISO 5.
    - We made several batches of these products and found that no compromise in the sterility and endotoxin limit.

H. Department of Health Observation:

"Failure to ensure ISO classified compounding rooms are provided with HEPA filtered air critical in compounding process."
"Certification reports indicate SEC HEPA filters have not been leak tested during the last two certifications."

- Resolution:
  - See section "C".

I. Department of Health Observation:

"Failure to maintain required minimum negative pressure of -0.01w.c."
"CR #2 (hazardous drug cleanroom) does not retain required negative pressure."

- Resolution:
    - During the "mock" inspection, no pressure anomalies were observed, and PEC's and SEC's were operating normally. Hybrid Pharma will carefully document any pressure excursions in the future.

J. Department of Health Observation:

"Failure to qualify compounding personnel with appropriate media fill simulation mimicking most challenging or stressful condition."
"Media fill process for Lyophilization of HCG formulations completed by compounding personnel have not been completed."

- Resolution:
    - Hybrid Pharma staff now understand that "most challenging or stressful condition" refers to sterile operations involving multiple manipulations and high volume. Accordingly, they will perform media fill challenge operations biannually with that understanding. Results will be made available.

K. Department of Health Observation:

"Failure to support CSP extended BUD with stability indicating assays."
"*All high risk CSP's that are assigned BUD's from USP Chapter <797> are non-patient specific."
"*All high risk CSP's that are patient specific are assigned BUD 45 days frozen."
"*Patient specific CSP's include ingredients that are incompatible with storage conditions."
"*CSP's stored in freezer are in liquid state, unfrozen."
"*Stability testing is conducted on-site; equipment not validated for intended use. Appropriate stability studies not completed for any CSP to ensure unintended substances are not created between the container and "sterile" product inside."

- Resolution:
    - High risk CSP's BUD's when extended, have this evidence based on the expertise of the in-house chemist, Dr. Rajalingam. The HPLC equipment has been validated for this use and such documents are available upon request. Testing is done both for potency and degradation products, as per stability indicating assays. Again, this information is available upon request. All products intended for storage at "frozen" temperatures are monitored daily in a freezer with a NIST certified thermometer.

L. Department of Health Observation:

"Failure to ensure all high risk, patient specific, CSP's that are not tested for sterility maintain solid frozen state.
"*MDV's stored in freezer in liquid state"

- Resolution:
    - These are oil-based products which are stored at temperatures per USP guidelines.

M. Department of Health Observation:
"Failure to test for potency of all patient specific, high risk CSP's."

- Resolution:
    - Potency is measured on all batches in excess of 25 units.

N. Department of Health Observation:
"Failure to indicate entry or discard date for a punctured, high risk, in-house finished product."

- Resolution:
    - An auxiliary label will be added to all multi-dose vials indicating discard after 28 days of first puncture.

O. Department of Health Observation:
"Failure to indicate route of administration for spinal, high-risk CSP injections."

- Resolution:
    - Route of administration will be included on all injectables.

Department of Health Observation:
"Failure to provide compounding records for high risk CSP's."
"*Labeled high risk "mixture" no batch record, expiration, lot.
"*Vial of unidentified mixture no batch record, expiration, lot>"
"*Number of units produced unknown, two different vial sizes."
"*Multiple batch records with no expiration/lot number of alprostadil stock solution used in Trimix formula."
"*NO Pharmacist oversight; Pharmacist signature/initials missing from many batch records."

- Resolution:
    - Pharmacists have been instructed on the importance of proper documentation of all CSP batches and the importance of confirming all entries on the compounding record.

P. Department of Health Observation:
"Failure to remove foot covers from dedicated shoes stored within line of demarcation in unclassified space outside of ISO 8 prep room."

- Resolution:
    - This policy has been added to SOP and will be enforced by management.

Q. Department of Health Observation:
"Failure to clean under nails using fingernail tool."

- Resolution:
  - Disposable fingernail tools have been purchased and used. Process has been added to SOP.

R. Department of Health Observation:
"Failure to qualify compounding personnel using observational audits"
"*All sterile compounding operations are completed by one person"
"*Facility was unable to provide documentation compounding individual is proficient in necessary requirements to ensure:
-compounding environment is clean (cleaning and disinfecting assessments)
-aseptic process is done proficiently without introduction of microorganisms (aseptic technic)
-hand hygiene and garbing is done in a manner to prevent contamination of product from compounder (hand hygiene and garbing)"

- Resolution:
  - All observational audits had been completed at the time of inspection, but were not completely supplied to inspector. Hybrid Pharma will reorganize document files to make this information more readily available and continue biannual observational audits. Audits available upon request.

1. Observation/Resolution Related to FDA 483 Items:

A. FDA 483 Observation 1

1. "Media fills conducted between 9/23/16 and 3/15/19 were not performed that closely simulated aseptic production operations incorporating, as appropriate, worst case activities and conditions that provide a challenge to aseptic operations."

- Resolution: as per above mentioned Florida Department of Health Item A:
  - This was an isolated incident involving one or two batches. USP<71> allows "early release" of compounded preparations under two (2) qualifiers, (1) the product being tested for sterility is being monitored daily for signs and turbidity and not released before 3 days, and (2) that the facility has a complete SOP for recall of CSP's in the case of a sterility failure after release.
  - Hybrid Pharma has met both of these criteria with data showing daily observations of the growth plates and an upgraded recall procedure (available upon request).

2. "Each batch of drug product required to be free of objectionable microorganisms is not tested through appropriate laboratory testing. You have no assurance that the endotoxin level of your intrathecal products are safe since you do not have any endotoxin data, and your firm does not perform endotoxin testing of finished product. These drug products are made using nonsterile starting material."

- Resolution:
    - Hybrid Pharma does appropriate endotoxin testing on all batches of medication. The exception was low volume production of certain intrathecal medications. USP <71> does not require endotoxin testing for small batches. Hybrid Pharma no longer compounds intrathecal medications but will test for endotoxins if production resumes.

3. "HEPA filter first-air was intermittently blocked by the aseptic techniques of the sterile technician during the during the filtration of Procaine 20mg/ml., lot 190524A as observed on 5/24/2019. The technician's forearm passed over the filled vials as they were filled from front to back."

- Resolution:
    - A longer needle has been purchased (5") for vial filling in order to avoid the need for the technician to "overreach" into the ISO 5 air zone.

4. "The technician's hand washing, and gowning procedures observed during the production of Procaine 20mg/ml lot 190524A were deficient in that:

    - Hand washing techniques do not include the use of a nailbrush to effectively remove debris underneath the nail bed."

- Resolution:
    - As per above mentioned Florida Department of Health Item Q:

Disposable fingernail tools have been purchased and used. Process has been added to SOP.

5. "Portions of the technician's sterile coveralls touched the flooring within the ISO 8 preparation room while donning"

- Resolution:
    - SOP upgraded to address this issue. Additionally, gowning will now occur on the ISO 7 "gowning" area.

6. "Nonsterile goggles are worn"

- Resolution:
    - Sterile goggles to be purchased.

B. FDA Observation 2

"Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the to produce aseptic conditions:"
"Specifically,

a. "On 5/20/19 a brown discoloration was observed on the HEPA filter inside the ISO 5 hood located in the ISO 7 Buffer Room #1. The same discoloration was also observed

on an inoperable HEPA filter within this buffer room, located to the left of the ISO 5 hood. This filter has been inoperable for an unknown length of time."

- Resolution:
  - As per Florida Department of Health Observation E:

The manufacturer of the LAFW in CR1 has validated that the brown substance is attached to the HEPA filter and in no way causing critical issues. (data available).

b. "On 5/20/19, a brown discoloration was observed on the interior wall above the doorway within the ISO 7 Buffer Room #2. This buffer room support the aseptic filling of hazardous compounds within the ISO 5 BSC hood.

- Resolution:
  - As per Florida Department of Health Observation E:

The "gum like" substance is a patch put on the wall by the vendor after drilling an incorrectly located hole. The vendor will correct this. (photo to be made available upon completion).

c. "The efficacy studies performed on 11/1/2018 and 2/4/2019 to demonstrate that Cidehol disinfectant and the Peridox RTU sporicidal solution used to disinfect work surfaces, floors, walls and ceilings within your cleanrooms was performed using unidentified locations outside of the cleanroom. The study is not well- defined and does not represent actual use."

- Resolution:
  - Hybrid Pharma will return to testing cleaner efficacies in the "real" conditions in the actual work surfaces. Data to be made available upon request.

C. FDA Observation 3

"Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.
Specifically,"

1. "Smoke studies are not properly conducted under dynamic conditions to assure uniform and unilateral HEPA air controls within ISO 5 hoods and during the transfer of partially stoppered vials from an ISO 5 zone to the lyophilizer."

- Resolution:
  - See response to Florida Department of Health Observation G:

2. "Non-viable monitoring within ISO 7 buffer rooms is not continuously performed during routine production. A one-minute sample is collected prior to vial filling."

- Resolution:
    - A continuous particle counter for the ISO 7 buffer room has been purchased and is in use.

D. FDA Observation 4

"Aseptic processing areas are deficient in that floors and ceilings are not smooth and/or hard surfaces that are easily cleanable."
Specifically,

1. "The flooring within the ISO 7 Buffer Room #2 to include underneath the ISO 5 BSC hood contained within this room is constructed of a vinyl tile-like surface with embedded grooves which are not easily cleanable."

- Resolution:
    - As per Florida Department of Health Observation E:

The owner has made arrangements to install a smooth, epoxy floor in all compounding areas. (photo to be made available upon completion).

2. "There were several loose ceiling tiles observed above the ISO 7 Buffer Room 1 and 2.

- Resolution:
    - As per Florida Department of Health Observation E:

All cleanroom ceiling tiles are now sealed.

E. FDA Observation 5

"Aseptic processing areas are deficient regarding air supply that is filtered through high-efficiency particulate air filters under positive pressure.
Specifically:"

1. "HEPA filter leak testing within the ISO 8 preparation room was not completed"
2. "HEPA filter leak testing within the ISO 7 buffer rooms were not completed."

- Resolution:
    - As per Florida Department of Health Observation F:

Certificates in the pharmacy indicates leak testing of hoods occurred in ISO 5 and ISO 7 areas. Anteroom HEPA filters were not leak tested. Hybrid Pharma is rectifying this. Results available when completed.

F. FDA Observation 6

"There are no written procedures for production and process controls designed to assure that the drug products have the identity, quality, and purity they purport or are represented to possess."
Specifically,

1. "The lyophilization parameters used to terminally sterilize your HCG drug products have not been validated to ensure such parameters are adequate."

- Resolution:
  - Validation of lyophilizer cycle is in process. Results available when complete.

2. "Autoclave steam sterilization cycle parameters used to terminally sterilize the following drug products have not been validated:
   - Pyridoxine Hydrochloride 100mg/ml -121C/15minutes
   - Calcium Gluconate 10% Inj -105C/15minutes
   - Cyanocobalamin 100mcg/ml-121C/15minutes"

- Resolution:
  - These three CSP's are actually sterilized via filtration. The Autoclave portion is used as a second assurance of quality. There are no known validations for this process. Hybrid Pharma should discontinue this process.

G. FDA Observation 7

"Laboratory records do not include complete data derived from all tests, examinations and assay necessary to assure compliance with established specifications and standards.
Specifically,"

1. "The procedures utilized in validating the HPLC, UV Spectrometry, and Titrimetric methods used for potency analysis of finished drug products are not properly designed such that all data generated can be properly assessed to establish that such methods consistently meet standards of accuracy and reliability."

- Resolution:
  - Hybrid Pharma will develop SOP's based on USP standards, for validating testing equipment. Data will be logged and maintained in a central repository. SOP's will be made available.

2. "Routine finished product release testing records do not include a compete record of all data obtained during the analysis to include (but not limited to):'
   a. "System suitability determinations
   b. Standards and sample preparations
   c. All calculations performed during the analysis."

- Resolution:
    - This information is largely available, but not readily accessible by inspectors or by the Hybrid personnel in general. Management is committed to create a central data Repository for easier access to critical data.

H. FDA Observation 8

1. "There is no formal written stability program to assess all stability characteristics of finished drug product."

- Resolution:
    - Hybrid Pharma has used reliable scientific literature as a template to determine drug stability, the operation will create an SOP specific to the existing operation.

2. "Stability studies performed to establish a six-month beyond use date for your finished products are based on trial batches and not on actual finished product lots."

- Resolution:
    - Lots for initial testing are made under the same circumstances, materials, environment and personnel that are used in production. There is no expectation of variance in BUD results.

I. FDA Observation 9

"The responsibilities and procedures applicable to the quality control unit are not in writing and fully followed.

- Resolution:
    - This document has been completed and is available upon request.

J. FDA Observation 10

"Employees engaged in the manufacture, processing, packing and holding of a drug product lack the training required to perform their assigned functions."
"Specifically,
1. There are no records documenting the training provided to the staff pharmacist in her areas of responsibility."

- Resolution:
    - Although there are training documents covering general pharmacy processes, the pharmacist overseeing the sterile compounding area has no documented training. A didactic course such as "critical point" should be adopted for all staff participating in sterile compounding. This should be renewed and documented annually. This should be documented on an SOP and kept with the personnel records.

2. "Training records are not maintained covering all responsibilities and duties assigned to technicians in the production, processing, and packaging of drug products."

- Resolution:
  - An SOP and Documentation records are being put in place to train and monitor sterile compounding staff. Documents will be available on request.

3. "Visual inspection training procedures and records are not documented for technician performing visual inspections of finished product to detect defects or product contamination."

- Resolution:
  - SOP for training has been created. Results of visual inspection are documented on the compounding sheet. SOP available upon request.

4. "There is no established frequency or documentation of GMP training provided to employees."

- Resolution:
  - A template has been created for GMP employee training. Initial training will be given and documented, along with training needed for specific compounding functions. This training will be tested and retraining If needed on a scheduled basis.

K. FDA Observation 11

"The labels of your outsourcing facility's drug products are deficient.
"Specifically,
The labels of your outsourcing facility's drug products do not include information required by section 503B(a)(10)(A). Specifically, the following information is not found on your drug products labels:

The statement "This is a compounded drug""

- Resolution:
  - This has been corrected and the statement now appears on all 503B compounded drugs.

5. **Additional Comments/Resolutions**

1. Document Organization: It is recommended that a central area be established where documents relative to sterile compounding can be organized. In some cases, the operation received unfavorable comments because, although process was followed, document could not be readily retrieved.
2. Processing software: a software that has been designed for compounding would be a great asset to the operation. Many manually loaded items (some missed) could be automated into such a system. Compounding records could then be retained

electronically. Errors could be reduced since such systems do not allow the entry of items that are past expiration date, for example.

3. Monitoring software: There are several versions of programs that notify the staff as to when specific tasks need to be executed. For example, environmental monitoring, staff training, etc. This would be another step in organizing data.
4. Anteroom door to non-classified area: This door is wood and paint, both items that are particle generator. It is recommended that the door be replaced with one made of steel and glass.

SOP 1.072 a: Evaluation of the complaints about commercial and compounded drug products:

If there is any complaint from a patient or doctor's clinic or hospital follow the immediate actions.

1. Identify the products in question commercial or compounded product with lot number.
2. Isolate the problem if it is particular to one lot number or one particular type of drug. Isolate the problem pertaining to a single patient or multiple patients.
3. If it is a commercially available and distributed report to the wholesale supplier and ask them to investigate further in their supply chain.

   Request the doctor's office look for any drug interaction, side effect or any other cause may be. If it is a multiple case issue recall the entire drug with lot number immediately. If it is an isolated case ask the doctor/hospitals follow through the patient.
4. Write an incident report CAPA folder.
5. If it is a compounded product for patient specific:

   Call all the doctor's office, patients and hospitals not to use the product if they have received the particular drug /lot number until the investigation.

   Check the lot number(s) of the product do the in-house investigation such as

- the lot number matches the product in question and its beyond-use date.
- check the compounding record for the raw materials and their lot numbers, suppliers, quantities of different ingredients used, mode of compounding, filter integrity values, depyrogenated vials, stoppers, caps or any other possible errors in the processing and handling of the drug for the possible contamination.
- check for any particulates formation, pH and/or any visible color changes.
- if there is any deficiency was found, recall all the products in the entire lots

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- both in the released batch and in the accelerated early release batch [if there is any] and proceed the internal investigations such as raw materials and their COA, weighing and mixing of the ingredients.
    - Do all the internal investigations and document properly in the CAPA folder. Update the CAPA folder with possible precautions you are going take in the future such a mistake will not happen again.
- -if there is no error related to Hybrid's product quality, request the doctor to investigate the patient's chart further for possible drug interaction or any other side effect.

7. If the compounded product is for office use.

a. If we receive a compliant from a patient or more than one patient, doctors office, or hospital, check the name of the drug, lot number/batch number immediately call all the customers who received these medications not to use the particular drug till the investigations are complete. Get the report from the other customers also if there is any issue/problem/complaint pertaining to the particular drug and lot number.

b. Analysis: Critically analyze the following information. Investigate the formula sheets for the name, quantity of all the ingredients used and the accurate calculations.

- Check the COA of all the ingredients used for their purity and beyond use date.
- Check the compounding procedure including the clean room environmental monitoring on that compounding day.
- Check for the potency data, sterility, endotoxin, pH, filter integrity and their range.
- Check for all the visual inspections data such as, particulates, cloudiness, and closure integrity.
- Check for potency, sterility, endotoxin and pH from the retention samples for their consistency.
- If any out of specifications products were found, report to the FDA and start the process of recall as per the recall procure in the recall SOP.

- If there is a recall initiated by any of the raw materials suppliers or any of the components [sterile filter, sterile transfer tube, sterile syringes, needles] used in the manufacturing and testing processes, then recall the entire lot of the products where such a components are used including the items in shelf, in QC Hold, Quarantine, Accelerated Early release, retention samples.
- Call immediately all the customers who received this product with the lot number not to use the product anymore until the investigation is complete.

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SOP 1.064_Rev2: Recall Procedure

Purpose: The purpose of this SOP is to provide an efficient method to handle and document recalls that involve commercial products, compounding ingredients and /or compounded preparations that do not meet their labeled claim.

Hybrid Pharma maintain a SOP for Drug Recall so that any drug that is recalled by a manufacturer or FDA will be removed from the Hybrid Pharma. This SOP also defines the process and responsibilities for the initiation, implementation, and administration of a Hybrid initiated product recall.

Supplier or FDA initiated recalls must be promptly communicated to the Hybrid Purchasing department along with the quality control department.

If the product is not stocked in Hybrid, the notice will be disregarded. After notification from manufacturer or FDA of a stocked item, the Purchasing department or designee will thoroughly search the Pharmacy to recover the specific lot number of drug involved and/or determine if the product has been used within the pharmacy.

If the specific drug/product identified in the recall is found on the premises, it must be logged into the Recalled Drug Inspection Record.

The letter or notice of recall from the manufacturer or supplier will be kept on file by the Purchase department or designee, along with the Recalled Drug Inspection Record documenting action taken for the items recalled. If the drug/device is located at Hybrid, all units will be quarantined until such time they are returned to the manufacturer or are destroyed as advised in the recall.

Responsibility: It is the responsibility of the pharmacist-in charge and the quality control officer to oversee this SOP

Compounded Products

Recalls to sterile or non-sterile products may be based on evidence obtained by ongoing quality control testing or complaints from physicians or patients.

A determination will be made if the reported problem is isolated, pertaining to one sample or affects an entire batch. Isolated problems can be defined as a unique situation whereby a drug, for example has been exposed to improper storage, shipping or handling conditions. Contamination after leaving the pharmacy would be another example of an isolated incident.

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The type of recall depends on the nature of the product, urgency of the situation, the depth the product has been distributed.

Only the specific lot numbers are usually recalled should be pulled from dispensing stock. If any batch has been found to require a recall, regardless of origin, immediate steps will be taken to insure any remaining (unsold) affected batches/lot numbers are quarantined and are unavailable for sale.

If no product is found in the shelf, such notice should also be in the noted in the record. Include the quantity of the products released in the accelerated early release if any.

A report will be generated using Abacus Pharmacy Software which shall identify all persons receiving an affected lot number(s). The procedure to obtain referenced report follows:

From the Main Abacus screen chose Reports from top menu. Then choose in sequence, Report Menu > Prescription Report > Print > enter from/to date filled > enter Lot Number in "only RX with Lot Number" field >OK

This procedure will print a report of all persons receiving affected Lot number(s). This is the most accurate, time sensitive report/record available. Prescription numbers hand written on batch sheets may suffer from transcription and other errors.

- All persons receiving affected Lots will be contacted ASAP and informed to discontinue use immediately. Arrangements will be made to return affected products to the Pharmacy for destruction / quarantine. Patients will be informed to contact their prescriber to advise them of the recall.
- Hybrid Pharma will contact all prescribers and inform them of the recall. A pharmacist shall be available for consultation with the physician if requested. A fill incident report will be written and filed in the appropriate binder.

Returned shipping or destruction documentation is kept on file along with the Recalled Drug Inspection Record.

If a **controlled substance** is involved, the drug will be destroyed as advised by the Drug Enforcement Administration with proper documentation and confirming signatures or witnesses. If a specific recalled drug lot number has been used to prepare CSPs, an Investigation/Corrective Action Report will be completed for product impact assessment Customers confirmed to have received the drug/device will, as applicable, be notified via phone and/or mail.

Approved By Quality Control Manager June 22, 2019

Upon investigation, Hybrid will obtain a complete list of all affected catalog/prescription numbers (if appropriate), lot numbers and the original release/dispensed quantity. Packing lists will be pulled to determine shipments of affected lots. A mailing list of customers will be prepared from the packing list documentation. Mailing labels will be created for each customer that will be contacted with a recall letter or advisory notice.

If Hybrid has internally identified the need for a recall after reviewing internal complaint reports and/or internal investigations, Hybrid will make appropriate notifications to the U.S. Food and Drug Administration. If deemed appropriate, a recall Letter or advisory notice will be prepared and signed by the Regional Director of Operations including the statement "URGENT – COMPOUNDED STERILE PREPARATION RECALL" prominently displayed in the document header. Customer specific recall letters will be prepared as appropriate. A Recall Information form will be prepared to accompany the letter containing the following information:

List of affected catalog numbers/drug;

- List of affected lot numbers including the items in shelf, in QC Hold, Quarantine, Accelerated Early release

Preparation description;

Preparation disposition information;

Return information or destruction information as necessary;

Customer signature/title/date;

Inventory of the affected lots;

Return addressed envelope for the Recall Information form.

The outer envelope will be stamped with a statement such as "URGENT – COMPOUNDED STERILE PREPARATION RECALL." Return of the Recall Information forms will be monitored and a follow-up letter with another Recall Information form will be sent to all non-respondents. Recalled products which are returned to Hybrid will be quarantined until disposition is determined. Copies of all information regarding the recall are maintained in a recall file. The recall will be closed after preparation disposition, tracking and documentation has been completed according to Hybrid recall procedures. Inquiries will follow Hybrid investigation procedures. This includes any patient specific or facility specific inquiries.

All corrective & preventive actions and deficiencies shall be documented in the recall report.

- CQI report will be written along with ways to insure the problem is identified and corrected.

- Changes to SOP will be made if necessary to reflect any changes in procedures required to assure all products meet or exceed quality standards.

Sterility test (Membrane Filtration Method) in finished sterile drug preparations

1.0 OBJECTIVE

The Objective of this SOP is to test for sterility of the Sterile drug products by Membrane filtration method and document the results.

2.0 SCOPE

This protocol is applicable for Sterility test of the finished pharmaceutical products. The sterility test will be conducted in accordance with the methods outlined in the current USP <71> [Harmonized Pharmacopeia Method/ 21 CFR 610.12.]

3.0 RESPONSIBILITIES

	Responsibilities	Name of the Department
1	Validation Protocol, Approval & Report	Quality Control

4.0 PRE-REQUISITES

1. Method Suitability Test or Bacteriostatic and Fungistatic Test

In order to efficiently conduct the sterility suitability test by Membrane Filtration method, ensure that the following requirements are fulfilled.

a. Validated Aseptic facility, an independent testing Facility to carry out the Sterility test validation
b. Follow the proper GMP procedure and share the procedure to develop proper method(s) to do the sterility test.
c. Method suitability follows the validated GMP protocol and Sterility test follows USP <71> protocol.
d. After the method suitability is done, perform the sterility test for the different batches of the same product as per USP <71>.

5. STERILITY TESTING.

a. Follow the strict protocols described in USP <71> and method suitability tests.
b. All Equipment to be used for Sterility test are qualified and operational SOP's established and followed.
c. All the equipment and culture media required for the sterility test should be sterile.

d. Trained personnel for conducting Sterility test

6.0 IDENTIFICATION OF CRITICAL CONTROL / MONITORING PARAMETER

Before proceeding for sterility test, following parameters are checked

a. Each lot of sterility test medium must be tested for its growth promoting qualities as provided by manufacturer.

b. During validation carry out environmental monitoring by settle plate (Plate Exposure) and Personnel monitoring by gloved finger dab.

7. TEST FOR ANTIMICROBIAL ACTIVITY /STERILITY TEST

Objectives: The test is performed to ensure that, the absence of Antimicrobial Activity in the finished sterile products under the experimental conditions.

Sample Procedure: For a batch of 200 vials of 10mL; 10 vials for testing

Step No	Product Control
1.	Rinse the membrane with approx. 10 ml of sterile fluid D before starting the filtration under vacuum.
2.	Select 10 vials randomly and pour half the contents into a filter holder & start the filtration
3.	Rinse the membrane three times with fluid D
4.	Aseptically transfer the filter paper using sterile S.S. tweezer to sterile FTM
5.	Repeat step 1-3 using another sterile filter and aseptically transfer the filter paper using sterile S.S. tweezer to sterile TSB/SCDM
6.	Incubate the TSB/SCDM glass containers at 20- 25°C and FTM glass bottles at 30-35°C for 14 days
7.	After incubation observe the samples for growth and document the observation.
8.	After 14 days incubation and Document the observation in Forms 122A & 122B
9.	In case of accelerated early release of the compounded batch, follow it up on the day of release and everyday onwards till 14th day. Early release only after 7 days of incubation. Record the number of units dispensed before the 14 days in the Master batch record.
10.	Document the observations of the Negative control also.

Acceptance Criteria:

a. After incubation, observe all the negative control of each medium i.e. FTM and SCDM for absence of growth.

b. Observation: - Observe the samples for any evidence of microbial growth by means of turbidity. If evidence of microbial growth is observed in terms of turbidity or cloudy, the test article does not pass the sterility test unless it can be clearly demonstrated that the test is invalid for causes unrelated to the test article.

If no evidence of microbial growth is observed and the sample is clear for the incubation period of 14 days, the test article passes sterility test. **Page 3 114. Rev.3**

If a test article renders the media turbid so the presence or absence of microbial growth cannot be readily determined by visual examination, a portion (not less than 1mL) of the media will be transferred to a fresh container of the media on Day 14. The transfer solution will be incubated for not less than 4 days.

8.0 Reporting:

The final report will include but will not be limited to: the dates of test initiation and completion and the final test results.

9.0 PRECAUTION:

a. Personnel conducting sterility testing or associated aseptic manipulations should wear sterilized garments. Following the completion of the test, the personnel will gently press their gloved fingertips onto the surface of the TSA w L/PS plate. The glove plates will be aerobically incubated at 30^0C to 35^0C for 48-72 hours.

The BSC/LAFH will be wiped with an approved disinfectant immediately prior to testing.

b. All equipment, vessels and materials, which are used for sterility test, should be sterilized by autoclaving or by dry heat sterilization.

10. Independent Testing Lab-validation work

a. Validation tasks are to be carried out by trained personnel using techniques and equipment, which minimize the risk of accidental microbial contamination of the test and of the testing environment.

b. Validation tests should be conducted in sterile environment and positive control tests in Microbiological testing room under LAFH

11. Test Article Identification:

All the necessary documentation for the identification of the test article are documented in Form 122A, 122B, 122C and the dates are marked in the samples. The minimum number of articles to be used in relation to the number of articles in the batch and the minimum quantity to be used for each medium by USP 71 guidelines. Out of this 50% of the samples are reserved as retention sample, which will be used for any repeating of tests or other testing needed.

12. **Compliance:**

This study will be performed in accordance with applicable Good laboratory practices and follow USP 71 sterility test protocol.

R.M

13. **Testing Environment:**

All sterility tests will be performed in ISO 5 hood.

Personnel will be gowned as suitable for the testing environment. Sterile gloves, mask, goggles and sleeves are required in the ISO 5 hood. Sterile coverall suit, mask and goggles are required in ISO 7 suite.

Settling plates will be placed in the hood during testing to confirm ISO 5 conditions were in effect during testing. Tryptic Soy Agar or Malt Extract Agar or equivalent settling plates will be opened during testing. When testing is complete TSA will be incubated for 48 – 72 hours, and MEA will be incubated 5 – 7 days.

Contact plates will sample surface of hood after testing, to confirm the surface of the Hood is sterile. TSA+ contact plates will be used to neutralize any residual disinfectant. TSA+ will be incubated for 48 – 72 hours.

Contact plates will also sample microbiology technician fingertips after testing, to ensure technician maintained aseptic technique. TSA+ plates will be incubated for 48 – 72 hours.

In case of a failing sample, the environmental monitoring results will be helpful in determining whether there was laboratory error.

HYBRID PHARMA

Indicate X if cloudy or turbid and record Fail. When it is clear with no cloudiness or turbidity record Pass If it is not monitored these days [holidays or missed] they shall be followed ASAP.

Sterility Test Inspection Log TSB 20-25^0 C [68-77F] **Incubator 5** **Form 122A_ Rev.1**

Broth Lot# Broth Expiry Date	U71TSB USP 100mL	Days of Inspection				Results		
		1	3	7	14	Pass	Fail	
Sample Lot #								Start Date
Negative Control								Finish Date

Sterility Test Inspection Log FTM 30 - 35^0 C **Incubator 2** **Form 122B_Rev.1**

Broth Lot# Broth Expiry Date	Hardy U41 FTM USP 100mL	Days of Inspection				Results		
		1	3	7	14	Pass	Fail	
Sample Lot #								Start Date
Negative Control								Finish Date

*For accelerated early release of the batch, follow the product sample and the Negative control on Day 7 or the release date after incubation and then daily till Day 14. Do not release the batch without 7 days incubation.

Hybrid Pharma SOP

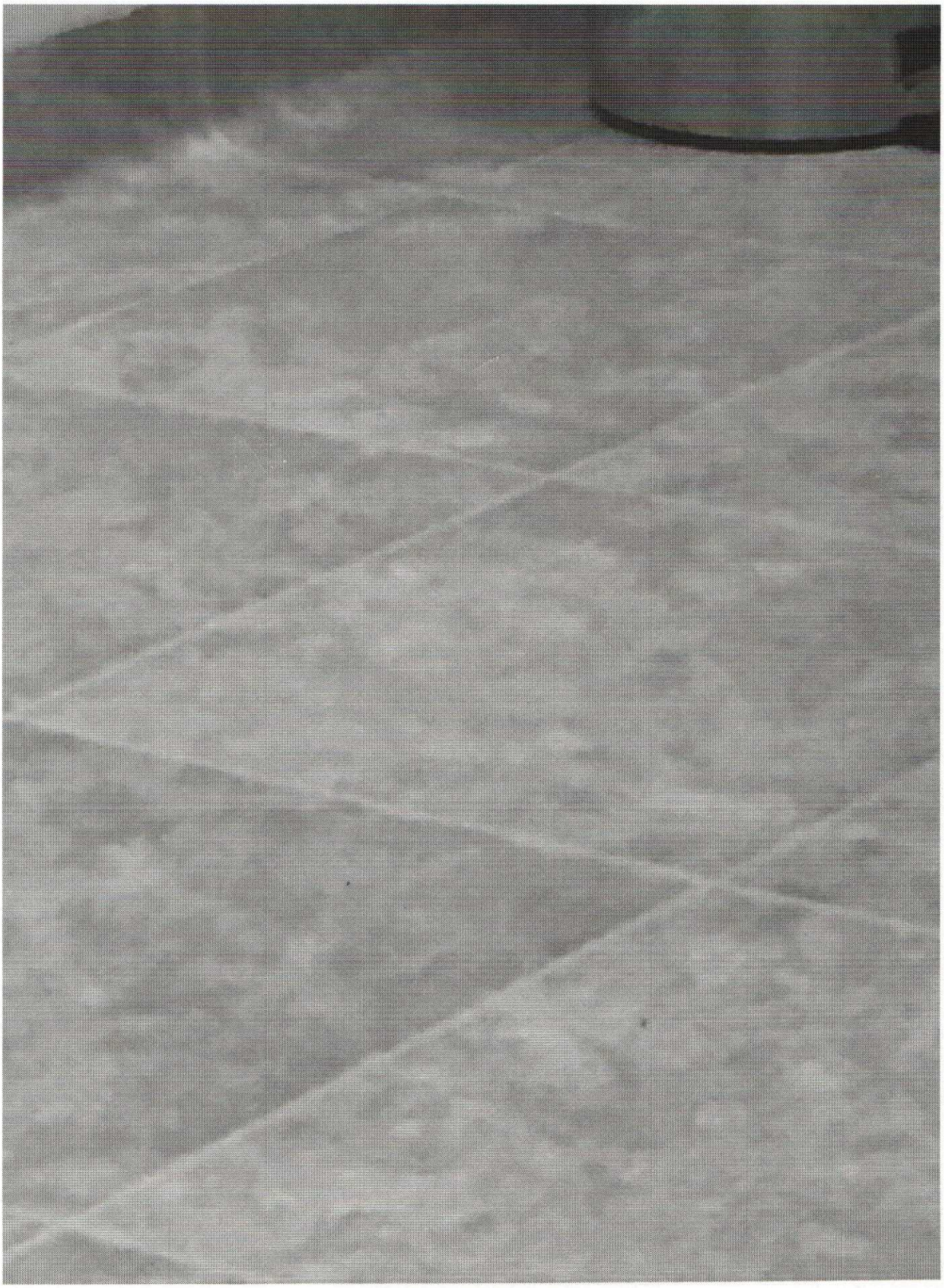
123b-Rev1. Title: Investigation when Microbial Growth Indicated in Finished Products

Evaluate the Risk Investigation:

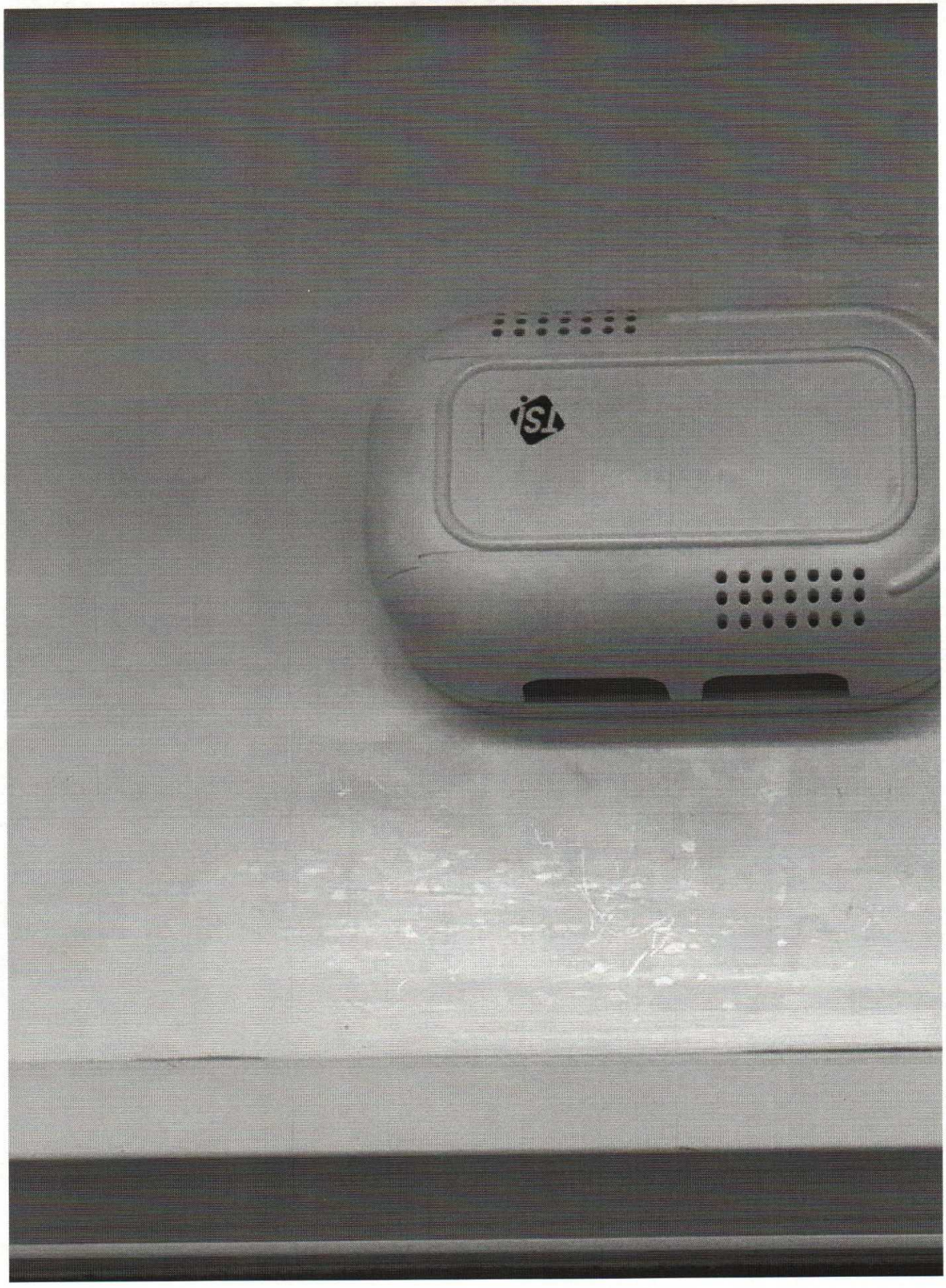
1. Bring all the documentation of all the records indicating contamination of the particular batch and gather all the lots that manufactured before and after that contaminated batch.
2. Review all associated activity and equipment/tools used in the contaminated lot as mixing vessel, tubing, raw materials, sterilizer, filters, stir bars, vials that might have been cross contaminated and transferring microbes to subsequent lots of products.
3. Review the established validation studies for product sterilization and the components sterilization and look for any equipment/tool has been modified; whether there is any change in Personnel or training or procedure; any new source material for equipment as filters, gaskets, filter manufacturer etc.
4. Review any changes in the Environment, any construction elsewhere in the facilities, any room modifications or any process changes.
5. Review Environmental Monitoring procedures and results for manufacturing and laboratory area.
6. Determine potential source -Staphylococcus [skin, insect etc], Pseudomonas [water, plants, etc] yeast and mold[spores-environmental]
7. The Investigation Report will include
   1. the possible source of contamination,
   2. Corrective Action,
   3. repeat testing and release
   4. does it include related lots
   5. was the product rejected or released?
   6. If the batch was released, evaluate justification.
   7. Pull out the dispensing records of the batch if it has any accelerated early release before the 14 days incubation time
   8. Initiate the Recall procedure for the particular batch product.

Revision date: 6/8/19

APPROVED BY: R. Uma 6/8/'19



Attachment 2



Attachment 1

dba ENV Services Testing & Certification, Inc.

Test Report Number
FL0101:190809:121248

LAMINAR FLOW TEST REPORT

Customer	Hybrid Pharma	**ENV Services Technician**	Bob Hoffman
Address	1015 West Newport CTR DR #106A Deerfield Beach, FL 33442	**Test Date**	08/09/2019
		Test Frequency	Certification - S/A
		Equipment Manufacturer	Purair
		Model	VLF-48
		Serial Number	VLF 74051
Contact	Raja	**Type**	Clean Bench
Telephone	954/708-2771	**Location**	Buffer Room
Extension			

Testing and Certification: The purpose of field testing this equipment is to assess whether it is functioning as designed in compliance with manufacturer specifications IES-RP-CC-002 Current Version, or other specifications which may apply. We perform all test procedures in accordance with these standards and specifications as detailed in ENV Services Protocols, applicable copies of which are available upon request. Our testing and certification applies only to the equipment identified above, and does not signify approval of the use of any hazardous agents or operational procedures.

SERVICE SUMMARY

	PASS	FAIL	N/A
OVERALL CERTIFICATION	☒	☐	☐
Per IES-RP-CC-002 velocity specifications			

Containment tests performed:

HEPA Filter Leak Test	☒	☐	☐
Airflow Smoke Patterns	☒	☐	☐
Airflow Velocity Test	☒	☐	☐

Work environment tests performed:
Corrected noise level meets RP-2 criteria
Light intensity meets RP-2 criteria
Electrical results: 116 VAC Polarity was correct
0.100 ohms

Repairs performed:

- ☒ **None**
- ☐ **Filter Leaks Repaired**
- ☐ **Structural Repairs Made**
- ☐ **Filters Replaced**
- ☐ **Airflow Adjusted**
- ☐ **Pressure Gauge Adusted**
- ☐ **Electrical System Repaired**
- ☐ **Other:** _____

COMMENTS AND RECOMMENDATIONS

PREFILTERS AND MISCELLANEOUS

Prefilters Quantity & Size	(2)19x22x1	**Condition of Unit Plenum**	like new
Type of Prefilters	spun glass	**Condition of Electrical and Mechanical Components**	like new
Condition of Prefilters	new		

Service Technician: Robert Hoffman _____ Date: _____
Signature

Digitally signed by Robert Hoffman
DN: cn=Robert Hoffman, o=ENV Services, ou=Field Supervisor, email=bob.hoffman@envservices.com, c=US
Date: 2019.08.09 22:52:01 -04'00'

ENV SERVICES
(800) 292-5255

LAMINAR FLOW TEST REPORT

Test Report Number
FL0101:190809:121248
For: Hybrid Pharma
Model: VLF-48
S/N: VLF 74051

HEPA FILTER LEAK TEST

Supply Filter Quantity/Size: (1) HEPA
Leaks Detected Media: 0 Gasket: 0 Structural: 0
Leakage Repaired with N/A
Approximate Filter Obstruction Caused by Repairs 0 %
Aerosol Challenge Concentration: 11ug/l PAO
Filter Scanning Rate: 2 inches per second

L R

O = leakage
X = repair

Cal Chal:

LEAK MAP

Overall Test Result: PASS

AIRFLOW SMOKE PATTERNS

No Induction at Air Exit Opening: PASS
Uniform Air Flow Pattern: PASS
No Refluxing or Backstreaming: PASS
No Intrusion via Construction Seams into Enclosure: PASS
No External Turbulence at Front Access Opening: PASS
Cause of external turbulence, if any

Overall Test Result: PASS

SECONDARY TESTS AND TEST EQUIPMENT

	Test Results	Criteria	
NOISE	Total 67dbA Ambient 55dbA Corrected	67dbA <= 67 dbA Corrected	Meets
LIGHTING	Average 138 FC Minimum 129 FC	Avg. >= 75 FC, minimum >= 70% of Avg.	
ELECTRICAL	Line Voltage 116 VAC	N/A	N/A
	Ground Resistance 0.100 ohms	N/A	N/A
	Polarity PASS	Must be correct	Meets
	Ground Fault Interrupter N/A	Trips when tested	N/A

Velometer Model: TSI/9535 Asset: ID 996 Cal. Date: 07/10/2020 Photometer: PH-5 Asset: ID Cal. Date: 04/16/2020

AIRFLOW VELOCITY TEST

Avg. Vel.	Specification	Uniformity	Area	Volume
84 fpm	80 - 100 fpm	5%	7.42 ft^2	623 cfm

Pressure/Flow Gauge Reading 0.50 Gauge Zeroed YES
Specification Used S1236
Fan Speed Adjustment Made No Fan Speed n/a
Dens. Corr. 1.000 0 elevation

Overall Test Result: PASS

AIR VELOCITY PROFILES:

Supply Grid:

84	84	87	87
80	80	85	85

Level IV Form - Title	Document Number	Approval Date	Author
Cleanroom Test Report Data Sheet	**1148.7**	**16Nov2017**	**R. Ross**

Date Tested/Time 09 AUG 2019

Work Order # 5006-201286

USP ☑ NON USP ☐ Other ☐

Frequency: Semi-Annual ☑ Annual ☐ Other ☐

Customer No. FL0101-001

Name Hybrid Pharma

Address 1015 West Newport Center Drive

City/State Deerfield Beach, Florida Zip 33442

Location Pharmacy Cleanroom

Contact Dr. Raja

Phone 904-519-8900

Email Address DRRAJA@HYBRIDPHARMA.COM

Type	Manufacturer	Model Number	Asset Number	Cal. Due Date
Photometer	TEC Services	PH-5	103316	16 APR 20
Particle Counter	Lighthouse	Solaire 3100	01325	06 MAR 20
Velocity Meter	Alnor	EBT 731	103266	28 DEC 19
Pressure	Alnor	EBT 731	103266	28 DEC 19
Light Meter				
Sound Meter				
Temp Meter				
Humidity Meter				
Bio Air Sampler				

Name of Room (Customer's Designation)	Classification (Cust. Request)	Room Condition: As Built	Static/At Rest	Dynamic/Oper.
Buffer Room	7	☐	☐	☑
Buffer Room 2	7	☐	☐	☑
Ante Room	7	☐	☐	☑
Prep Room	8	☐	☐	☑
		☐	☐	☐
		☐	☐	☐

Room dimensions REQUIRED for Particle Counts and Air Changes/Hour.

Tests Performed: (check off information included)

Must be filled in if using velgrid

☑ Volumes ☑ Air Changes/Hour ☑ Room Pressurization **Measured Filter area**

☐ Velocities Indicate Stand-Off Length - Check one ☐ 2" ☐ 4" ☐ 6" ☐ 12"

☐ Light ☐ Sound ☐ Temperature ☐ Humidity ☐ Other

☑ HEPA Filter Leak Test Indicate upstream challenge, **either** measured or calculated: Calculated

☑ Particle Counts/Room Were counts taken in **at least** 5 locations? ☑ Y ☐ N Micron size: >=0.5 microns Probe Height: 9" Sample Volume 1cf

☑ Particle Counts/Hood Were counts taken in **at least** 5 locations? ☑ Y ☐ N Micron size: >=0.5 microns Probe Height: 40" Sample Volume 1cf

☐ Biological Air Sampling ☐ Biological Surface Sampling

Notes: (1) Minimum of 1 count in each of 5 locations in each room/hood required for classification certificates.

Larger rooms may require counts in more than five locations. CONFIRM BY RUNNING PARTICLE COUNT UTILITY or look up Table 1 in Certification - Air Cleanliness Classification (4388).

If ISO 4 (Class 10) or lower is required by customer, call Reports Dept. in Hatfield, PA for grid size and air sample volume.

(2) If Air Changes/Hour is required and there is no access for volume readings with Balometer, then effective filter area and K factor required to calculate air supply volumes.

If using a copy of a prior cleanroom report to enter current data, line through data and circle any comments you want carried over to the new report. If updating an electronic report, all new data must be reflected in red.

Comments:

FAX/Email all drawings and test data to Region Officewithin 24 HOURS.

Serviced by: Bob Hoffman

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10 J: High Risk – Media Fill Challenge Personnel - aseptic handling.

Lyophilizer Process Validation

Name of the Person performing	R. Uma.
Number of vials Size of the vials (5ml)	657 vials
Date: 4/1/19	Process validation: Lyophilizer Process & Personnel aseptic handling

:

METHOD: VALIDATION OF HIGH RISK PROCESS -weighing, measuring, mixing, dissolving, aseptic manipulation of the filtration process, dispensing, stoppering, capping in the Lyophilizer process.

TECHNIQUE/ PROCEDURE: DISSOLUTION: stage 1

1. Weigh growth media TSB powder in scale 42.5gm ~~42-49~~ 49gm)
2. Measure 100 ml in a graduated container. (350 ml
3. Transfer sterile water for injection [1350 ml] to a Glass container of size 1/2 litre without splashing. The mouth shall be half covered Aluminum foil.
4. Set up the stirrer. Speed ---375-- rpm for ---25---minutes
5. Turn on the stirring slowly using the knob. As a good swirling of liquid is seen, add TSB powder in the water and close the mouth with the aluminum foil. Allow for stirring to get a clear liquid. **Keep sample solution at this stage 1 in sterile vial for positive control before filtration.**
6. **STERILIZATION: stage 2**

   Filter Details: Sterile 0.2 micron Filter

   Collect the filtered solution in depyrogenated 5ml clear vials set up in ISO 5 Hood.

   STERILIZATION: is carried out under ISO 5 Hood.
7. After filtration , dispense 2 ml through the sterile 0.2 micron filter

into sterile and depyrogenated vials, 5ml arranged in Lyophilizer trays asceptically

8. Stopper the vials without touching the open end of the vials or touching the inner surface of the Lyophilizer stoppers using a depyrogenated Tweezer and press with sterile gloved finger tips. A gap is seen between the prongs of the stopper. Place the tray inside the Stainless Steel surgical Bin, cover with an autoclaved sterile wrap and cover with the lid. Transport the partially stoppered vials inside the covered Bin to ISO 5 Hood in Buffer room 1. Open the Lyophilizer Freeze drying chamber and from the ISO 5 hood, open the lid and remove the lyophilizer tray with the vials and place it inside the lyophilizer chamber. Which is 2 foot from the ISO 5 Hood and move it under the two of the 2X4 Hepa filters in the ceilings, that is in front of the Lyophilizer door.
9. Close the Lyophilizer door once the loading is done. Turn on the Lyophilizer. After placing all the three trays in the same way of handling under Hepa filter. Close the door.
10. Complete stoppering of the vials by pressing the "UP" button for the hydraulic stoppering mechanism installed in the Lyophilizer.
11. Inspect visually and make sure the stoppers are sealed tight in all the trays by gently pressing the UP control.
12. Finish the ISO 5 hood work by taking a surface sample in a TSA L/PS, gloved finger tip samples for both left and right hands of the operator/s
13. Crimp Cap the vials in ISO 7 bench, and keep them in the plastic bin, cover them submit it for microbiological evaluation, label with date and initial.

10 J: High Risk – ...edia Fill Challenge Personne. aseptic handling.

Lyophilizer Process Validation

NOTES:

Temperature F:	73
Humidity %:	41
ISO 5 Hood : Differential Pressure" w.c: BR2	BSC Hood. -0.03"
Activites interruptions: Number of exits and entries to buffer room. Other activities inside the buffer room	2 exits + 2 entries. (gave a break @ 15 minutes and continued)

Materials used:

Bubble Point Test value: 750 psi Pass 56 psi

	Details
Stoppers autoclaved: Steam Sterilizer at 121°C for 30 minutes	AC 439; AC 440
Glasswares , vials, beakers, graduated jars, depyrogenated: Using dry heat Oven, Lindberg/Blue U01F305604-WF, Temp: 250° C, 30 min	DPLB 377 DPLB 374
Sterile water for Injection: Baxter 03380013-04	Y298133 02 28 2020
Criterion Hardy dehydrated culture medium	Cat# C7571 #429342; 08/06/2021
Sterile 0.2 micron Filter DKS-S MDI DKS-X3101UUXX301	DK3908G 2020-08

10 J: High Risk – ...edia Fill Challenge Personne. . aseptic handling.

Lyophilizer Process Validation

Positive Control Stage 1 5ml clear vials number of vials, size ~~10~~ml clear	6
Number of Vials [Stage 2] made: size ~~10~~ml clear 5ml clear vials	657
Location	Quality control room
Incubation Temperature: [Temp. 20 -25 ^{0}C,] (68-77 F)	Keep them in a plastic container cover them with a lid.
Incubation Time for 14 Days	Watch for any turbidity or cloudiness and the clarity.
Start Date:	7/1/19 74F
End Date:	7/15/19 75F B

PASS IF THE FOLLOWING CRITERIA MET

1. Positive control samples are turbid → 6 samples Turbid.
2. All the filtered solution in vials is clear. Filtered vials clear, no turbidity Pass B 7/15/19

FAIL IF NOTICED THE FOLLOWING

1. Positive control samples are turbid.
2. Any filtered solution in vials is also turbid.

Summary: R. Uma ------ is qualified to handle the Lyophilizer ✓ process under aspetic conditions. 2. The process of transporting the partially stoppered vials to the Lyophilizer also validated. ✓

Reviewer Protoc 7/19/19

INTERPRETATION OF RESULTS

- In the "Positive Control" vials, the expected result is growth or turbidity because the medium was not sterile and was unfiltered.

- Visible turbidity or growth observed in the vials containing filtered medium, on or before 14 days of incubation, is a positive test for the presence of bacteria. The media-fill challenge test has failed and indicates that a non-sterile technique was used during the test.

- No growth or turbidity observed in the vials containing filtered medium within 14 days, indicates the media-fill challenge test was successful and technique used during the media-fill challenge test was aseptic.

10 J: High Risk – Media Fill Challenge Personnel's aseptic handling.

Lyophilizer Process Validation

Form 75B_MF **Environmental / Personnel monitoring post media fill**

Batch details	Simulation of Lyophilizer Process			
Batch size and Vial size	1350 ml,	650 vials		
Details of settle plate TSA, batch, expiry, manufacturer used to collect air in the LAFH Hardy 26ml USP W64 15X100mm ; Incubation Temp: 30 – 35°C		123781 2019 09 21		
During Compounding ISO 5 Hood settle air Plates	0 Cfu Pass/ Fail	Start date	End Date	
Negative control	0 Cfu Pass/ Fail	7/1/19	7/3/19	
Details of TSA W/LEC &P80 batch, expiry, manufacturer Temp: 30-35°C, Inc. 2 Hardy P34		123426 2019 08 07		

Post Media fill Gloved fingertip Personnel: OR	LEFT 1 Cfu Pass/ Fail	RIGHT 0 Cfu Pass/ Fail	HOOD SURFACE 0 Cfu Pass/ Fail	Start date	End Date
		Sleeve 0 Cfu Pass/ Fail	Negative control 0 Cfu Pass/ Fail	7/1/19	7/3/19

HYBRID PHARMA

ENVIRONMENTAL MONITORING

VIABLE ENVIRONMENTAL MONITORING -LYOPHILIZER
Form: ENV-70L

Date 7/1/'19	Details of Plate, Lot#, Expiry	TSA W/LEC /POLY80 H-TSA w/ L/T P34 123426 2019 08 07	Surface sampling- contact/ swab		Incubation 30-35° C / 86 -95° F 48-72 hrs		Pass Fail
Location in Lyophilizer			By	Incu. Temp.	CFU	Date	By
Stainless steel shelf 1 SS1		Inside Lyophilizer			0	7/3	
Stainless steel shelf 2 SS2		Inside Lyophilizer	B 7/1/'19	32°C	0	7/3	Pass
Stainless steel shelf 3 SS3		Inside Lyophilizer			0	7/3	B
Lyophilizer Door -inside LD 1		Inside Lyophilizer			0	7/3	
Lower Condenser section- Inside LC1		Inside condenser			0	7/3	
		H-TSA 26ml, USP W64 123781 2019 09 21	Air settling Plates		Incubation 30-35° C / 86 -95° F 48-72 hrs		
Stainless steel Table # 5 SST5		Buffer room 2	B 7/1/'19	32°C	0	7/3	Pass
Stainless steel Table # 3 SST3		Ante room			0	7/3	
Stainless steel Table # 6 SST6		Buffer room 1			0	7/3	B

105

APPROVED BY

mdi
Membrane Technologies

Certificate of Quality

The Polyethersulfone Membrane Capsule filters have been manufactured in a mdi facility in compliance with ISO 9001 regulations using *validated production processes.*

AseptiCap KS-γ PES Membrane Capsule Filters

Catalog No. : DKSX3101UUXX301
Type : DKS-S
Pore Size : 0.2 µm (0.45 µm + 0.2 µm)
Lot Number : DK3908G Cl.No: 211
Ster. No. : R086
Date of Sterilization : 2018 - 08
Expiry Date : 2020 - 08

SPECIFICATION

Length	1"
Filter Media	Polyethersulfone Membrane
Drainage Layers	Polyester
Differential Pressure	< 4Kg/cm² at 30 °C
Housing	Polypropylene
Maximum Operating Temperature	80 °C @ < 2Kg/cm²
Sterilization	Pre sterilized by Gamma Irradiation at ≥ 25 kGy

LOT RELEASE CRITERIA

100% Integrity Tested : The capsule filter has been tested for integrity by Bubble point test using DI water. Bubble point value with DI water was: ≥ 50 psi (3.44 Bar)
The capsule filter is also certified for integrity by Bubble point test using 50% IPA/Water solution.
Bubble point with 50% IPA/Water solution is ≥ 16 psi (1.10 Bar)

Water Flow Rate : ≥ 600 ml/min @ 0.70 Kg/cm² @ 27 °C

Microbial Challenge Test : Retains ≥ 10^7 organisms/cm² of *B. diminuta* ATCC 19146 challenge as per ASTM F838-05 methodology.

VALIDATED FOR

Sterility : The sterilization process has been validated to assure Sterility Assurance Level (SAL) of 10^{-6} in accordance with ISO 11137.

Extractable : Within limits as specified in USP.

Oxidizable matter : Passes test as per USP.

Bacterial Endotoxins : Filtrate meets the USP requirements for Sterile WFI of ≤ 0.25 EU/ml as determined by Limulus Amebocyte Lysate (LAL) test.

Biosafety : Passes Biological Reactivity Tests, *In Vivo* for Class VI plastic as described in USP <88>.

Cytotoxicity : Passes Biological Reactivity Tests, *In Vitro* as described in USP <87>.

Indirect Food Additives : Passes as per FDA 21CFR 177.1520(a)1(i).

Particle Release : Passes test as per USP <788>, "Particulate matter in Injections".

Fiber Release : Complies with FDA 21CFR 210.3(b)(6).

CUSTOMER SUPPORT
mdi offers its unique interdisciplinary skills to provide solutions to specific problems. Please contact our factory or the local application specialist.

Head of Quality Assurance

Issue Date: 06 Sep 18

Advanced Microdevices Pvt. Ltd.
21, Industrial Area, Ambala Cantt, INDIA.
Tel: +91-171-2699290/ 2699274
Website: www.mdimembrane.com
Email: info@mdimembrane.com

IDJ

10 N: High Risk – Media Fill Challenge Personnel's aseptic handling. 287 vials x 10ml Media fill Process validation

Name of the Person performing: Uma.R Date: 3/15/19

METHOD: VALIDATION OF HIGH RISK PROCESS -weighing, measuring, mixing, dissolving, aseptic manipulation of the filtration process, dispensing, stoppering, capping.

TECHNIQUE/ PROCEDURE: DISSOLUTION: stage 1

1. Place the empty clean container on the balance and record the tare weight. Press "ZERO" of the balance and weigh the required quantity of material, note the weighed material and then remove the container from balance and press Zero.
2. Weigh growth media TSB powder in scale ~~6.0gm~~ 60.08 gm. After dispensing, clean the surrounding area, balance and wipe with 70% IPA solution.
3. Reseal the TSB powder original container and shift to their original place.
4. Measure in a 100ml graduated container and transfer sterile water for injection [~~300~~ 3000ml ml] to a Glass container of size ~~1/2~~ 4 litre without splashing. The mouth shall be half covered with aluminum foil.
5. Set up the stirrer. Speed --275-- rpm for ~~40~~ minutes
6. Turn on the stirring slowly using the knob. As a good swirling of liquid is seen, add TSB powder in the water and cover the mouth with the aluminum foil. Allow for stirring with slight warming to get a clear liquid. Keep sample solution at this **stage 1** in sterile vial for positive control before filtration.
7. Set up the Pre sterilization to remove particulates as in 7a. In ISO 7 Work Bench.

STERILIZATION: stage 2 is carried out under ISO 5 Hood.

Filter Details: Sterile 0.2 micron Filter MDI DKS-S KS-P DK 3908G 2020 08

Collect the filtered solution in depyrogenated 10ml clear vials set up in ISO 5 Hood.

STERILIZATION:

1. After filtration , dispense 10 ml through the sterile 0.2 micron filter into sterile and depyrogenated vials, 10ml. clear vials DPLB339
2. Stopper the vials without touching the open end of the vials or touching the inner surface of the stoppers using Tweezer and press with sterile gloved finger tips. Move the stoppered vial trays to ISO 7 work bench.
3. Finish the ISO 5 hood work by taking a surface sample in a TSA L/PS, gloved finger tip samples for both left and right hands of the operator
4. Crimp Cap the vials in ISO 7 bench, and keep them in the plastic bin, cover them, submit it for microbiological evaluation, label with date and initial.

NOTES:

Temperature F:	Humidity %:	Differential Pressure" w.c: ISO 5 Hood :	Number of exits and entries to buffer room:	Other activities inside the buffer room:
72	37	0.5	one exit to bring autoclaved stoppers	No other compounding

1223852 ; 20200831

Materials used: Baxter Repeater Pump fluid transfer tube set H93821

- Sterile water for Injection: Baxter 03380013-0B54 Y275974 7/31/19
- TSB powder: #429342 Criterion A-1 Medium Hardy # C7571 06-Aug-21
- Stoppers autoclaved: Steam Sterilizer at 121°C for 30 minutes AC405 ; Sterigage 2020 0654 2020 06
- Depyrogenated glasswares , vials, beakers, graduated jars,

  Depyrogenation using dry heat Oven, Lindberg/Blue U01F305604-WF, Temp: 250° C, 30 min

Bubble Point Test value of the 0.2 micron filter: 59 psi >50 psi Pass

- Number of Positive Control vials prepared in Stage 1:-----8 vials
- Number of Vials prepared in Stage 2, post filtration: -----279

Incubation Temperature: [Temp. 20 -25 °C,] Incubate all media filled units in normal position after leak test at of 20 to 25°C (68-77F) for 14 days. Incubation temperature should be maintained within 22.5 ± 2.5° C.

Incubation Time for 14 Days

- Start Date: 3/15/19 End Date: 3/22/19 Incubator Temperature: 75F 22°C

PASS

1. Positive control samples are turbid ✓ Pass B ✓ 3/22/19 Noreen Bradley R.Ph.
2. All the filtered solution in vials is clear. ✓

FAIL

1. Positive control samples are turbid.
2. Any filtered solution in vials is also turbid.

ION

Form 75A **Environmental / Personnel monitoring during Production**

Batch details, Name of the drug, strength				
Batch size and Vial size	ml, vials			
Details of settle plate TSA, batch, expiry, manufacturer used to collect air in the LAFH Hardy 26ml USP W64 15X100mm ; Incubation Temp: 30 – 35^{0}C			121026 2019 03 24	
During Compounding ISO 5 Hood settle air Plates	0 Cfu	Pass/ Fail	Start date	End Date
Negative control	0 Cfu	Pass/ Fail	3|15|19	3|18|19
Details of TSA W/LEC &P80 batch, expiry, manufacturer Temp: 30-35^{0}C, Inc. 2 Hardy P34			121915 2019 05 02	

Post Media Fill / compounding Gloved fingertip Personnel: VR	LEFT 0 Cfu Pass/ Fail	RIGHT 0 Cfu Pass/ Fail	HOOD SURFACE 0 Cfu Pass/ Fail	Start date 3|15|19	End Date 3|18|19
		Sleeve 0 Cfu Pass/ Fail	Negative control 0 Cfu Pass/ Fail B 3ic		

The investigation should survey the possible causes of contamination during media fill trials i.e. Environmental, personnel and surface monitoring.

(HYBRID PHARMA) STANDARD TESTING PROCEDURE

Calibration and Performance Maintenance of HPLC, Perkin-Elmer-200

Test Procedures for Performance Certification of an HPLC UV Detector

1.0 PURPOSE

1.1 The purpose of this procedure is to document in detail the test methods used to verify the performance and function of an HPLC UV Detector.

2.0 SCOPE

2.1 This test procedure will be performed at suitable intervals in accordance with an established programs and is designed to ensure the operation of the instrument in accordance with its intended use. The instrument will be tested as a part of the complete system defined by the client.

3.0 REFERENCE DOCUMENTS

3.1 21 CFR 211 Subpart I 211.160

3.2 UV Detector Users Manual (manufacturer specific)

3.3 Test Report Attachment 1

4.0 TEST MATERIALS AND TEST EQUIPMENT

4.1 25 mg Caffeine/ Liter Water

4.2 Deionized Water

4.3 Mobile Phase Water

4.4 Restrictor – 0.007" OR 0.010" ID PEEK Tubing (5 meter length)

5.0 PROCEDURE

5.1 Using the Component Identification form in Attachment 1, document the following information:

- § Engineer's Name
- § Certification Date
- § Recertification Due Date
- § System ID Number
- § Instrument Location
- § Component Make, Model and Serial Number

5.2 Using the Test Materials and Test Equipment Certification form in Attachment 1, document the applicable information for all test materials and test equipment used.

5.3 To verify the wavelength accuracy of the UV detector. Set up the instrument as stated below:

5.3.1 Connect the restrictor tubing in place of the column.

5.3.2 Mobile Phase (DI water).

5.3.3 Set flow rate to 2.0 mL/min and prime the unit.

5.3.4 Configure the data acquisition for a 1.0 minute run with a sampling period of ≅ 400 milliseconds 2.5 points per second, or as needed.

5.3.5 Inject 10 µl of the sample solution at each wavelength stated in the table below. Record the Peak Area in the wavelength calibration (UV) section of Attachment 1.

INJECTION	WAVELENGTH	INJECTION	WAVELENGTH
1	202 nm	8	270 nm
2	203 nm	9	271 nm
3	204 nm	10	272 nm
4	205 nm	11	273 nm
5	206 nm	12	274 nm
6	207 nm	13	275 nm
7	208 nm	14	276 nm

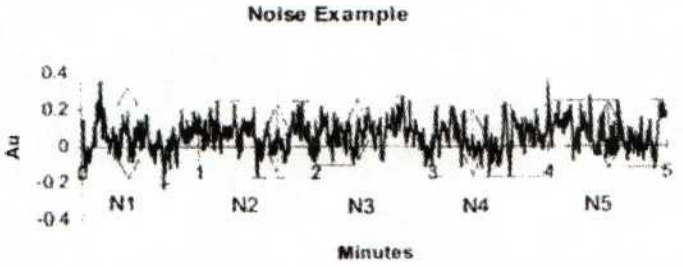
5.3.6 Record the wavelength corresponding to the greatest Peak Area as the Actual Lambda Max

5.4 To determine the System Noise and Drift of the instrument, configure the data acquisition for a 10.0 minute run with a sampling period of ≅ 400 milliseconds or 2.5 points per second. Set the wavelength to 273 nm. Set the pump to run at 1 mL/min. for 10 minutes.

5.4.1 Collect and print the plot.

5.4.2 Calculate the system noise using 5 consecutive minutes of data. Measure the average noise level of each one-minute interval as shown in the example below. Calculate the average noise of the scan and record the results as the Actual System Noise in Attachment 1.

Example N1 + N2 + N3 + N4 + N5 / 5

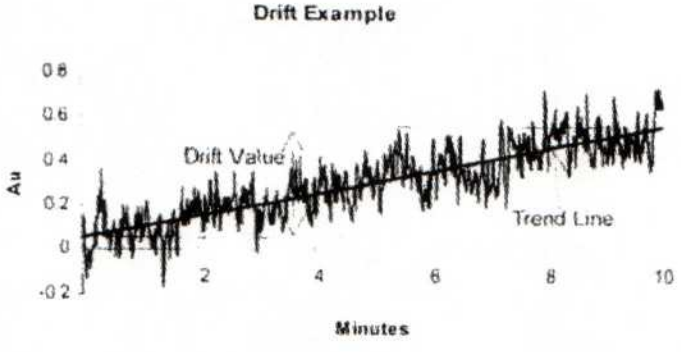


The calculated value for system noise should be ≤50 (uV or uAU)

5.4.3 Calculate the System Drift (Pump/Detector), using all 10 minutes of data (Peak to Peak drift). Multiply the drift value times 6 and record the results as system drift in Attachment 1.

Example: Drift Value * 6

Drift = (Drift Value) * 6



The calculated value for system drift should be ≤ 0.60 (mV/hr or mAU/hr).

6.0 HISTORY

STP HISTORY

REVISION NUMBER	CHANGE/REASON
1	Updated to change Integrator to A/D Interface. Changed Data to Documentation attached to this report and included list of documentation to be included.
2	Updated to add incorporated to company's name.
3	Delete "Prepared" on Approval page.
4	Updated Scope to include the statement that "The instrument will be tested as part of the complete system defined by the client" and to eliminate repetitive documentation of system components in Attachment 1. Addition of statement for documentation of Test Materials and Test Equipment.
5	Section 5.1: changed 25 mg/Liter Caffeine to 25 mg Caffeine/Liter Water. Section 5.7: changed Restrictor 0.007 ID PEEK to 0.007" OR 0.010" ID PEEK. Section 6.3.2 changed (water) to (DI water)
6	The following disclaimer was added to the front page of this document: This document is the proprietary property of AMS, Inc.. No part of this document may be reproduced in any form whatsoever, or translated into any language, without the prior, written approval of AMS. The CUSTOMER acknowledges and understands that nothing contained herein shall be construed as conveying title of this document to the CUSTOMER. The CUSTOMER is granted a non-transferable, non-exclusive right to use this document, supplied by AMS, as necessary for archive or backup purposes only. Further, the CUSTOMER agrees to hold this document in confidence and shall not disclose any part of it, except to its employees to whom disclosure is necessary for use, or as required by regulatory agencies to whom disclosure is necessary for their review. Any comments about this document shall be addressed to AMS, Inc.
7	Reviewed but no change

Performance Certification of an HPLC UV Detector

Test Report

Attachment 1

Component Identification

Qualifying Engineer	Dr. Raja
Certification Date	06/18/2018
Recertification Period	12 months
Recertification Due Date	06/2019
System ID Number	HPLC #1
Instrument Location	QC LAB

Component	Make	Model	Serial Number
Detector	Perkin Elmer	Series 200 4V	292N2061903

Performance Certification of an HPLC UV Detector

Test Report

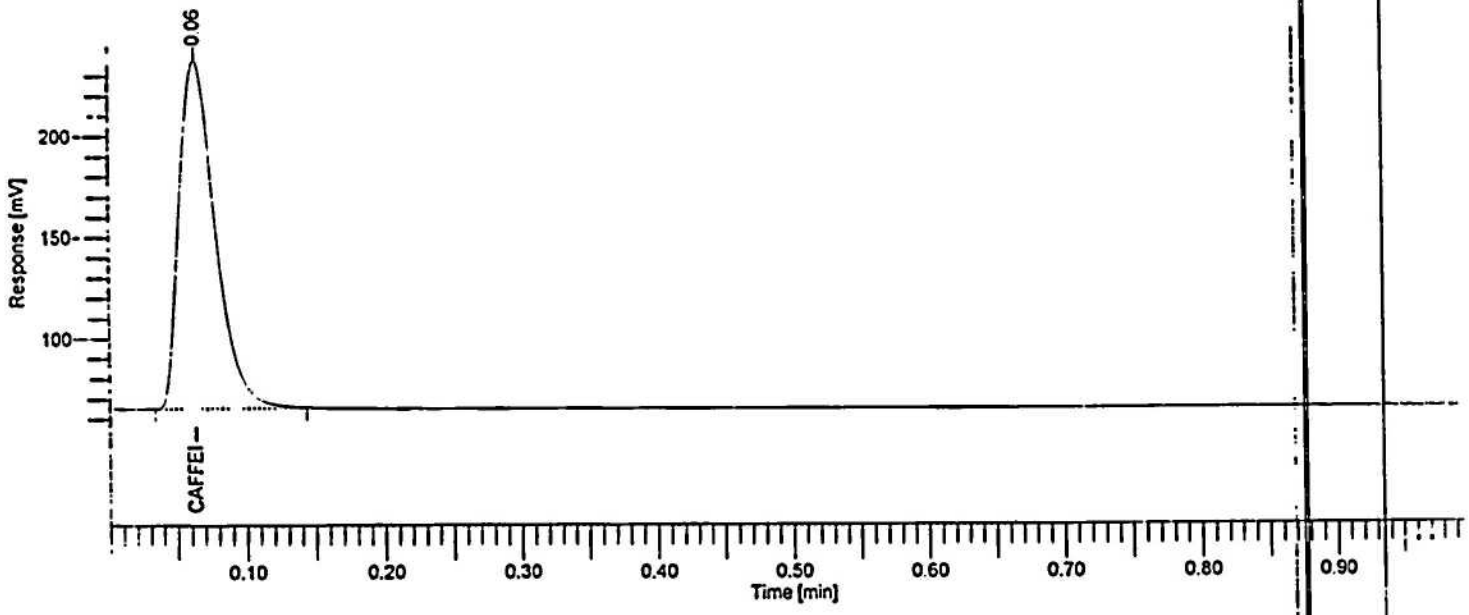
Attachment 1 (Cont.)

Test Materials and Test Equipment Certification

Material	Preparation Reference	Lot Number	Expiration Date
Caffeine Standard	RESTEK - 31804 HPLC QC Linearity Test mixture	A0124503	1/2020

Software Version	: 6.3.2.0646	Date	: 8/19/2018 12:30:51 PM
Reprccess Number	: hplc: 1578		
Sample Name	:		
ınstrument Name	: HPLC	Data Acquisition Time	: 8/19/2018 12:29:45 PM
Rack/Vial	: 0/1	Channel	: A
Sample Amount	: 1.000000	Operator	: tcprocess
Cycle	: 3	Dilution Factor	: 1.000000

Result File : c:\ams\data\081918\wl-270.rst
Sequence File : C:\AMS\seq\caf_wavelength.seq



HPLC-1

Peak #	Component Name	Time [min]	Area [uV*sec]	Height [uV]
1	caffeine	0.063	311617.12	172552.10
			311617.12	172552.10

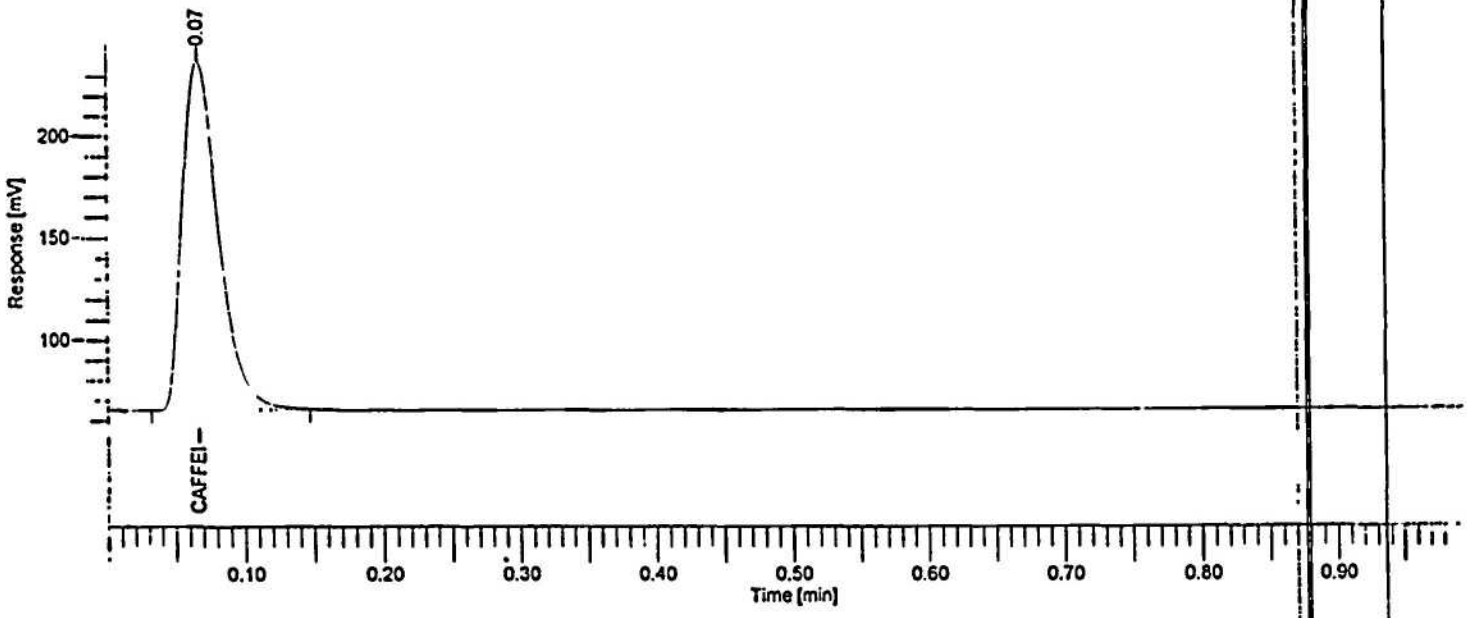
Missing Component Report

Component	Expected Retention (Calibration File)

All components were found

Software Version	: 6.3.2.0646	Date	: 8/19/2018 12:32:59 PM
Reprocess Number	: hplc: 1579		
Sample Name	:		
.nstrument Name	: HPLC	Data Acquisition Time	: 8/19/2018 12:31:53 PM
Rack/Vial	: 0/1	Channel	: A
Sample Amount	: 1.000000	Operator	: tcprocess
Cycle	: 4	Dilution Factor	: 1.000000

Result File : c:\ams\data\081918\wl-271.rst
Sequence File : C:\AMS\seq\caf_wavelength.seq



HPLC-1

Peak #	Component Name	Time [min]	Area [uV*sec]	Height [uV]
1	caffeine	0.067	311254.97	172243.32
			311254.97	172243.32

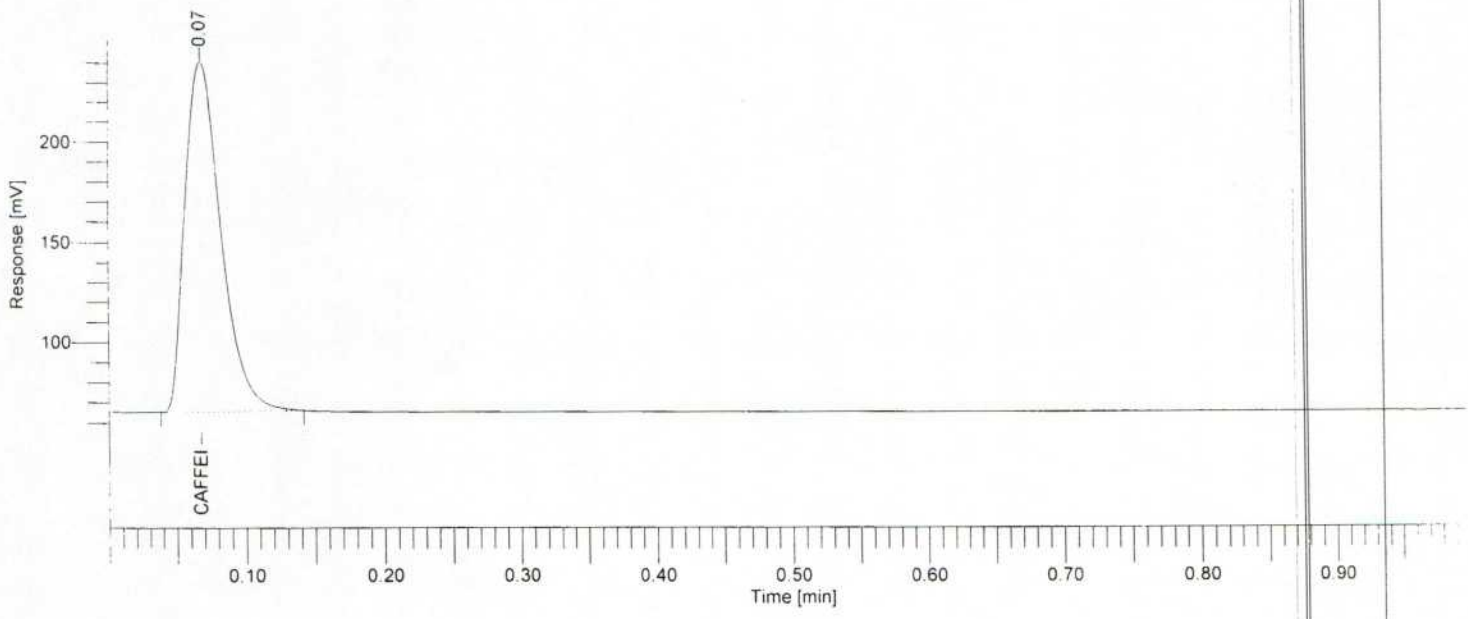
Missing Component Report

Component	Expected Retention (Calibration File)

All components were found

Software Version	: 6.3.2.0646	Date	: 8/19/2018 12:35:07 PM
Reprocess Number	: hplc: 1580		
Sample Name	:		
Instrument Name	: HPLC	Data Acquisition Time	: 8/19/2018 12:34:01 PM
Rack/Vial	: 0/1	Channel	: A
Sample Amount	: 1.000000	Operator	: tcprocess
Cycle	: 5	Dilution Factor	: 1.000000

Result File : c:\ams\data\081918\wl-272.rst
Sequence File : C:\AMS\seq\caf_wavelength.seq



HPLC-1

Peak #	Component Name	Time [min]	Area [uV*sec]	Height [uV]
1	caffeine	0.068	316153.00	175160.51
			316153.00	175160.51

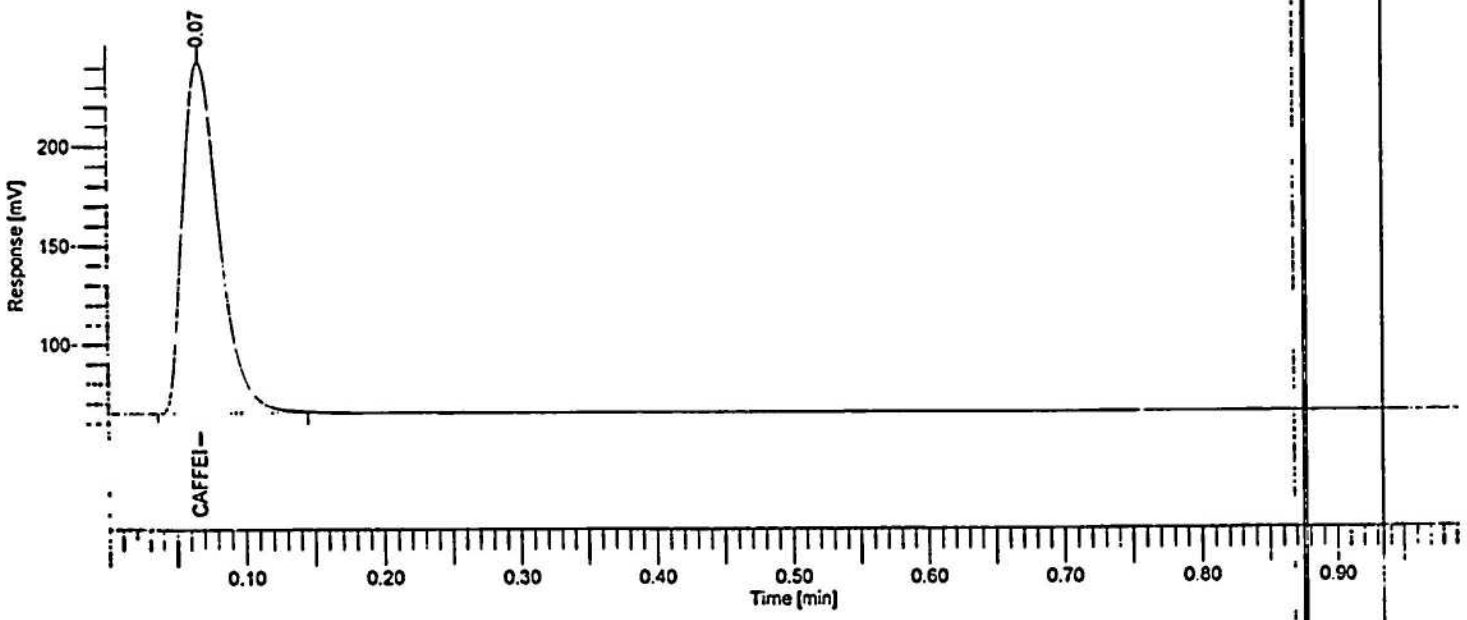
Missing Component Report

Component	Expected Retention (Calibration File)

All components were found

Software Version	: 6.3.2.0646	Date	: 8/19/2018 12:57:26 PM
Reprocess Number	: hplc: 1581		
Sample Name	:		
Instrument Name	: HPLC	Data Acquisition Time	: 8/19/2018 12:56:19 PM
Rack/Vial	: 0/1	Channel	: A
Sample Amount	: 1.000000	Operator	: manager
Cycle	: 1	Dilution Factor	: 1.000000

Result File : c:\ams\data\081918\wl-273.rst
Sequence File : C:\AMS\seq\caf_wavelength.seq



HPLC-1

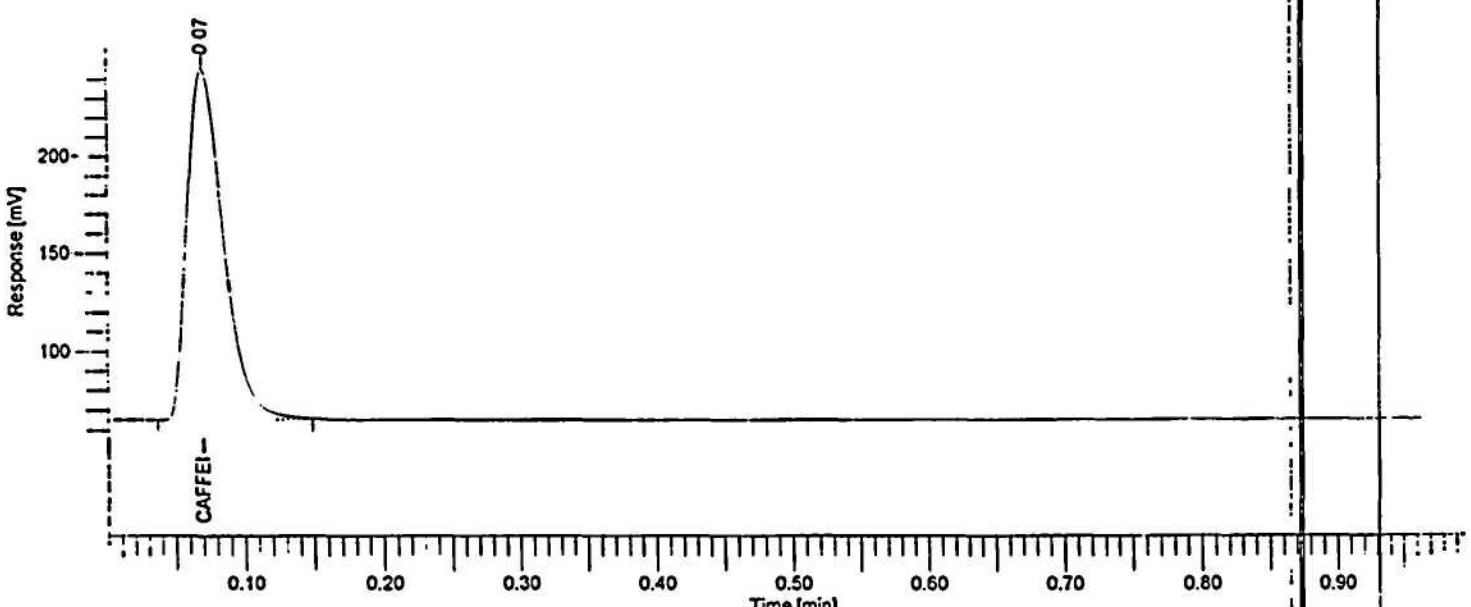
Peak #	Component Name	Time [min]	Area [uV*sec]	Height [uV]
1	caffeine	0.067	322585.09	178004.47
			322585.09	178004.47

Missing Component Report
Component Expected Retention (Calibration File)

All components were found

Software Version	: 6.3.2.0646	Date	: 8/19/2018 12:59:33 PM
Reprocess Number	: hplc: 1582		
Sample Name	:		
Instrument Name	: HPLC	Data Acquisition Time	: 8/19/2018 12:58:25 PM
Rack/Vial	: 0/1	Channel	: A
Sample Amount	: 1.000000	Operator	: manager
Cycle	: 2	Dilution Factor	: 1.000000

Result File : c:\ams\data\081918\wl-274.rst
Sequence File : C:\AMS\seq\caf_wavelength.seq



HPLC-1

Peak #	Component Name	Time [min]	Area [uV*sec]	Height [uV]
1	caffeine	0.070	324610.47	179324.37
			324610.47	179324.37

Missing Component Report

Component	Expected Retention (Calibration File)

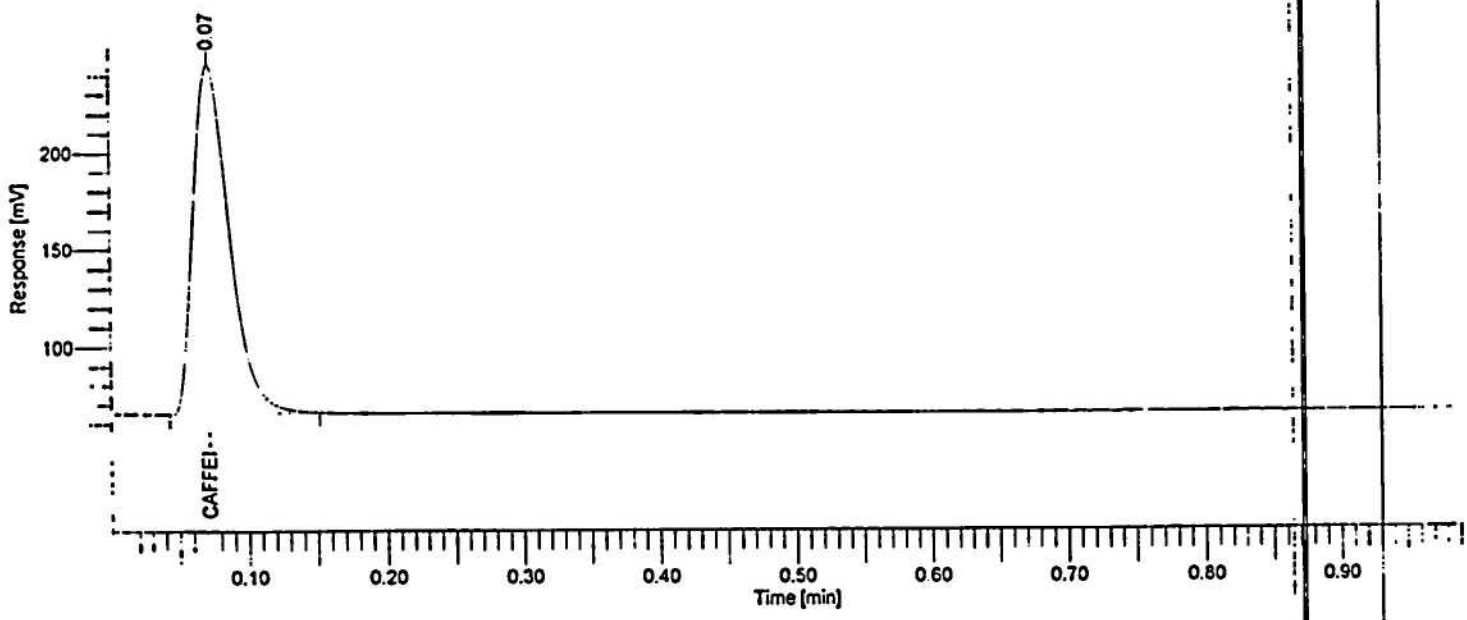
All components were found

Software Version : 6.3.2.0646
Reprocess Number : hplc: 1583
Sample Name :
Instrument Name : HPLC
Rack/Vial : 0/1
Sample Amount : 1.000000
Cycle : 3

Date : 8/19/2018 1:01:40 PM

Data Acquisition Time : 8/19/2018 1:00:33 PM
Channel : A
Operator : manager
Dilution Factor : 1.000000

Result File : c:\ams\data\081918\wl-275.rst
Sequence File : C:\AMS\seq\caf_wavelength.seq



HPLC-1

Peak #	Component Name	Time [min]	Area [uV*sec]	Height [uV]
1	caffeine	0.072	325443.42	180388.95
			325443.42	180388.95

Missing Component Report

Component	Expected Retention (Calibration File)

All components were found

PACKING SLIP

RESTEK CORPORATION
110 BENNER CIRCLE
BELLEFONTE, PA 16823-8812
www.restek.com

PHONE: (814) 353-1300
FAX: (814) 353-1309
EIN #: 25-1497733

ORDER NUMBER	247468-1
ORDER DATE	05-30-18

247468-1

SHIP TO
30151*1 PO# 05/30/18
Attn: Receiving
Hybrid Pharma LLC
1015 W Newport Ctr Dr
Deerfield Beach, FL 33442
United States

SOLD TO
30151
Attn: Accounts Payable
Hybrid Pharma LLC
Ste 106A
1015 W Newport Ctr Dr
Deerfield Beach, FL 33442
United States

SHIP VIA	F.O.B.	PURCHASE ORDER NUMBER	TERMS	SALESPERSON
FED EX GROUND	Bellefonte, PA	05/30/18	ONLY Credit Car	Kaitlyn Gephart

ORDER NUMBER	247468	SHIP DATE		FROM	Bellefonte, PA	FREIGHT	496433629 Collect

ITEM NO.	ORDERED	SHIPPED	BACKORDERED	PRODUCT NO.	DESCRIPTION
1	1	1	0 GHS	31805	Test Mix Kit See Components HPLC OQ Linearity Test Mix Kit, H2O
		Component List			
31800	SU Stock Standard Allocated Lot A0134461				EA FGRF26 (1)
31801	SU Stock Standard Allocated Lot A0135848				EA FGRF15 (1)
31802	SU Stock Standard Allocated Lot A0137622				EA FGRB04 (1)
31803	SU Stock Standard Allocated Lot A0134134				EA FGRE04 (1)
31804	SU Stock Standard Allocated Lot A0124503				EA FGRE04 (1)

Allocated: 06-06-18
Printed : 06-06-18 13:38:06

Note-All items on this order have not been shipped. Back ordered items(s) will be shipped as soon as possible. If you have concerns please contact us at 800-356-1688, Ext. 3.

PULLED BY	CHECKED BY	SHIPPED BY	WEIGHT	FREIGHT AMOU
	RLH			

Bill To User: Receiving
Buyer : Dr. Raja
Phone # : 9547082771

THANK YOU FOR YOUR ORDER! WE APPRECIATE YOUR BUSINESS.

"If receiving this product outside of the United States, these commodities, technology or software were exported from the United States in accord Administration Regulations

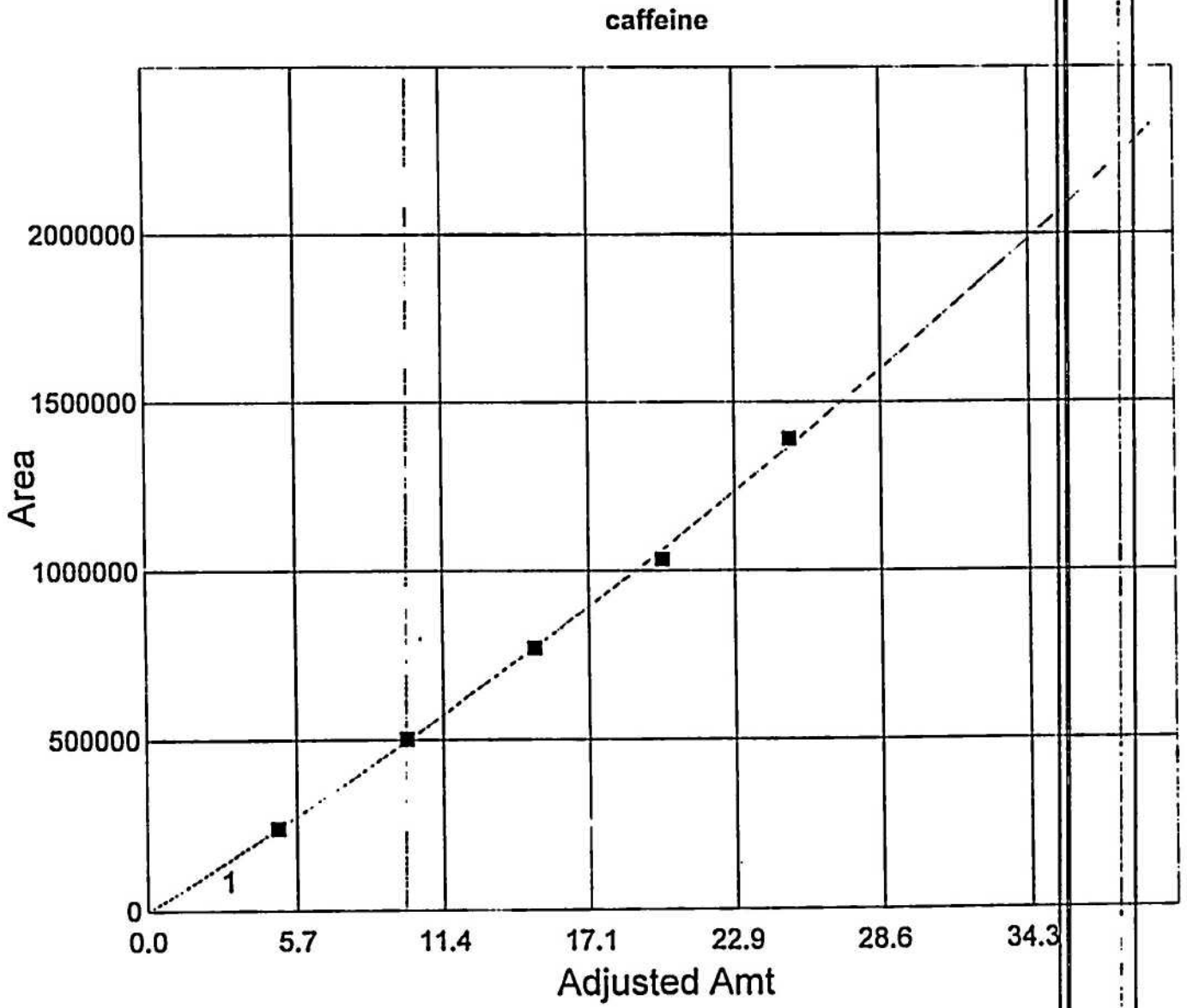
106-54
106-50

Fit Analysis Output For Method File: C:\AMS\METH\LIN50.MTH
Reprocess Number : hplc: 1614
Component Name : caffeine
Date : 8/19/2018 5:49:45 PM

Curve Parameters:

Curve #1 2nd Order - Incl Origin
Weighting Factor = 1/(x*x) R-Squared = 0.999763
Calibration Curve: Y = (10.759099) +(46370.219439) X +(335.193753) X^2

Curve #1 Level Name	Observed X-Value	Calculated X-Value	Delta	%Diff.	Observed Y-Value	Calculated Y-Value	Delta	%Diff
10	5.000000	4.994796	0.005204	0.104	239982.933592	240241.700	-258.767	-0.108
20	10.000000	10.110924	-0.110924	-1.097	503123.625165	497232.329	5891.296	1.185
30	15.000000	14.971907	0.028093	0.188	769397.759517	770982.645	-1584.886	-0.206
40	20.000000	19.547496	0.452504	2.315	1034511.496204	1061492.649	-26981.153	-2.542
50	25.000000	25.362577	-0.362577	-1.430	1391695.848847	1368762.340	22933.508	1.675



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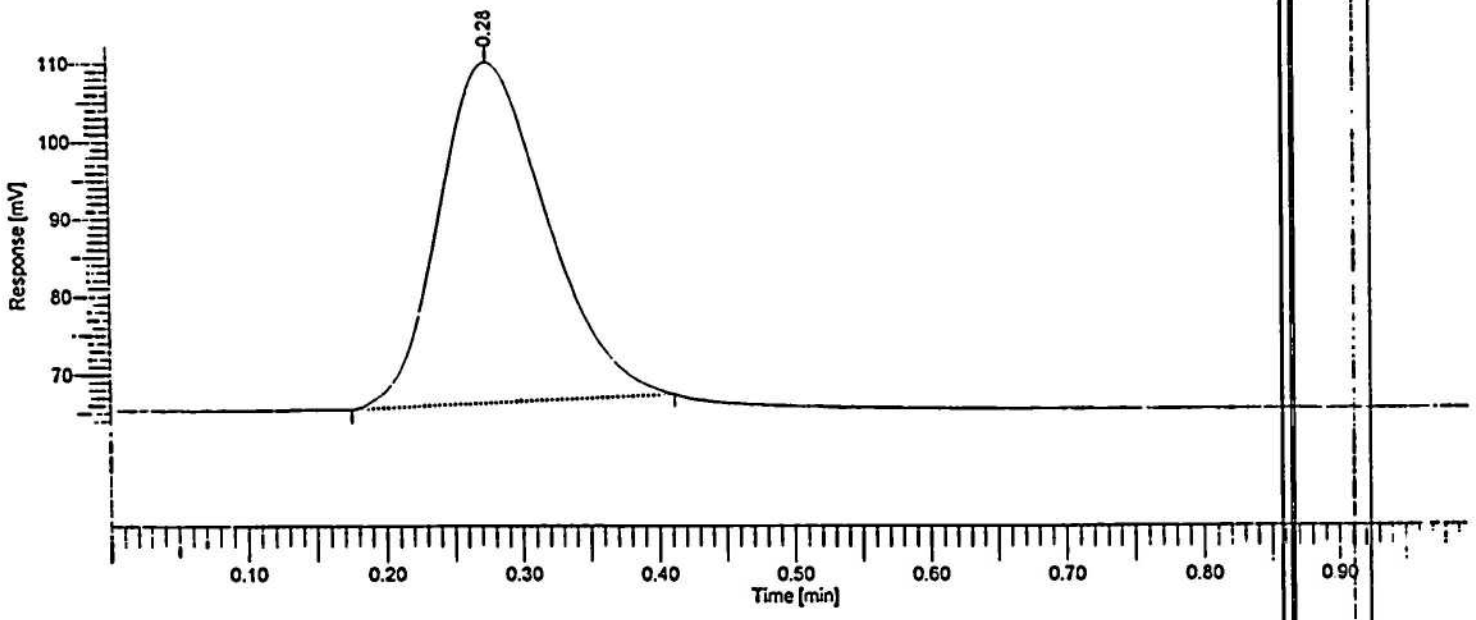
Reprocess Number	: hplc: 1602		
Sample Name	: 10 uL	Data Acquisition Time	: 8/19/2018 3:37:04 PM
Instrument Name	: HPLC	Channel	: A
Rack/Vial	: 0/1	Operator	: manager
Sample Amount	: 1.000000	Dilution Factor	: 1.000000
Cycle	: 2		

Result File : c:\ams\data\061918\10uL-010-20180819-153814.rst
Sequence File : C:\AMS\seq\caf_linearity.seq



HPLC1

Peak #	Component Name	Time [min]	Area [uV*sec]	Height [uV]
1		0.275	239982.93	43794.35
			239982.93	43794.35

Missing Component Report

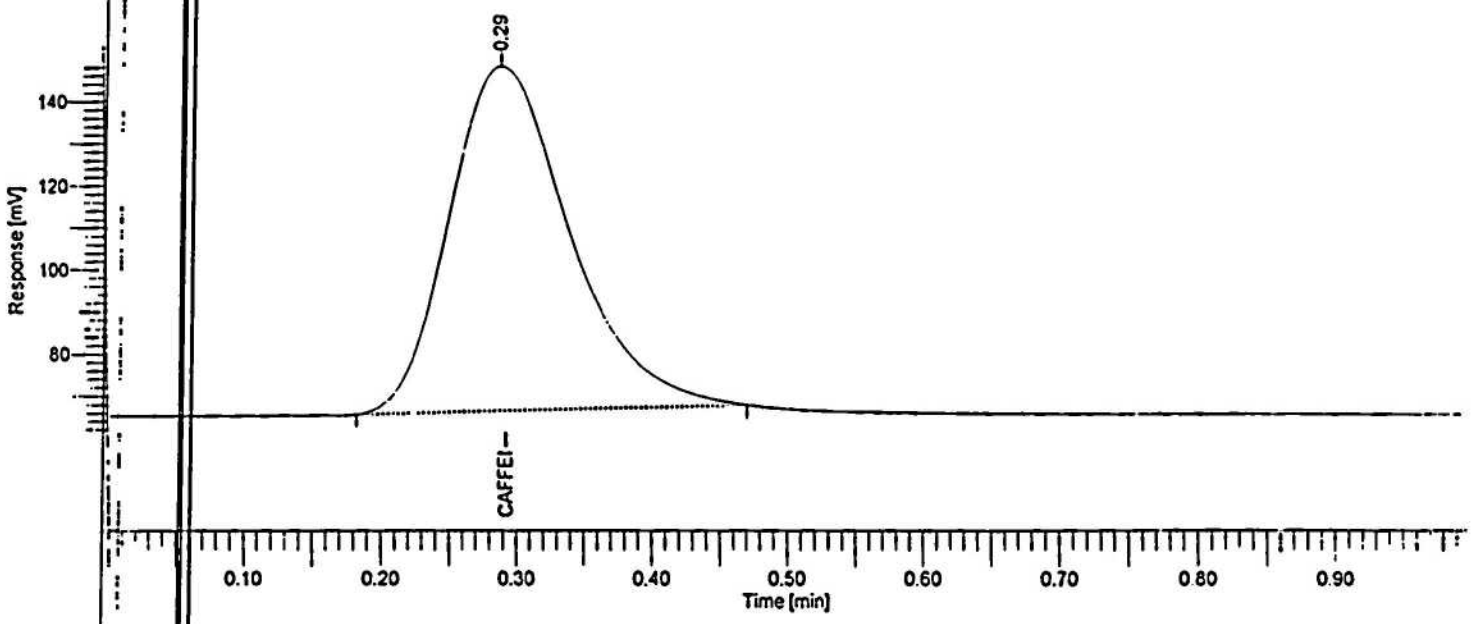
Component	Expected Retention (Calibration File)
caffeine	2.000

Software Version : 6.3.2.0646
Reprocess Number : hplc: 1603
Sample Name : 20uL
Instrument Name : HPLC
Rack/Vial : 0/1
Sample Amount : 1.000000
Cycle : 3

Date : 8/19/2018 3:39:50 PM

Data Acquisition Time : 8/19/2018 3:38:41 PM
Channel : A
Operator : manager
Dilution Factor : 1.000000

Result File : c:\ams\data\061918\20uL-011-20180819-153949.rst
Sequence File : C:\AMS\seq\caf_linearity.seq



HPLC1

Peak #	Component Name	Time [min]	Area [uV*sec]	Height [uV]
1	caffeine	0.293	503123.63	81710.08
			503123.63	81710.08

Missing Component Report
Component Expected Retention (Calibration File)

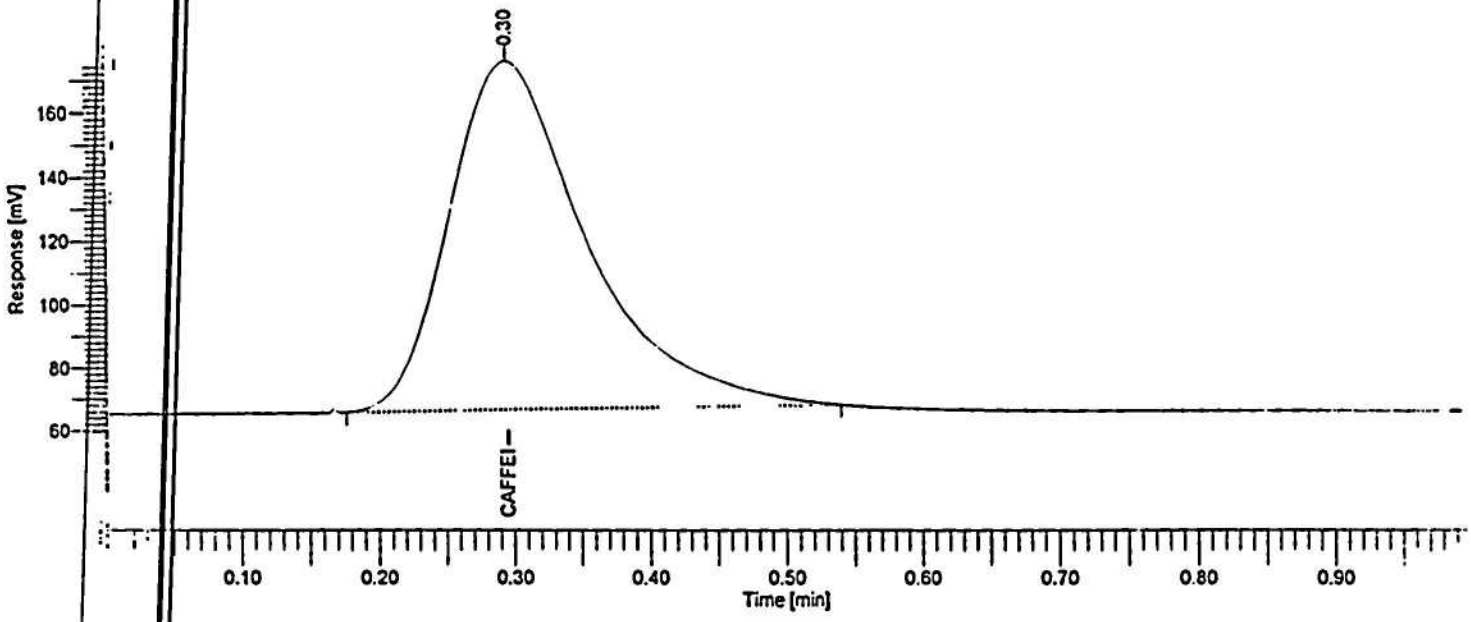
All components were found

Software Version : 6.3.2.0646
Reprocess Number : hplc: 1604
Sample Name : 30uL
Instrument Name : HPLC
Rack/Vial : 0/1
Sample Amount : 1.000000
Cycle : 4

Date : 8/19/2018 3:42:07 PM

Data Acquisition Time : 8/19/2018 3:40:59 PM
Channel : A
Operator : manager
Dilution Factor : 1.000000

Result File : c:\ams\data\061918\30uL-012-20180819-154206.rst
Sequence File : C:\AMS\seq\caf_linearity.seq



HPLC1

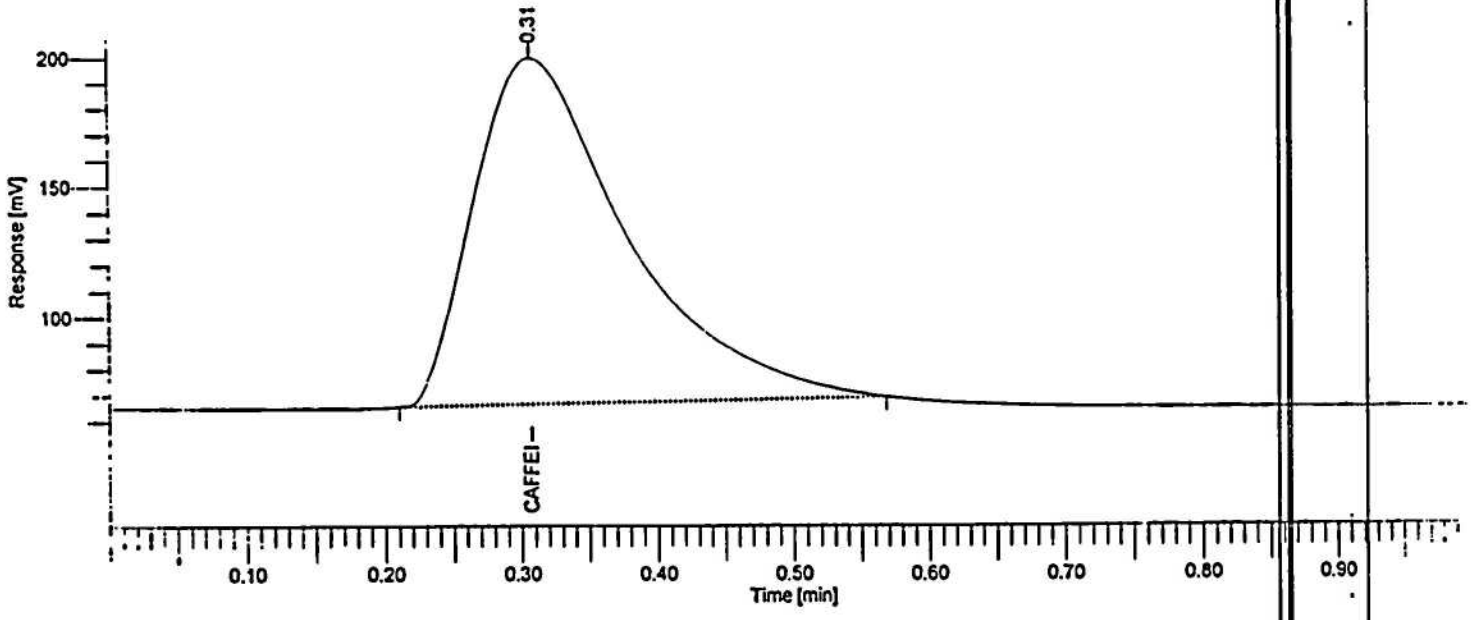
Peak #	Component Name	Time [min]	Area [uV*sec]	Height [uV]
1	caffeine	0.295	769397.76	108933.11
			769397.76	108933.11

Missing Component Report
Component Expected Retention (Calibration File)

All components were found

Software Version	: 6.3.2.0646	Date	: 8/19/2018 5:09:34 PM
Reprocess Number	: hplc: 1612		
Sample Name	: 40uL		
nstrument Name	: HPLC	Data Acquisition Time	: 8/19/2018 5:08:24 PM
Rack/Vial	: 0/1	Channel	: A
Sample Amount	: 1.000000	Operator	: tcprocess
Cycle	: 1	Dilution Factor	: 1.000000

Result File : c:\ams\data\061918\40uL-013-20180819-170933.rst
Sequence File : C:\AMS\seq\caf_linearity.seq



HPLC1

Peak #	Component Name	Time [min]	Area [uV*sec]	Height [uV]
1	caffeine	0.307	1034511.50	133351.87
			1034511.50	133351.87

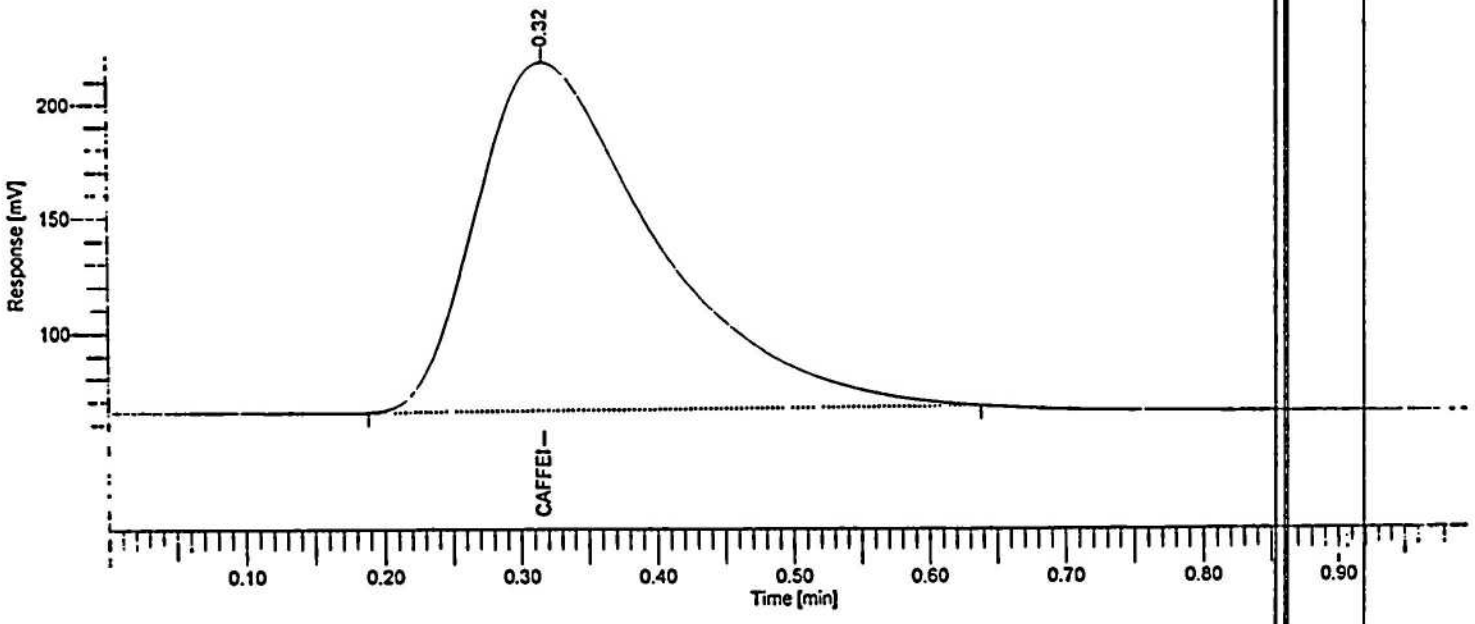
Missing Component Report

Component	Expected Retention (Calibration File)

All components were found

Software Version	: 6.3.2.0646	Date	: 8/19/2018 5:12:01 PM
Reprocess Number	: hplc: 1613		
Sample Name	: 50uL	Data Acquisition Time	: 8/19/2018 5:10:52 PM
Instrument Name	: HPLC	Channel	: A
Rack/Vial	: 0/1	Operator	: tcprocess
Sample Amount	: 1.000000	Dilution Factor	: 1.000000
Cycle	: 2		

Result File : c:\ams\data\061918\50uL-014-20180819-171201.rst
Sequence File : C:\AMS\seq\caf_linearity.seq



HPLC1

Peak #	Component Name	Time [min]	Area [uV*sec]	Height [uV]
1	caffeine	0.317	1391695.85	152945.66
			1391695.85	152945.66

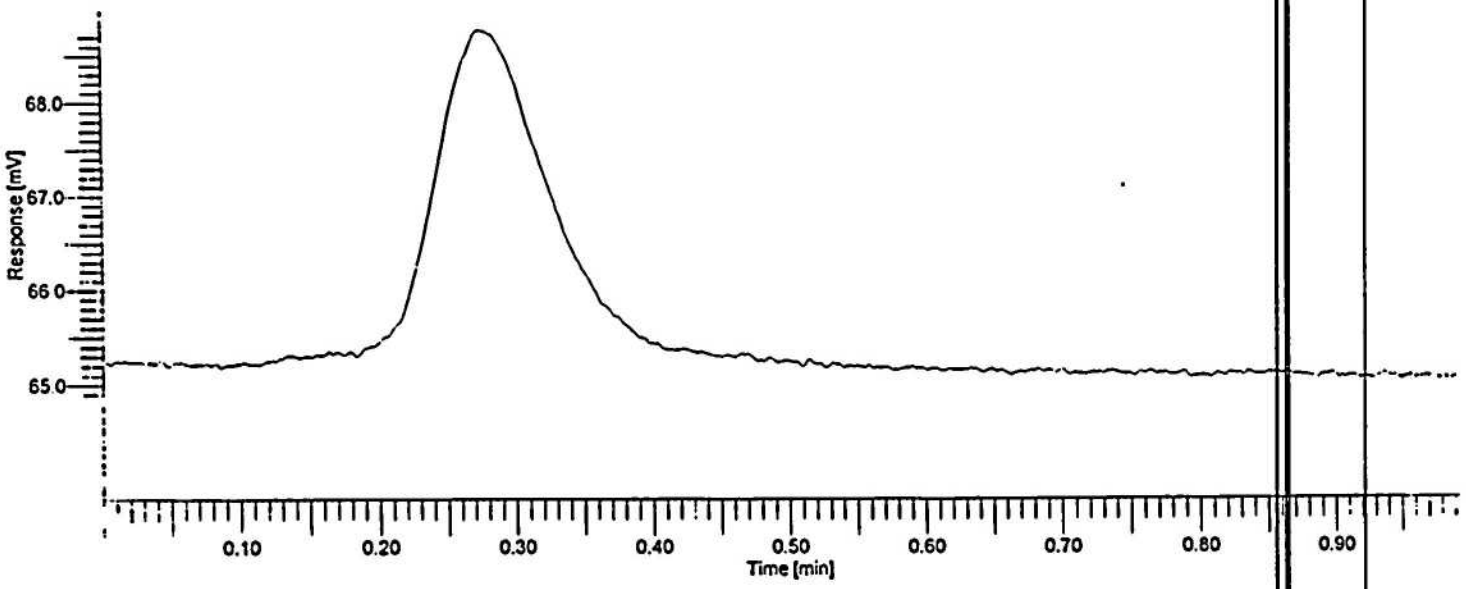
Missing Component Report

Component	Expected Retention (Calibration File)

All components were found

Software Version	: 6.3.2.0646	Date	: 8/19/2018 5:14:08 PM
Reprocess Number	: hplc: 1614		
Sample Name	: CO		
nstrument Name	: HPLC	Data Acquisition Time	: 8/19/2018 5:13:01 PM
Rack/Vial	: 0/2	Channel	: A
Sample Amount	: 1.000000	Operator	: tcprocess
Cycle	: 3	Dilution Factor	: 1.000000

Result File : c:\ams\data\06191CO-015-20180819-171408.rst
Sequence File : C:\AMS\seq\caf_linearity.seq



HPLC1

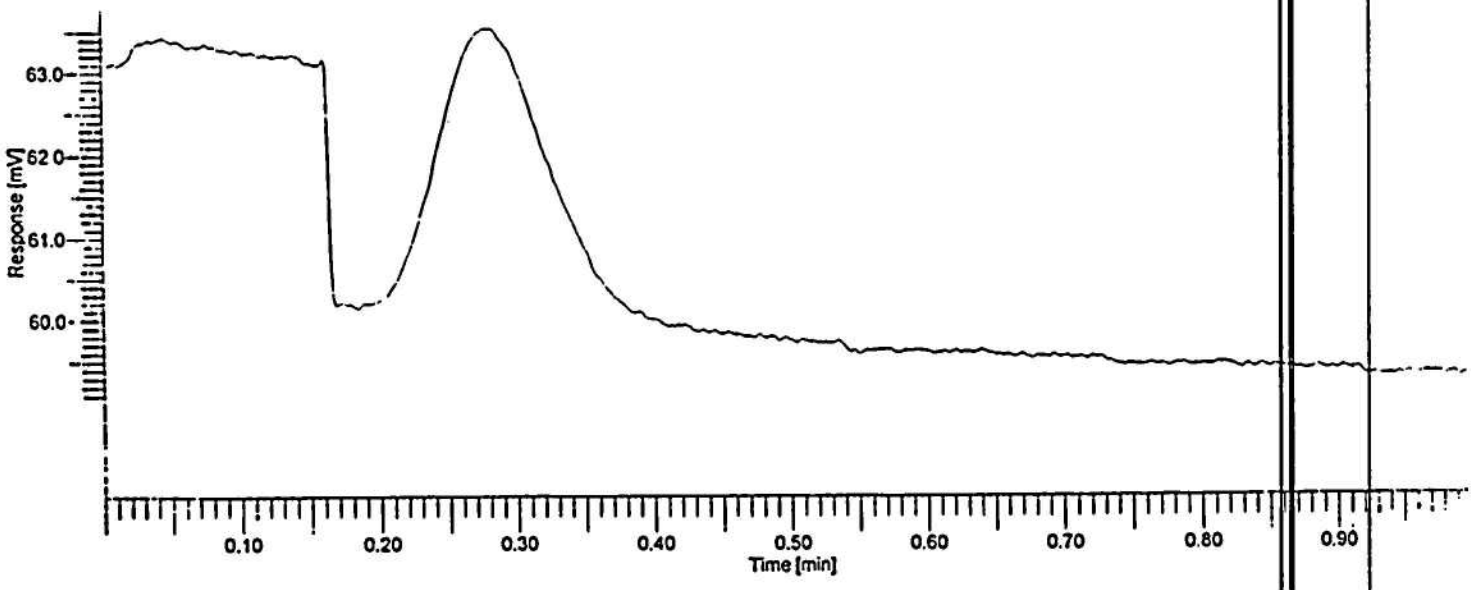
No peaks available to report
Missing Component Report

Component	Expected Retention (Calibration File)
caffeine	2.000

No 1

Software Version	: 6.3.2.0646	Date	: 8/19/2018 5:08:27 PM
Reprocess Number	: hplc: 1611		
Sample Name	: Blank		
nstrument Name	: HPLC	Data Acquisition Time	: 8/19/2018 5:02:17 PM
Rack/Vial	: 0/2	Channel	: A
Sample Amount	: 1.000000	Operator	: manager
Cycle	: 1	Dilution Factor	: 1.000000

Result File : c:\ams\data\061918\Blank-009-20180819-170326.rst
Sequence File : C:\AMS\seq\caf_linearity.seq



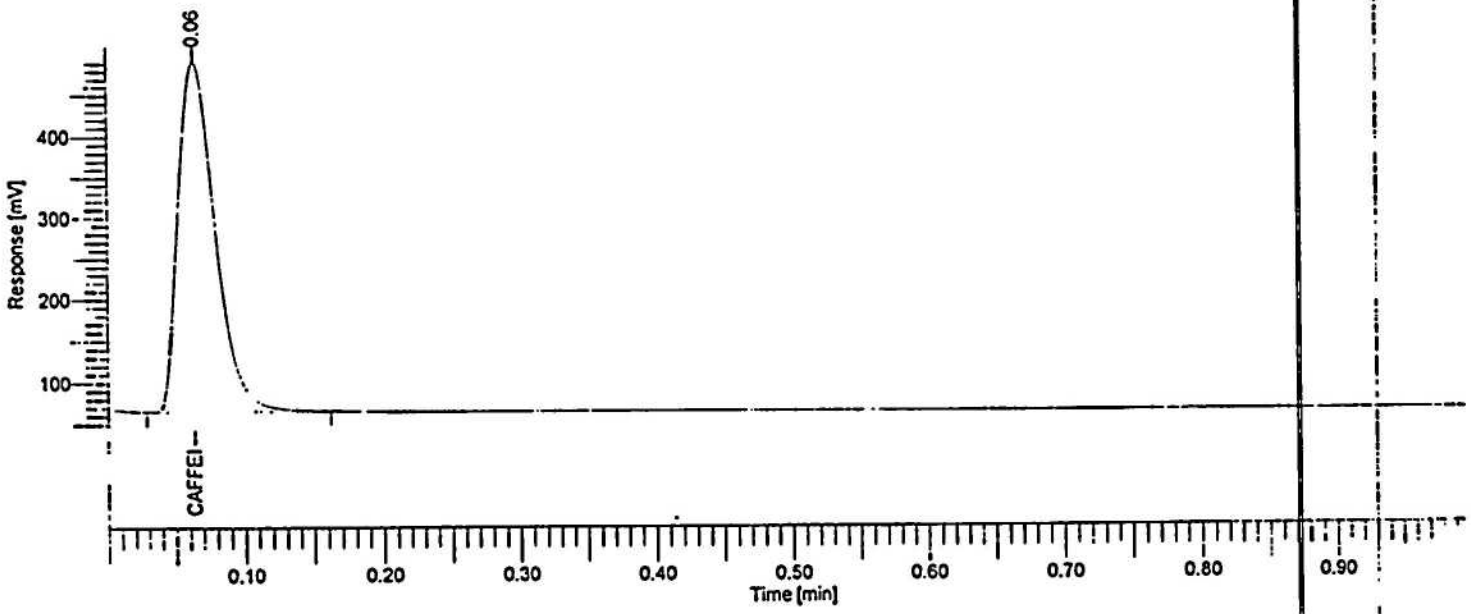
HPLC1

No peaks available to report
Missing Component Report

Component	Expected Retention (Calibration File)
caffeine	2.000

Software Version	: 6.3.2.0646	Date	: 8/19/2018 11:59:00 AM
Reprocess Number	: hplc: 1571		
Sample Name	:		
Instrument Name	: HPLC	Data Acquisition Time	: 8/19/2018 11:57:52 AM
Rack/Vial	: 0/1	Channel	: A
Sample Amount	: 1.000000	Operator	: manager
Cycle	: 1	Dilution Factor	: 1.000000

Result File : c:\ams\data\081918\wl202.rst
Sequence File : C:\AMS\seq\caf_wavelength.seq



HPLC-1

Peak #	Component Name	Time [min]	Area [uV*sec]	Height [uV]
1	caffeine	0.064	786745.04	427293.73
			786745.04	427293.73

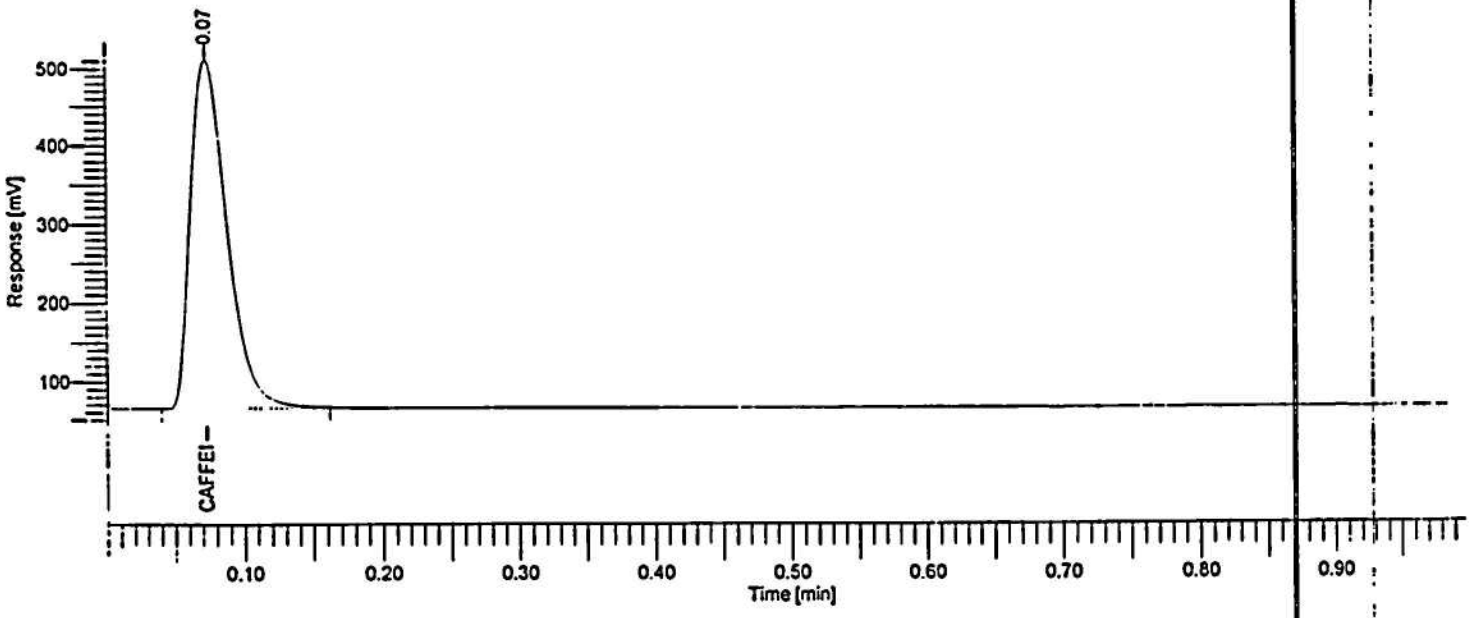
Missing Component Report

Component	Expected Retention (Calibration File)

All components were found

Software Version	: 6.3.2.0646	Date	: 8/19/2018 12:01:07 PM
Reprocess Number	: hplc: 1572		
Sample Name	:		
Instrument Name	: HPLC	Data Acquisition Time	: 8/19/2018 11:59:58 AM
Rack/Vial	: 0/1	Channel	: A
Sample Amount	: 1.000000	Operator	: manager
Cycle	: 2	Dilution Factor	: 1.000000

Result File : c:\ams\data\081918\wl203.rst
Sequence File : C:\AMS\seq\caf_wavelength.seq



HPLC-1

Peak #	Component Name	Time [min]	Area [uV*sec]	Height [uV]
1	caffeine	0.073	812817.67	447138.72
			812817.67	447138.72

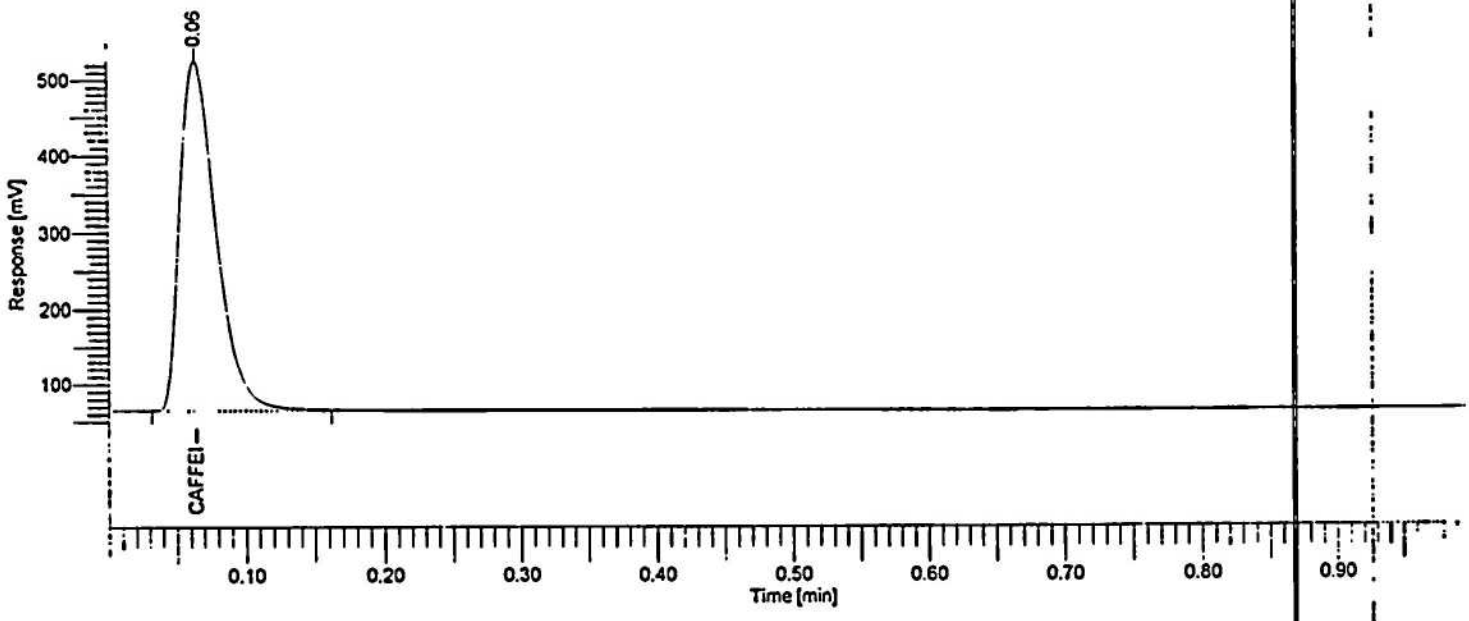
Missing Component Report

Component	Expected Retention (Calibration File)

All components were found

Software Version	: 6.3.2.0646	Date	: 8/19/2018 12:03:14 PM
Reprocess Number	: hplc: 1573		
Sample Name	:	Data Acquisition Time	: 8/19/2018 12:02:07 PM
Instrument Name	: HPLC	Channel	: A
Rack/Vial	: 0/1	Operator	: manager
Sample Amount	: 1.000000	Dilution Factor	: 1.000000
Cycle	: 3		

Result File : c:\ams\data\081918\wl-204.rst
Sequence File : C:\AMS\seq\caf_wavelength.seq



HPLC-1

Peak #	Component Name	Time [min]	Area [uV*sec]	Height [uV]
1	caffeine	0.064	839441.71	461618.49
			839441.71	461618.49

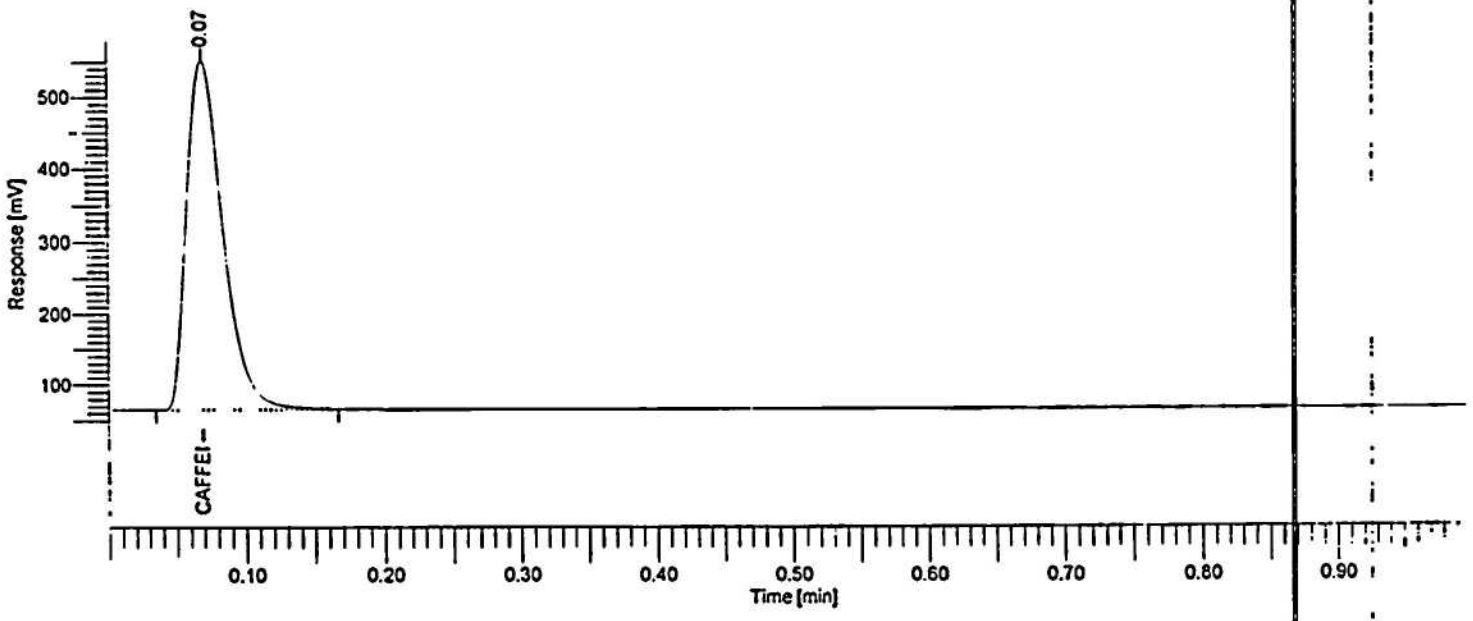
Missing Component Report

Component	Expected Retention (Calibration File)

All components were found

Software Version	: 6.3.2.0646	Date	: 8/19/2018 12:05:22 PM
Reprocess Number	: hplc: 1574		
Sample Name	:		
Instrument Name	: HPLC	Data Acquisition Time	: 8/19/2018 12:04:14 PM
Rack/Vial	: 0/1	Channel	: A
Sample Amount	: 1.000000	Operator	: manager
Cycle	: 4	Dilution Factor	: 1.000000

Result File : c:\ams\data\081918\wl-205.rst
Sequence File : C:\AMS\seq\caf_wavelength.seq



HPLC-1

Peak #	Component Name	Time [min]	Area [uV*sec]	Height [uV]
1	caffeine	0.069	885088.45	487180.66
			885088.45	487180.66

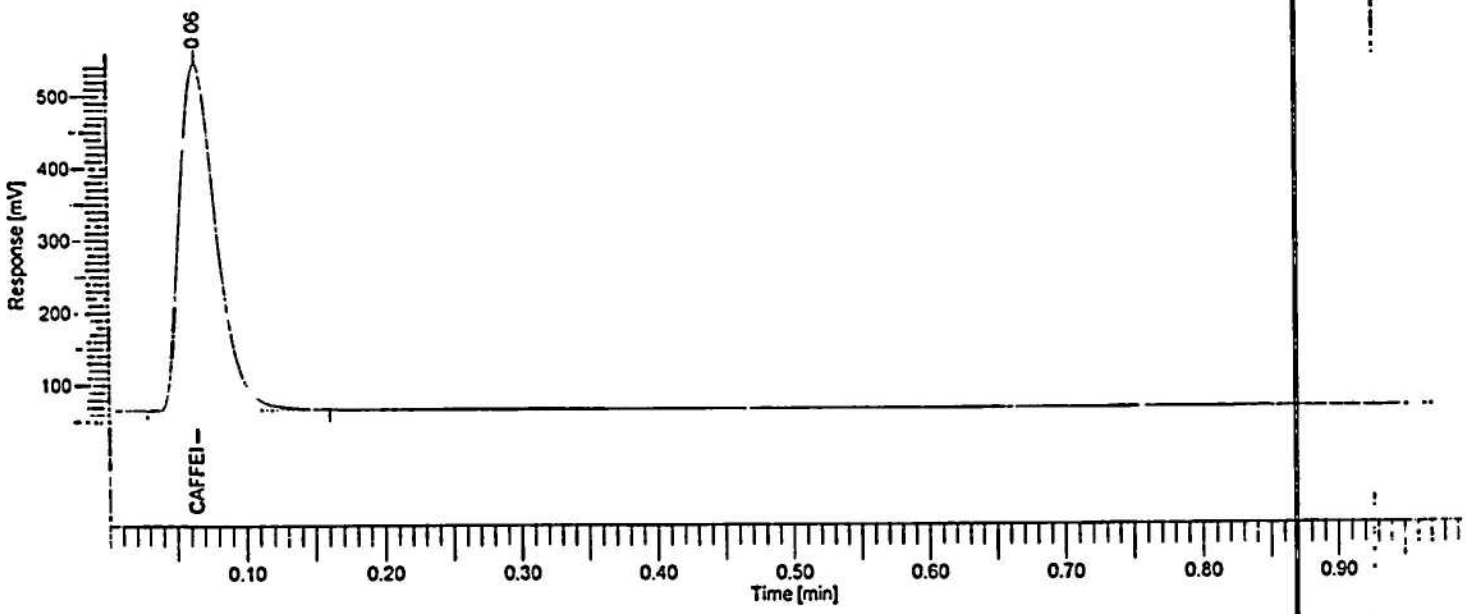
Missing Component Report

Component	Expected Retention (Calibration File)

All components were found

Software Version	: 6.3.2.0646	Date	: 8/19/2018 12:22:40 PM
Reprocess Number	: hplc: 1575		
Sample Name	:	Data Acquisition Time	: 8/19/2018 12:21:32 PM
.nstrument Name	: HPLC	Channel	: A
Rack/Vial	: 0/1	Operator	: manager
Sample Amount	: 1.000000	Dilution Factor	: 1.000000
Cycle	: 1		

Result File : c:\ams\data\081918\wl-206.rst
Sequence File : C:\AMS\seq\caf_wavelength.seq



HPLC-1

Peak #	Component Name	Time [min]	Area [uV*sec]	Height [uV]
1	caffeine	0.064	876657.55	480501.63
			876657.55	480501.63

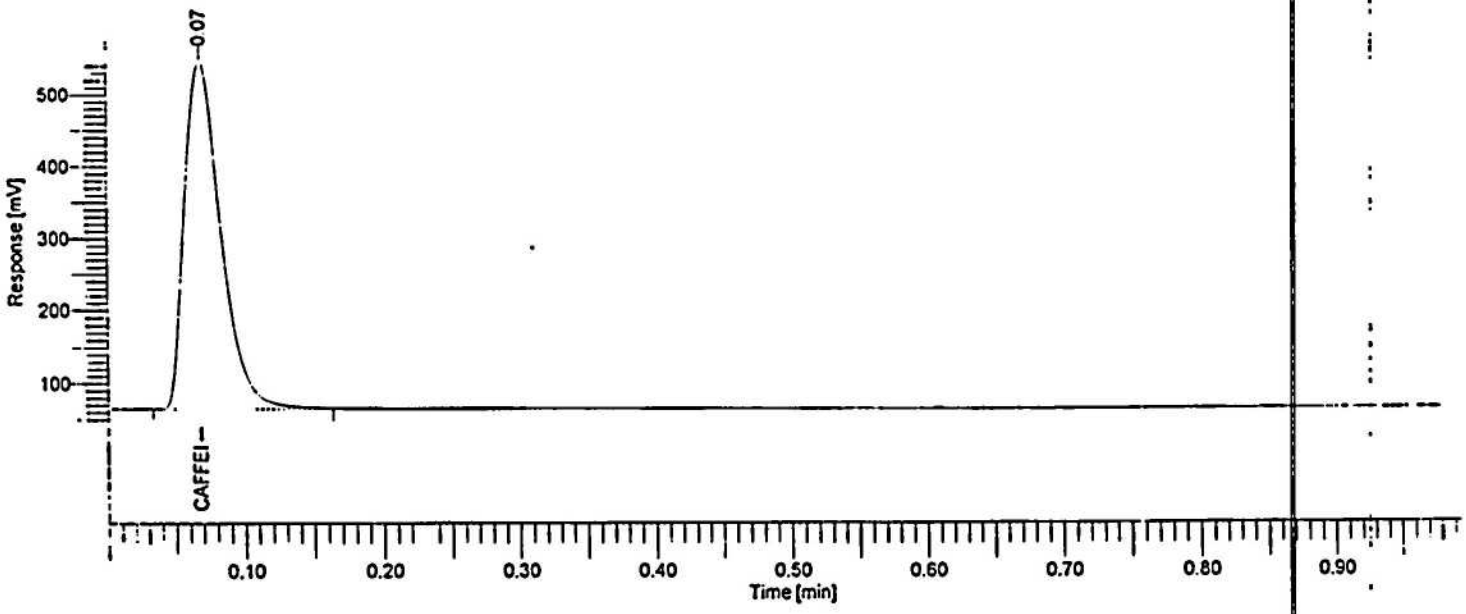
Missing Component Report

Component	Expected Retention (Calibration File)

All components were found

Software Version	: 6.3.2.0646	Date	: 8/19/2018 12:26:35 PM
Reprocess Number	: hplc: 1576		
Sample Name	:	Data Acquisition Time	: 8/19/2018 12:25:27 PM
.nstrument Name	: HPLC	Channel	: A
Rack/Vial	: 0/1	Operator	: tcprocess
Sample Amount	: 1.000000	Dilution Factor	: 1.000000
Cycle	: 1		

Result File : c:\ams\data\081918\wl-207.rst
Sequence File : C:\AMS\seq\caf_wavelength.seq



HPLC-1

Peak #	Component Name	Time [min]	Area [uV*sec]	Height [uV]
1	caffeine	0.068	873309.89	481834.95
			873309.89	481834.95

Missing Component Report

Component	Expected Retention (Calibration File)

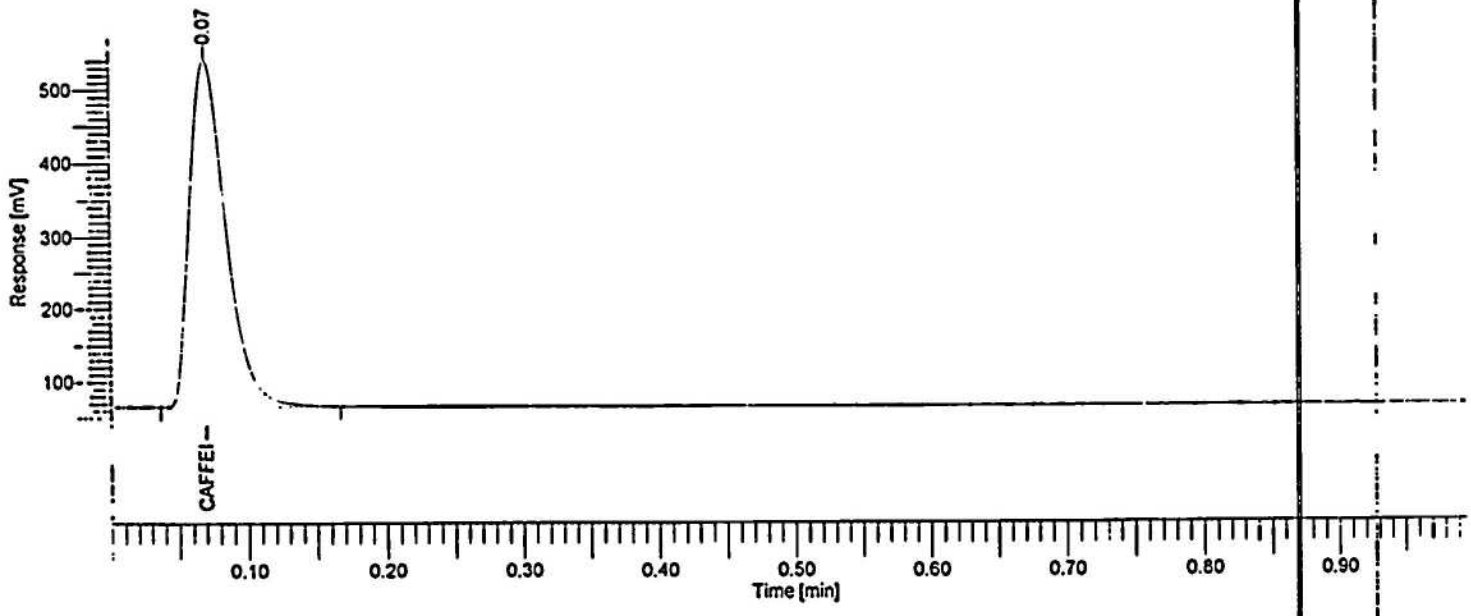
All components were found

Software Version : 6.3.2.0646
Reprocess Number : hplc: 1577
Sample Name :
Instrument Name : HPLC
Rack/Vial : 0/1
Sample Amount : 1.000000
Cycle : 2

Date : 8/19/2018 12:28:43 PM

Data Acquisition Time : 8/19/2018 12:27:37 PM
Channel : A
Operator : tcprocess
Dilution Factor : 1.000000

Result File : c:\ams\data\081918\wl-208.rst
Sequence File : C:\AMS\seq\caf_wavelength.seq



HPLC-1

Peak #	Component Name	Time [min]	Area [uV*sec]	Height [uV]
1	caffeine	0.070	867719.17	476814.34
			867719.17	476814.34

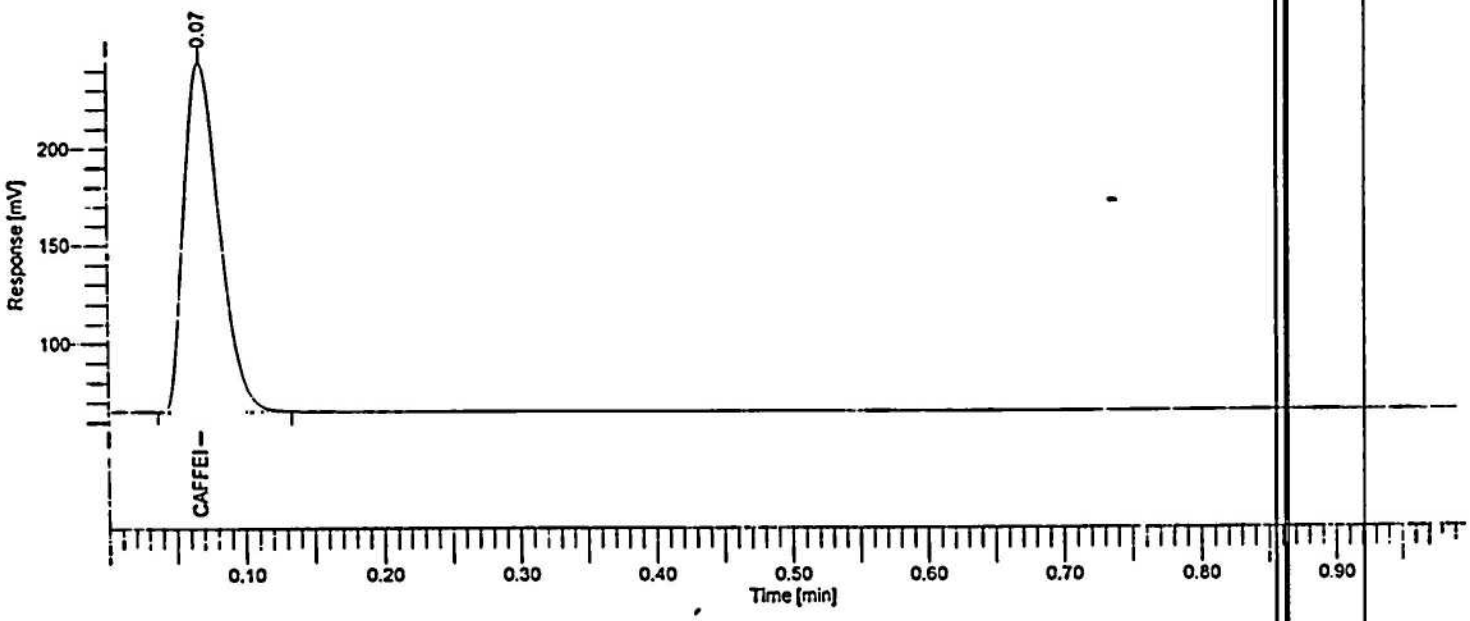
Missing Component Report

Component	Expected Retention (Calibration File)

All components were found

Software Version	: 6.3.2.0646	Date	: 6/29/2018 11:16:08 AM
Reprocess Number	: hplc: 1517		
Sample Name	: RSD	Data Acquisition Time	: 6/29/2018 11:15:00 AM
Instrument Name	: HPLC	Channel	: A
Rack/Vial	: 0/1	Operator	: ams
Sample Amount	: 1.000000	Dilution Factor	: 1.000000
Cycle	: 1		

Result File : c:\ams\data\061918\rsd-001-20180629-111607.rst
Sequence File : C:\AMS\seq\Full Calibration.seq



HPLC1

Peak #	Component Name	Time [min]	Area [uV*sec]	Height [uV]
1	caffeine	0.068	318389.94	179173.52
			318389.94	179173.52

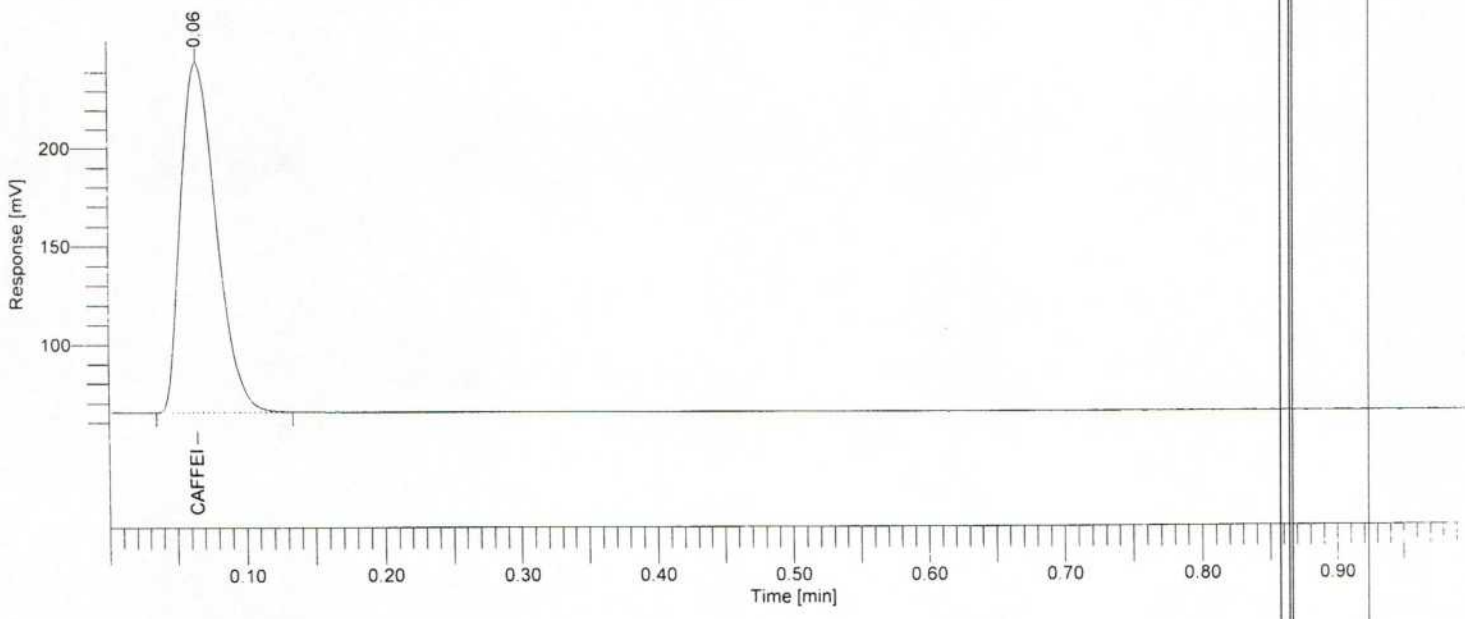
Missing Component Report

Component	Expected Retention (Calibration File)

All components were found

Software Version	: 6.3.2.0646	Date	: 6/29/2018 11:18:04 AM
Reprocess Number	: hplc: 1518		
Sample Name	: RSD		
Instrument Name	: HPLC	Data Acquisition Time	: 6/29/2018 11:16:57 AM
Rack/Vial	: 0/1	Channel	: A
Sample Amount	: 1.000000	Operator	: ams
Cycle	: 2	Dilution Factor	: 1.000000

Result File : c:\ams\data\061918\rsd-002-20180629-111804.rst
Sequence File : C:\AMS\seq\Full Calibration.seq



HPLC1

Peak #	Component Name	Time [min]	Area [uV*sec]	Height [uV]
1	caffeine	0.065	320876.23	180344.41
			320876.23	180344.41

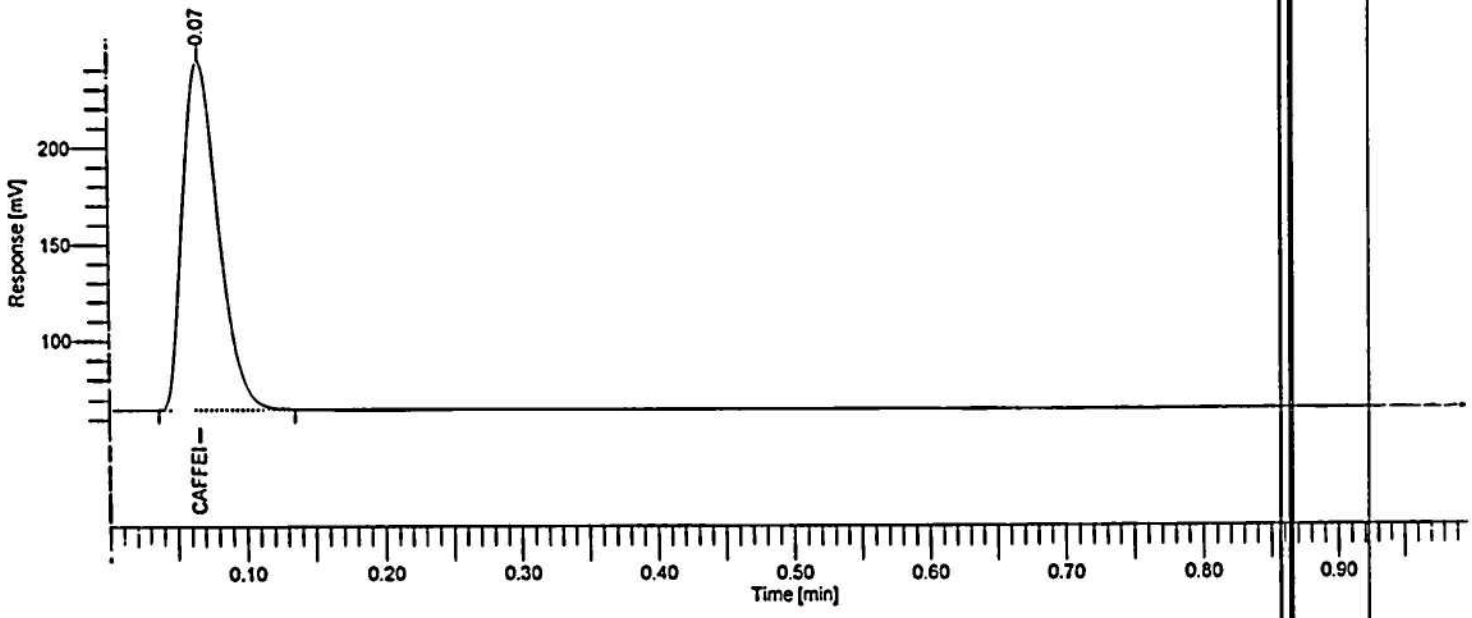
Missing Component Report

Component	Expected Retention (Calibration File)

All components were found

Software Version	: 6.3.2.0646	Date	: 6/29/2018 11:20:01 AM
Reprocess Number	: hplc: 1519		
Sample Name	: RSD	Data Acquisition Time	: 6/29/2018 11:18:53 AM
Instrument Name	: HPLC	Channel	: A
Rack/Vial	: 0/1	Operator	: ams
Sample Amount	: 1.000000	Dilution Factor	: 1.000000
Cycle	: 3		

Result File : c:\ams\data\061918\rsd-003-20180629-112000.rst
Sequence File : C:\AMS\seq\Full Calibration.seq



HPLC1

Peak #	Component Name	Time [min]	Area [uV*sec]	Height [uV]
1	caffeine	0.066	319591.53	179814.57
			319591.53	179814.57

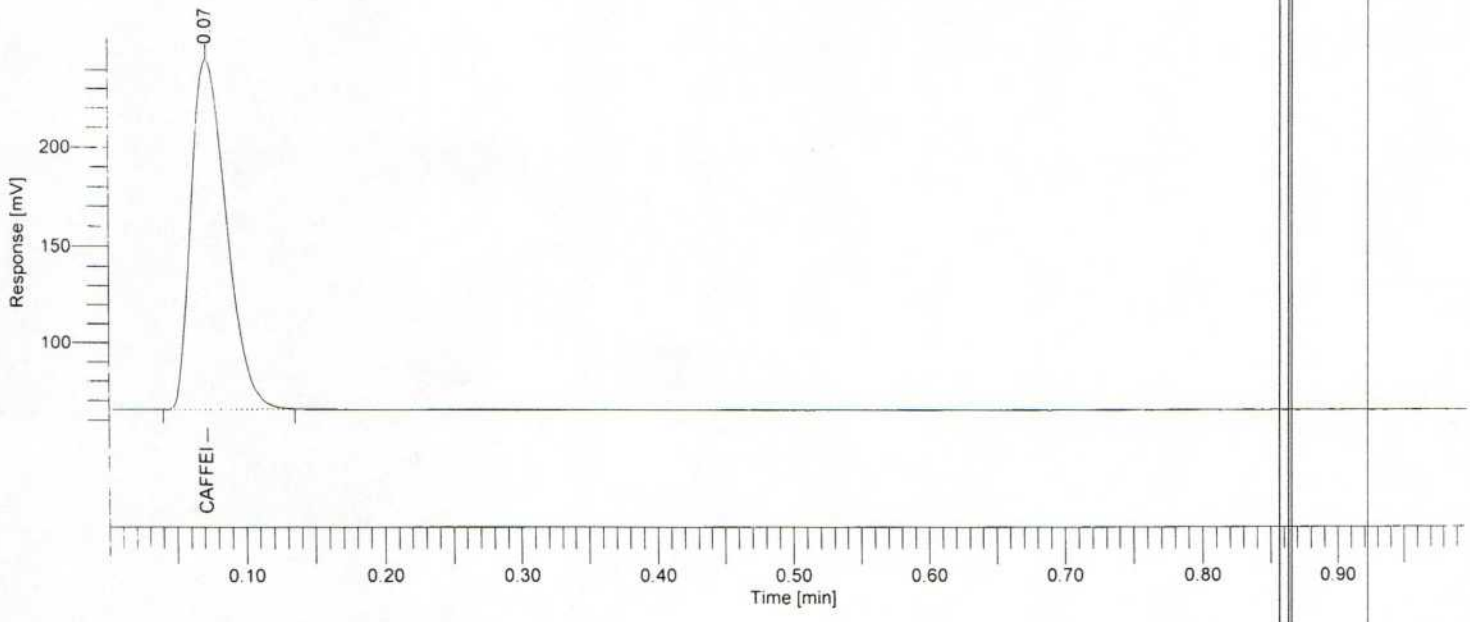
Missing Component Report

Component	Expected Retention (Calibration File)

All components were found

Software Version	: 6.3.2.0646	Date	: 6/29/2018 11:23:52 AM
Reprocess Number	: hplc: 1521		
Sample Name	: RSD		
Instrument Name	: HPLC	Data Acquisition Time	: 6/29/2018 11:22:44 AM
Rack/Vial	: 0/1	Channel	: A
Sample Amount	: 1.000000	Operator	: ams
Cycle	: 5	Dilution Factor	: 1.000000

Result File : c:\ams\data\061918\rsd-005.rst
Sequence File : C:\AMS\seq\Full Calibration.seq



HPLC1

Peak #	Component Name	Time [min]	Area [uV*sec]	Height [uV]
1	caffeine	0.072	319464.86	180156.08
			319464.86	180156.08

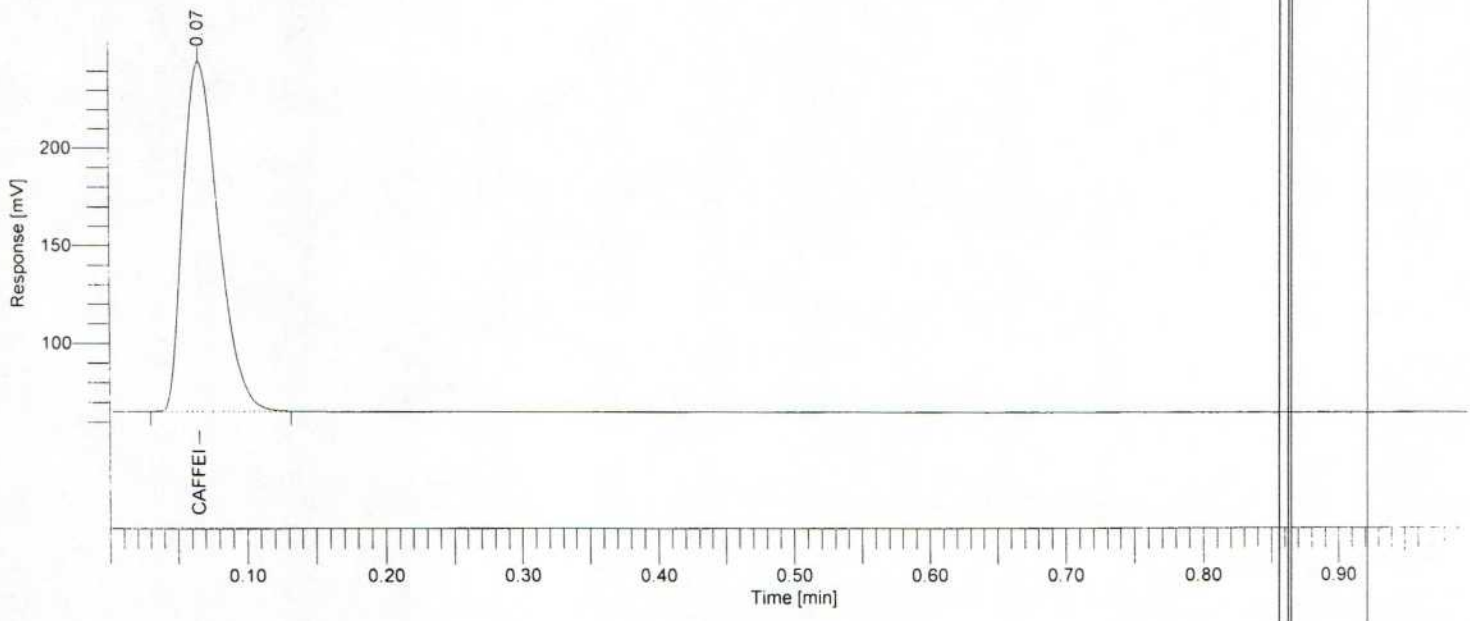
Missing Component Report

Component	Expected Retention (Calibration File)

All components were found

Software Version	: 6.3.2.0646	Date	: 6/29/2018 11:25:49 AM
Reprocess Number	: hplc: 1522		
Sample Name	: RSD		
Instrument Name	: HPLC	Data Acquisition Time	: 6/29/2018 11:24:41 AM
Rack/Vial	: 0/1	Channel	: A
Sample Amount	: 1.000000	Operator	: ams
Cycle	: 6	Dilution Factor	: 1.000000

Result File : c:\ams\data\061918\rsd-006.rst
Sequence File : C:\AMS\seq\Full Calibration.seq



HPLC1

Peak #	Component Name	Time [min]	Area [uV*sec]	Height [uV]
1	caffeine	0.066	319005.87	179921.34
			319005.87	179921.34

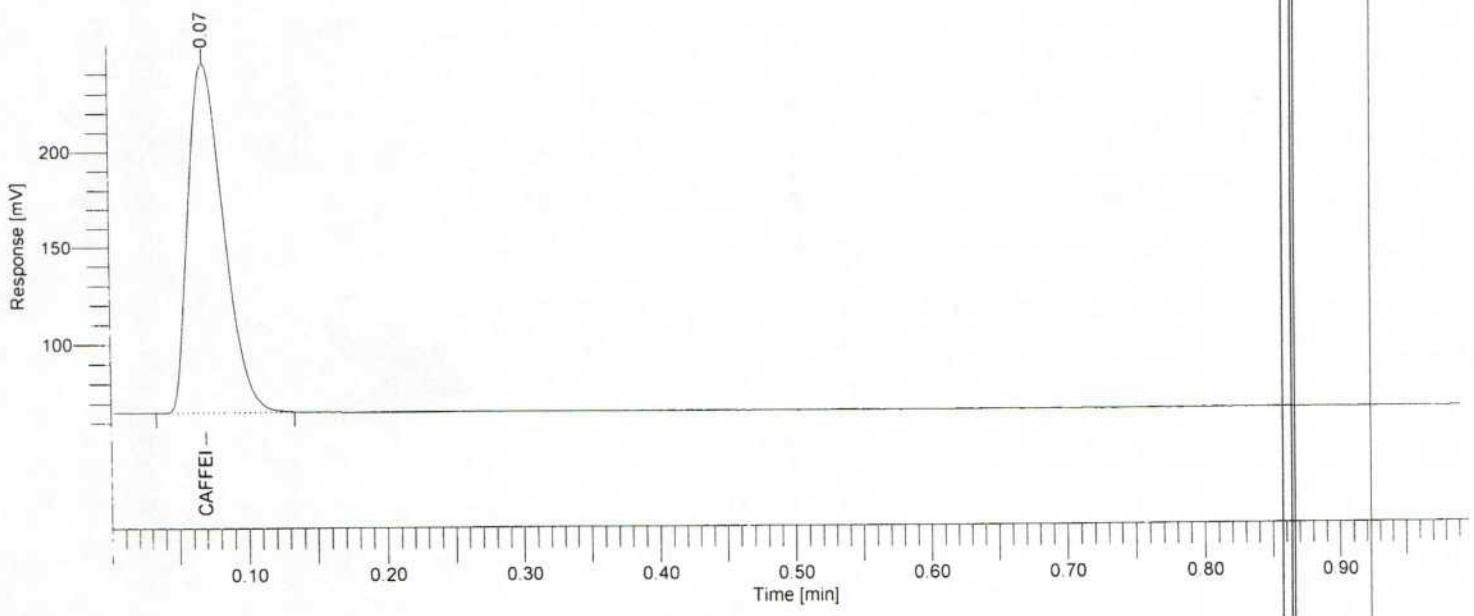
Missing Component Report

Component	Expected Retention (Calibration File)

All components were found

Software Version	: 6.3.2.0646	Date	: 6/29/2018 11:29:41 AM
Reprocess Number	: hplc: 1524		
Sample Name	: RSD	Data Acquisition Time	: 6/29/2018 11:28:33 AM
Instrument Name	: HPLC	Channel	: A
Rack/Vial	: 0/1	Operator	: ams
Sample Amount	: 1.000000	Dilution Factor	: 1.000000
Cycle	: 8		

Result File : c:\ams\data\061918\rsd-008.rst
Sequence File : C:\AMS\seq\Full Calibration.seq



HPLC1

Peak #	Component Name	Time [min]	Area [uV*sec]	Height [uV]
1	caffeine	0.070	319836.30	180316.81
			319836.30	180316.81

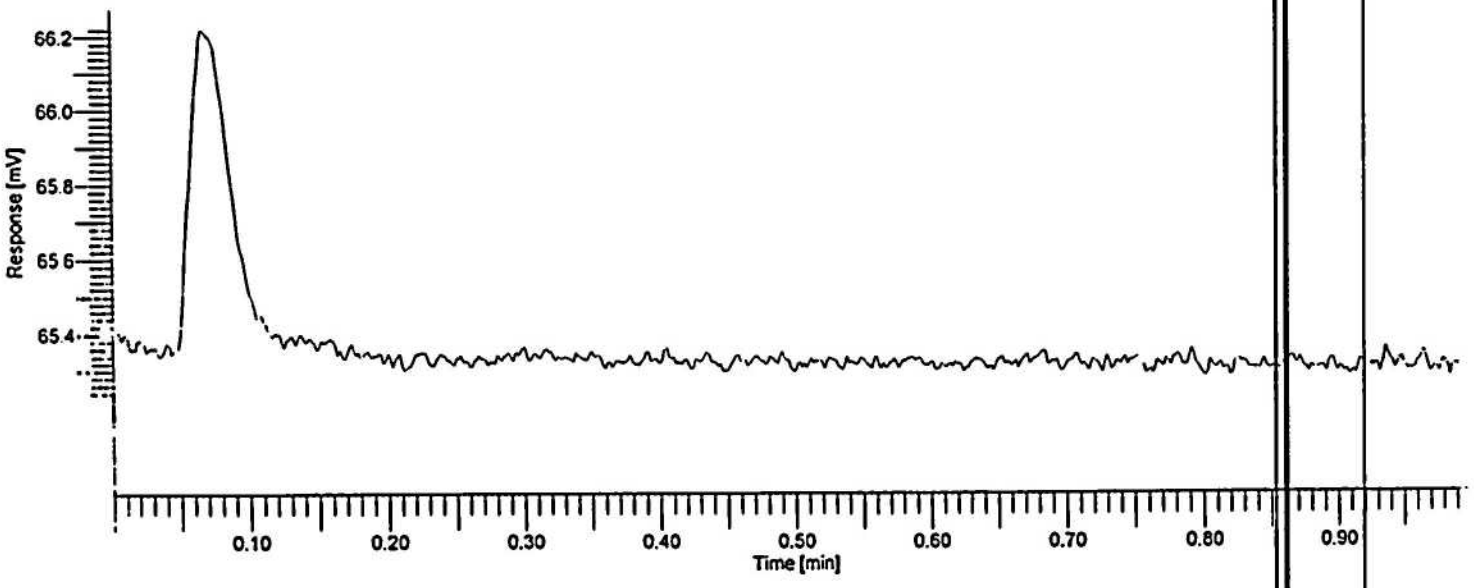
Missing Component Report

Component	Expected Retention (Calibration File)

All components were found

Software Version	: 6.3.2.0646	Date	: 6/29/2018 11:43:13 AM
Reprocess Number	: hplc: 1531		
Sample Name	: CO	Data Acquisition Time	: 6/29/2018 11:42:04 AM
Instrument Name	: HPLC	Channel	: A
Rack/Vial	: 0/2	Operator	: ams
Sample Amount	: 1.000000	Dilution Factor	: 1.000000
Cycle	: 15		

Result File : c:\ams\data\06191CO-015.rst
Sequence File : C:\AMS\seq\Full Calibration.seq



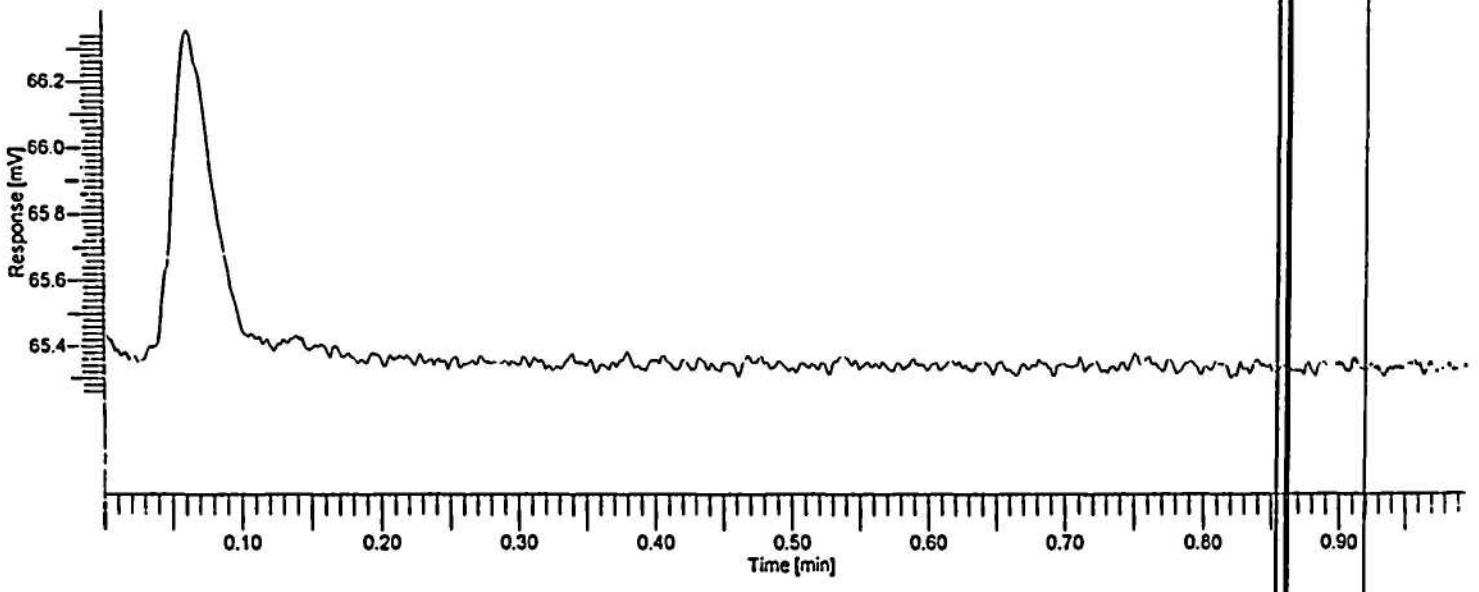
HPLC1

No peaks available to report
Missing Component Report

Component	Expected Retention (Calibration File)
caffeine	0.073

Software Version	: 6.3.2.0646	Date	: 6/29/2018 11:31:37 AM
Reprocess Number	: hplc: 1525		
Sample Name	: Blank	Data Acquisition Time	: 6/29/2018 11:30:29 AM
Instrument Name	: HPLC	Channel	: A
Rack/Vial	: 0/2	Operator	: ams
Sample Amount	: 1.000000	Dilution Factor	: 1.000000
Cycle	: 9		

Result File : c:\ams\data\061918\Blank-009.rst
Sequence File : C:\AMS\seq\Full Calibration.seq



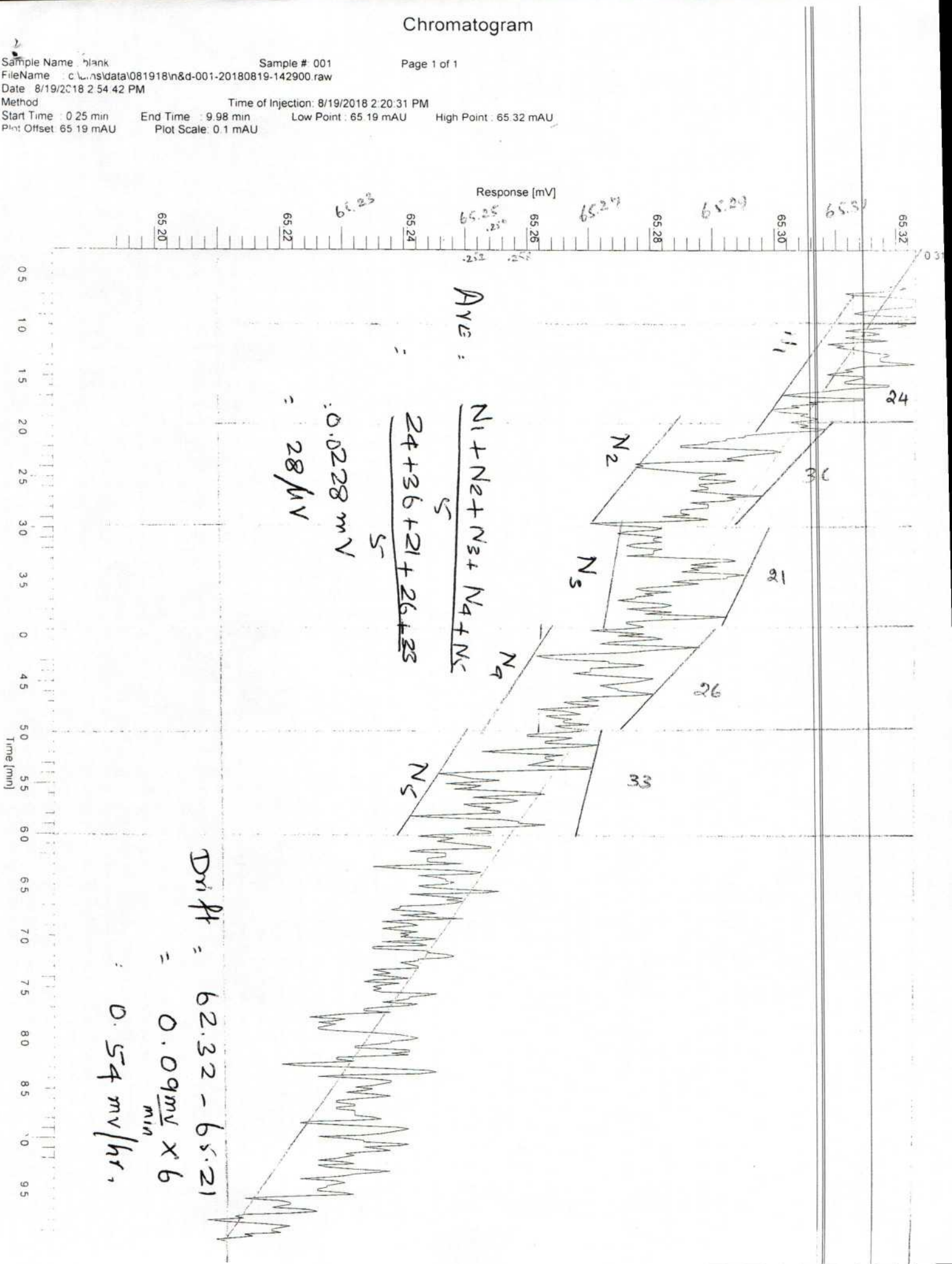
HPLC1

No peaks available to report
Missing Component Report

Component	Expected Retention (Calibration File)
caffeine	0.073

Chromatogram

Sample Name : blank Sample # : 001 Page 1 of 1
FileName : c:\...ns\data\081918\n&d-001-20180819-142900.raw
Date : 8/19/2018 2:54:42 PM
Method Time of Injection: 8/19/2018 2:20:31 PM
Start Time : 0.25 min End Time : 9.98 min Low Point : 65.19 mAU High Point : 65.32 mAU
Plot Offset: 65.19 mAU Plot Scale: 0.1 mAU



$$\text{Ave} = \frac{N_1 + N_2 + N_3 + N_4 + N_5}{5} = \frac{24 + 36 + 21 + 26 + 33}{5}$$

$$= 0.0228\ \text{mV}$$

$$= 28\ \mu\text{V}$$

$$\text{Drift} = 62.32 - 65.21 = 0.09\ \frac{\text{mV}}{\text{min}} \times 6$$

$$= 0.54\ \text{mV/hr.}$$

Software Version	: 6.3.2.0646	Date	: 8/19/2018 2:30:30 PM
Reprocess Number	: hplc: 1599		
Operator	: manager		
Sample Number	: 001	Sample Name	: blank
AutoSampler	: SER200	Study	: nosiedrift
Instrument Name	: HPLC	Rack/Vial	: 0/1
Instrument Serial #	: None	Channel	: A
Delay Time	: 0.00 min	A/D mV Range	: 1000
Sampling Rate	: 1.0000 pts/s	End Time	: 9.98 min
Sample Volume	: 1.000000 ul		
Sample Amount	: 1.0000	Area Reject	: 0.000000
Data Acquisition Time	: 8/19/2018 2:20:31 PM	Dilution Factor	: 1.00
		Cycle	: 2

Raw Data File : c:\ams\data\081918\n&d-001-20180819-142900.raw
Result File : c:\ams\data\081918\n&d-001-20180819-143029.rst
Inst Method : C:\AMS\meth\noisedrift from c:\ams\data\081918\n&d-001-20180819-142900.raw
Proc Method : C:\AMS\meth\noisedrift from c:\ams\data\081918\n&d-001-20180819-143029.rst
Calib Method : C:\AMS\meth\noisedrift from c:\ams\data\081918\n&d-001-20180819-143029.rst
Report Format File: C:\AMS\meth\noisedrift.rpt
Sequence File : C:\AMS\seq\noisedrift.seq

DEFAULT REPORT

Peak #	Time [min]	Area [µV·s]	Height [µV]	Area [%]	Norm. Area [%]	BL	Area/Height [s]
1	0.152	1118.16	205.83	67.62	67.62	BV	5.4324
2	0.306	535.33	67.78	32.38	32.38	VB	7.8986
		1653.49	273.61	100.00	100.00		

Missing Component Report

Component	Expected Retention (Calibration File)

All components were found

HYBRID PHARMA

Performance Certification of an HPLC UV Detector

Test Report

Attachment 1 (Cont.)

Wavelength Verification (UV)

Wavelength	Peak Area	Wavelength	Peak Area
202nm	786745	270nm	311617
203nm	812817	271nm	311254
204nm	839442	272nm	316153
205nm	885088	273nm	322885
206nm	876657	274nm	324610
207nm	873310	275nm	325443
208nm	867719	276nm	325312

Lambda Max. UV

Lambda Max. UV		Performance	Pass/Fail
205	(nm)	205 +/–2 (nm)	Pass
275	(nm)	273 +/–2 (nm)	Pass

Noise

Lambda Max. UV		Performance	Pass/Fail
25	(µV)	≤50 (µV)	Pass
	(µAU)	≤50(µAU)	

Drift

Lambda Max. UV		Performance	Pass/Fail
0.54	(mV/hr)	≤0.60 (mV/hr)	Pass.
	(mAU/hr)	≤0.60 (mAU/hr)	

Performance Certification of an HPLC Autosampler

Test Report

Attachment 1 (Cont.)

Test Materials and Test Equipment Certification

Material	Preparation Reference	Lot Number	Expiration Date
Caffeine Standard	RESTEK - 31804 HPLC QC Linearity Test mixture	A0124503	1/2020

Performance Certification of an HPLC UV Autosampler

Test Report

Attachment 1 (Cont.)

Notes

Performance Certification of an HPLC Autosampler

Test Report

Attachment 1 (Cont.)

Reproducibility Test

Injection	Area
1	318389.94
2	320876.23
3	319591.53
4	319464.86
5	319005.87
6	319836.30
%RSD	0.5%
Performance ≤0.5%	PASS/FAIL

Linearity Test

Injection	Volume	Area
1	50 µl Blank	0.00
2	10 µl Caffeine	239982
3	20 µl Caffeine	503123
4	30 µl Caffeine	769397
5	40 µl Caffeine	1034511
6	50 µl Caffeine	1391695
7	50 µl Blank	0.00
Correlation Coefficient (r^2)		0.999763
Performance ≥ 0.9990		PASS/FAIL
Carryover		0.00%
Performance ≤0.10%		PASS/FAIL

Performance Certification of an HPLC Autosampler

Test Report

Attachment 1 (Cont.)

Documentation attached to this report

Documentation Type	Pages
Reproducibility test reports	
Linearity and carryover test reports	

(HYBRID PHARMA) STANDARD TESTING PROCEDURE

Calibration and Performance Maintenance of HPLC, Perkin-Elmer-200

Test Procedures for the Performance Certification of an HPLC Autosampler

1.0 PURPOSE

1.1 The purpose of this procedure is to document in detail the test methods used to verify the performance and function of a HPLC Auto-sampler.

2.0 SCOPE

2.1 This test procedure will be performed at suitable intervals in accordance with an established programs and is designed to ensure the operation of the instrument in accordance with its intended use. The instrument will be tested as a part of the complete system defined by the client.

3.0 REFERENCE DOCUMENTS

3.1 21 CFR 211 Subpart I 211.160

3.2 Autosampler Users Manual (manufacturer specific)

3.3 Test Report Attachment 1

4.0 TEST MATERIALS AND TEST EQUIPMENT

4.1 25 mg Caffeine/Liter H2O

4.2 Mobile Phase (DI water)

4.3 Restrictor – 0.007" OR 0.010" ID PEEK Tubing (5 meter length)

5.0 PROCEDURE

5.1 Using the Component Identification form in Attachment 1, document the following information:

- § Engineer's Name
- § Certification Date
- § Recertification Due Date
- § System ID Number
- § Instrument Location
- § Component Make, Model and Serial Number

5.2 Using the Test Materials and Test Equipment Certification form in Attachment 1, document the applicable information for all test materials and test equipment used.

5.3 To verify the Reproducibility of the HPLC Auto-sampler, set up the instrument as stated below:

5.3.1 Connect the restrictor tubing in place of the column.

5.3.2 Mobile Phase (DI water)

5.3.3 Set flow rate to 2.0 mL/min and prime the unit.

5.3.4 Set the detector wavelength to 273 nm or closest possible.

5.3.5 Configure the system for a 1.0 minute data collection run with an appropriate sampling rate.

5.3.6 Using a sample injection volume of 10µl, make 8 injections (two conditioners and 6 rsds) of the test solution. Calculate the % RSD, based on the peak area of the last 6 consecutive injections.

Example: $$\%\text{RSD} = \frac{Standard\ Deviation}{Average\ Area} \times 100$$

5.3.7 Record the %RSD of the peak areas in Attachment 1.

5.4 To verify Linearity and Carryover using a Variable Injection Autosampler, the system configuration will remain the same as in step 6.3 but the autosampler will be configured to make the following injections:

Solution	Blank 1	Test Solution (Caffeine 25mg/L)					Blank 2
Injection volume	50 µl	10 µl	20 µl	30 µl	40 µl	50 µl	50 µl

5.4.1 Report the peak areas and calculate the correlation coefficient of the test solution injections (r^2) in Attachment 1.

5.4.2 Calculate the carryover by dividing the peak are of Blank 2 Minus the peak area of Blank 1 by the peak area of the 50 µl caffeine sample.

Example: $$\frac{[(\text{area of Blank 2} - \text{area of Blank 1})]}{(\text{Area of 50 µl Caffeine})} \times 100$$

5.4.3 Report the % carryover results in Attachment 1.

6.0 HISTORY

STP HISTORY

REVISION NUMBER	CHANGE/REASON
1	Updated to change Integrator to A/D interface. Changed Data to Documentation attached to this report and included list of documentation to be included.
2	Clarification of calculation for Lincarity and Carryover (section 6.3). Should be Blank 1 and 2 not Mobile Phase 1 and 2.
3	Updated to add incorporated to company's name.
4	Delete "Prepared" on Approval page.
5	Updated Scope to include the statement that "The instrument will be tested as part of the complete system defined by the client." and to eliminate repetitive documentation of system components in Attachment 1. Addition of statement for documentation of Test Materials and Test Equipment.
6	Section 5.1 changed 25mg/Liter Caffeine to: 25 mg Caffeine/Liter H_20. Section 5.3 deleted. Section 5.3 changed 0.007 ID PEEK to: 0.007" OR 0.010" ID Peek Section 6.3.6 changed 6 test solution injections to:10 test solution injections, deleted "Report the peak areas and" and completed the section with: Calculate the % RSD, based on peak area of 6 consecutive injections. Added section 6.3.7: Report the areas and % RSD on Attachment 1.
7	Section 6.3.5 changed to more generic data handling criteria. 6.3.6 changed to two conditioners and 6 rsd standards
8	The following disclaimer was added to the front page of this document: This document is the proprietary property of AMS, Inc.. No part of this document may be reproduced in any form whatsoever, or translated into any language, without the prior, written approval of AMS. The CUSTOMER acknowledges and understands that nothing contained herein shall be construed as conveying title of this document to the CUSTOMER. The CUSTOMER is granted a non-transferable, non-exclusive right to use this document, supplied by AMS, as necessary for archive or backup purposes only. Further, the CUSTOMER agrees to hold this document in confidence and shall not disclose any part of it, except to its employees to whom disclosure is necessary for use, or as required by regulatory agencies to whom disclosure is necessary for their review. Any comments about this document shall be addressed to AMS, Inc.
9	Reviewed but no change.

Performance Certification of an HPLC Pump

Test Report

Attachment 1

Component Identification

Qualifying Engineer	
Certification Date	06/18/2018
Recertification Period	12 months
Recertification Due Date	06/18
System ID Number	HPLC #1
Instrument Location	QC LAB

Component	Make	Model	Serial Number
Injector	Perkin Elmer	Series 200	293N0013003

95, 96a

HYBRID PHARMA SOP

Title: Assessing Cleaning and Disinfection Procedures: FORM

Cleaning and Disinfection Practices:

The qualified evaluator will mark (×) each space for which the person being assessed has acceptably completed the described activity, prints N/A if the activity is not applicable to the assessment session or N/O if the activity was not observed.

Daily Tasks:

	Sterile ✓ Peridox RTU
Prepares correct concentration of disinfectant solution according to Hybrid Pharma's SOP instructions.	
Uses appropriately labeled container for the dilution of the disinfectant.	N/A
Documents disinfectant solution preparation.	N/A
Follows garbing procedures when performing any cleaning activities.	✓
At the beginning of each shift, cleans all ISO Class 5 devices prior to compounding in the following order: walls, and work surface.	✓
Uses a lint free wipe soaked with sterile 70% IPA or other approved disinfectant solution and allows to dry completely.	✓
Removes all compounder components and cleans all ISO Class 5 areas as stated above at the end of each shift.	✓
Cleans all counters and easily cleanable work surfaces/ counters.	✓
Mops floors, using the mop, starting at the wall opposite the room entry door; mops floor surface in even strokes toward the operator. Moves carts as needed to clean entire floor surface. Use of a microfiber cleaning system is an acceptable alternative to mops.	✓
In the preparation/ staging room, cleans sink and all contact surfaces; cleans floor with a disinfectant solution or uses microfiber cleaning system.	✓

The person assessed is immediately informed of all unacceptable activities (i.e., spaces lacking a Check marks, N/A and shown and informed of specific corrections.

Signature of Person Assessed --- Uma. Date 4/12/19
Printed Name
Signature of Qualified Evaluator --- Maureen Bradley Date 4/12/19.
Printed Name

Title: Assessing Cleaning and Disinfection Procedures: FORM

The qualified evaluator will mark (×) each space for which the person being assessed has acceptably completed the described activity, prints N/A if the activity is not applicable to the assessment session or N/O if the activity was not observed.

Monthly Tasks:

Performs monthly cleaning on a designated week. Prepares a disinfectant solution as stated in approved list at Hybrid Pharma that is appropriate for the surfaces to be cleaned.	✓
Cleans buffer area and ante-area ceiling, walls, and storage shelving with a disinfectant solution and a mop or uses a microfiber cleaning system.	✓
Once ISO Class 5 area is clean, cleans compounding room ceiling, followed by walls and ending with the floor. Uses appropriate labeled mops or microfiber cleaning system.	✓
Cleans all buffer area storage shelves by removing contents and using a germicidal detergent soaked lint free wipes. Allows to dry prior to replacing contents , wipes with sterile 70% IPA to remove disinfectant residue. Uses new wipe as needed.	✓
Cleans all buffer area carts by removing contents and using germicidal detergent soaked lint free wipe, cleans all carts starting with the top shelf and top of post, working down to wheels. Cleans the under side of shelves in a similar manner. Uses a new wipe for each cart. Allows to dry. Wipes carts with sterile 70% IPA wetted lint-free wipe to remove any disinfectant residue. Uses new wipe as needed.	✓
Cleans buffer area chairs, the interior and exterior of trash bins, and storage bins using disinfectant solution soaked lint free wipe.	✓
Documents all cleaning activities as to who performed such activities with date noted.	✓

The person assessed is immediately informed of all unacceptable activities (i.e., spaces lacking a Check marks, N/A and shown and informed of specific corrections.

Signature of Person Assessed ---------- Uma - Date 4/12/19.
Printed Name
Signature of Qualified Evaluator ---------- Maureen Bradley Date 4/12/19.
Printed Name

97 a Title: **Assessing Hand Hygiene and Garbing Related Practices of Compounding Personnel Form**

Hand Hygiene and Garbing Practices: The qualified evaluator will mark (x) each space for which the person being assessed has acceptably completed the described activity, prints N/A if the activity is not applicable to the assessment session or N/O if the activity was not observed.

Printed name and position/ title of person assessed: Uma

The person assessed is immediately informed of all unacceptable activities (i.e., spaces lacking a Check marks, N/A, or N/O) and shown and informed of specific corrections.

Signature of Evaluator Noreen Leach Date: 4/5/19.

Signature of the Personnel evaluated: Date:

R. Uma 4/5/19

HYBRID PHARMA SOP

97a. Hand Hygiene and Garbing Practices: Presents in a clean appropriate attire and manner. No street jackets allowed. Remove street shoe and wear lab shoes.	✓
Wears no cosmetics or jewelry (watches, rings, earrings, etc. piercing jewelry included) upon entry into prep/ staging areas.	✓
Brings no food or drinks into or stored in the ante-areas or buffer areas.	✓
Is aware of the line of demarcation separating clean and dirty sides and observes required activities.	✓
Dons shoe covers or designated clean-area shoes one at a time, plac ing the covered or designated shoe' on clean side of the line of demarcation, as appropriate.	✓
Dons beard cover if necessary. Dons head cover assuring that all hair and ears are covered.	NA
Dons face mask to cover bridge of nose down to include chin.	
Performs hand hygiene procedure by wetting hands and forearms and washing using soap and warm water for at least 30 seconds.	✓
Dries hands and forearms using lint-free towel or hand dryer.	✓
Selects the appropriate sized gown examining for any holes, tears, or other defects. Dons gown and ensures full closure.	✓
Disinfects hands again using a waterless alcohol-based surgical hand scrub with persistent activity and allows hands to dry thoroughly. before donning sterile gloves	✓
Dons appropriate sized sterile gloves ensuring that there is a tight fit with no excess glove material at the fingertips.	✓
in the direct compounding area (DCA) and after touching items or surfaces that may contaminate gloves.	✓
Removes PPE on the clean side of the ante-area. Removes gloves and performs hand hygiene.	✓
Removes gown and discards it, or hangs it on hook if it is to be reused within the same work day.	✓
Removes and discards mask, head cover, and beard cover (if used).	✓
Removes shoe covers or shoe one at a time, ensuring that uncovered foot is placed on the dirty side of the line of demarcation.	✓

HYBRID PHARMA SOP

Title: Assessing Cleaning and Disinfection Procedures: FORM 96a

Cleaning and Disinfection Practices:

The qualified evaluator will mark (×) each space for which the person being assessed has acceptably completed the described activity, prints N/A if the activity is not applicable to the assessment session or N/O if the activity was not observed.

Daily Tasks:

Prepares correct concentration of disinfectant solution according to Hybrid Pharma's SOP instructions.	✓
Uses appropriately labeled container for the dilution of the disinfectant.	✓
Documents disinfectant solution preparation.	✓
Follows garbing procedures when performing any cleaning activities.	✓
At the beginning of each shift, cleans all ISO Class 5 devices prior to compounding in the following order: walls, and work surface.	✓
Uses a lint free wipe soaked with sterile 70% IPA or other approved disinfectant solution and allows to dry completely.	✓
Removes all compounder components and cleans all ISO Class 5 areas as stated above at the end of each shift.	✓
Cleans all counters and easily cleanable work surfaces/ counters.	✓
Mops floors, using the mop, starting at the wall opposite the room entry door; mops floor surface in even strokes toward the operator. Moves carts as needed to clean entire floor surface. Use of a microfiber cleaning system is an acceptable alternative to mops.	✓
In the preparation/ staging room, cleans sink and all contact surfaces; cleans floor with a disinfectant solution or uses microfiber cleaning system.	✓

The person assessed is immediately informed of all unacceptable activities (i.e., spaces lacking a Check marks, N/A and shown and informed of specific corrections.

Signature of Person Assessed ----- R. Ulma Date 8/24/18
Printed Name
Signature of Qualified Evaluator ----- Date 8/24/18
Printed Name Jeff Goldich

APPROVED BY

HYBRID PHARMA SOP

Title: Assessing Cleaning and Disinfection Procedures: FORM 96b

The qualified evaluator will mark (×) each space for which the person being assessed has acceptably completed the described activity, prints N/A if the activity is not applicable to the assessment session or N/O if the activity was not observed.

Monthly Tasks:

Performs monthly cleaning on a designated week. Prepares a disinfectant solution as stated in approved list at Hybrid Pharma that is appropriate for the surfaces to be cleaned.	✓
Cleans buffer area and ante-area ceiling, walls, and storage shelving with a disinfectant solution and a mop or uses a microfiber cleaning system.	✓
Once ISO Class 5 area is clean, cleans compounding room ceiling, followed by walls and ending with the floor. Uses appropriate labeled mops or microfiber cleaning system.	✓
Cleans all buffer area storage shelves by removing contents and using a germicidal detergent soaked lint free wipes. Allows to dry prior to replacing contents , wipes with sterile 70% IPA to remove disinfectant residue. Uses new wipe as needed.	✓
Cleans all buffer area carts by removing contents and using germicidal detergent soaked lint free wipe, cleans all carts starting with the top shelf and top of post, working down to wheels. Cleans the under side of shelves in a similar manner. Uses a new wipe for each cart. Allows to dry. Wipes carts with sterile 70% IPA wetted lint-free wipe to remove any disinfectant residue. Uses new wipe as needed.	✓
Cleans buffer area chairs, the interior and exterior of trash bins, and storage bins using disinfectant solution soaked lint free wipe.	✓
Documents all cleaning activities as to who performed such activities with date noted.	✓

The person assessed is immediately informed of all unacceptable activities (i.e., spaces lacking a Check marks, N/A and shown and informed of specific corrections.

Signature of Person Assessed R. Uma Date 8/24/18
Printed Name
Signature of Qualified Evaluator ---- Date 8/24/18
Printed Name Jeff Goldrich

APPROVED BY

97 a Title: **Assessing Hand Hygiene and Garbing Related Practices of Compounding Personnel Form**

Hand Hygiene and Garbing Practices: The qualified evaluator will mark (x) each space for which the person being assessed has acceptably completed the described activity, prints N/A if the activity is not applicable to the assessment session or N/ O if the activity was not observed.

Printed name and position/title of person assessed: ----------

The person assessed is immediately informed of all unacceptable activities (i.e., spaces lacking a Check marks, N/A, or N/O) and shown and informed of specific corrections.

Signature of Evaluator [signature] Date: 8/24/18

Signature of the Personnel evaluated: UMA B Date: 8/24/18

APPROVED BY DATE:

HYBRID PHARMA SOP

97a. Hand Hygiene and Garbing Practices: Presents in a clean appropriate attire and manner. No street jackets allowed. Remove street shoe and wear lab shoes.	✓
Wears no cosmetics or jewelry (watches, rings, earrings, etc. piercing jewelry included) upon entry into prep/ staging areas.	✓
Brings no food or drinks into or stored in the ante-areas or buffer areas.	✓
Is aware of the line of demarcation separating clean and dirty sides and observes required activities.	✓
Dons shoe covers or designated clean-area shoes one at a time, placing the covered or designated shoe on clean side of the line of demarcation, as appropriate.	✓
Dons beard NA cover if necessary. Dons head cover assuring that all hair and ears are covered.	✓
Dons face mask to cover bridge of nose down to include chin.	✓
Performs hand hygiene procedure by wetting hands and forearms and washing using soap and warm water for at least 30 seconds.	✓
Dries hands and forearms using lint-free towel or hand dryer.	✓
Selects the appropriate sized gown examining for any holes, tears, or other defects. Dons gown and ensures full closure.	✓
Disinfects hands again using a waterless alcohol-based surgical hand scrub with persistent activity and allows hands to dry thoroughly. before donning sterile gloves	✓
Dons appropriate sized sterile gloves ensuring that there is a tight fit with no excess glove material at the fingertips.	✓
in the direct compounding area (DCA) and after touching items or surfaces that may contaminate gloves.	✓
Removes PPE on the clean side of the ante-area. Removes gloves and performs hand hygiene.	✓
Removes gown and discards it, or hangs it on hook if it is to be reused within the same work day.	✓
Removes and discards mask, head cover, and beard cover (if used).	✓
Removes shoe covers or shoe one at a time, ensuring that uncovered foot is placed on the dirty side of the line of demarcation.	✓

APPROVED BY [signature]

DATE: 8/24/18

SOP 90A_REV1. STANDARD OPERATING PROCEDURE: CLEANROOM ENTRY and EGRESS

CLEANROOM ENTRY:

1. Any item brought into the cleanroom must be thoroughly wiped down with an approved cleanroom wipes and solution such as alcohol (IPA) and Distilled water.

2. Seek approval before bringing tool boxes including contents, chemicals, Instruments, etc. into cleanroom. Wipe down completely before entry.

3. All supplies must enter the cleanroom either through the (a) gowning area and wipe using Lint Free Wipes.

4. Unbox equipment, parts, etc. and remove **packaging BEFORE** bringing them into the cleanroom.

5. Keep wood, pencils, cardboard, non-cleanroom rated paper, or materials that generate particulates out of the cleanroom.

6. Poly bags / Clean and Dried with IPA moist wipes Sterilite Storage containers may be employed for carrying essential items for PROCESSING into the cleanroom.

CLEANROOM ACTIVITY

1. Refrain from excess talking or shouting
2. **Activity - Do not:**

a. run or make fast movements
b. touch, rub, or scratch scalp, skin, hair, or eyes
c. write on walls, gloves, equipment, or garments
d. use a cell phone (unless an emergency)
e. use duct tape
f. Sand, drill, file, or weld

3. Apparel – **Do not**

a. remove any piece of cleanroom apparel
b. remove articles from underneath cleanroom garment
c.wear

(i) garments that shed lint or fibers; (ii) contaminated, soiled, or torn cleanroom garments; (iii) shorts, midriff tops, tank tops, or hats;
(iv) open-toe shoes, sandals, or fabric-covered shoes;

and (v) any jewelry if it will compromise safety attire or interfere with cleanroom activities

d. Do not **re-use disposable gloves**

4. Do not prepare or consume food or drink.

5. Do not wear or apply cosmetics.

6. Do not wear contact lenses.

7. Do not work in the cleanroom if coughing or sneezing.

CLEANROOM EGRESS

1. Enter gowning/control area to remove gowning. Discard gloves in a labeled trash can.

2. Remove articles in reverse order i.e., safety glasses/splash goggles, boots, arm sleeves (optional), coveralls, and hood. Exit control area.

3. Place reusable garments, hood, boots, arm covers (optional), and coverall on a hanger.

4. Exit the cleanroom /Ante Room zoning.

5. Remove shoe covers and hairnet.

SOP 90_REV1. STANDARD OPERATING PROCEDURE: GOWNING PROCEDURE ISO 5 through ISO 7 and 8

PURPOSE: Ensure that personnel protective equipment is worn at all times while in the cleanroom. To keep gowning area clean and adhere to cleanroom safety policies at all times.

GOWNING PROCEDURE:

1. Ensure that all **jewelry (including rings and watches) is removed before** entering into Gowning area /Prep Room and cover with protective wear and does not interfere with work.

2. Always **remove your street shoes and wear the assigned indoor clean room shoe before** entering into Staging /Prep room. Street shoes are strictly not allowed in the Prep Room. Then, put on shoe covers (booties) one foot at a time and hairnet/ haircover. Step on tacky mat with both feet and enter gowning area.

3. Follow Hand washing Procedure:
   Wash with antibacterial soap and warm water. Then scrub with microbicide Iodine solution and scrub. Wash thoroughly your both forearms, fingers, fingernails with plenty of water and disposable nail pick. Dry with lint-free Wipers. Sterilize with 70% IPA.

4. Continue to put on:
   bouffant cap or hood;
   facemask (Class 10 to Class 100).

NOTE: Ensure no gaps around nose or mouth ; and coveralls (or frock/lab coat).
Ensure that bouffant cap or hood **covers hair and ears completely.**

NOTE: **Take care not to tear garment.** If any tear occurs, remove garment and replace immediately with a new one.

5. Step over gowning section to controlled area/Ante Room . Put on the following:

1. Boots; tuck coverall legs into boots
2. Pair of gloves (to be worn over the sleeves of the coverall)
3. Wear safety glasses/splash goggles..
6. It is recommended to change garments (bouffant cap or hood; facemask; boots; arm sleeves, if applicable; and coveralls or frock/lab coat) **daily.**
7. If garments are heavily soiled or damaged then replace immediately. Garments may be changed at a higher frequency if specified by the

Supervisor.

a. It is recommended that gloves be changed at least once per work session/ between different batches/any sign of damaged/holes/contamination following a spill clean up.

b. **Disinfect gloves**

- prior to entering an aseptic area,
- regularly during operations, and
- before contact with an aseptically gowned person.

95, 96a

HYBRID PHARMA SOP

Title: Assessing Cleaning and Disinfection Procedures: FORM

Cleaning and Disinfection Practices:

The qualified evaluator will mark (×) each space for which the person being assessed has acceptably completed the described activity, prints N/A if the activity is not applicable to the assessment session or N/O if the activity was not observed.

Daily Tasks:

Prepares correct concentration of disinfectant solution according to Hybrid Pharma's SOP instructions.	Sterile ✓ Peridox RTU
Uses appropriately labeled container for the dilution of the disinfectant.	N/A
Documents disinfectant solution preparation.	N/A
Follows garbing procedures when performing any cleaning activities.	✓
At the beginning of each shift, cleans all ISO Class 5 devices prior to compounding in the following order: walls, and work surface.	✓
Uses a lint free wipe soaked with sterile 70% IPA or other approved disinfectant solution and allows to dry completely.	✓
Removes all compounder components and cleans all ISO Class 5 areas as stated above at the end of each shift.	✓
Cleans all counters and easily cleanable work surfaces/ counters.	✓
Mops floors, using the mop, starting at the wall opposite the room entry door; mops floor surface in even strokes toward the operator. Moves carts as needed to clean entire floor surface. Use of a microfiber cleaning system is an acceptable alternative to mops.	✓
In the preparation/ staging room, cleans sink and all contact surfaces; cleans floor with a disinfectant solution or uses microfiber cleaning system.	✓

The person assessed is immediately informed of all unacceptable activities (i.e., spaces lacking a Check marks, N/A and shown and informed of specific corrections.

Signature of Person Assessed --- Uma. Date 4/12/19
Printed Name
Signature of Qualified Evaluator --- Maureen Bradley Date 4/12/19.
Printed Name

Title: Assessing Cleaning and Disinfection Procedures: FORM

The qualified evaluator will mark (×) each space for which the person being assessed has acceptably completed the described activity, prints N/A if the activity is not applicable to the assessment session or N/O if the activity was not observed.

Monthly Tasks:

Performs monthly cleaning on a designated week. Prepares a disinfectant solution as stated in approved list at Hybrid Pharma that is appropriate for the surfaces to be cleaned.	✓
Cleans buffer area and ante-area ceiling, walls, and storage shelving with a disinfectant solution and a mop or uses a microfiber cleaning system.	✓
Once ISO Class 5 area is clean, cleans compounding room ceiling, followed by walls and ending with the floor. Uses appropriate labeled mops or microfiber cleaning system.	✓
Cleans all buffer area storage shelves by removing contents and using a germicidal detergent soaked lint free wipes. Allows to dry prior to replacing contents , wipes with sterile 70% IPA to remove disinfectant residue. Uses new wipe as needed.	✓
Cleans all buffer area carts by removing contents and using germicidal detergent soaked lint free wipe, cleans all carts starting with the top shelf and top of post, working down to wheels. Cleans the under side of shelves in a similar manner. Uses a new wipe for each cart. Allows to dry. Wipes carts with sterile 70% IPA wetted lint-free wipe to remove any disinfectant residue. Uses new wipe as needed.	✓
Cleans buffer area chairs, the interior and exterior of trash bins, and storage bins using disinfectant solution soaked lint free wipe.	✓
Documents all cleaning activities as to who performed such activities with date noted.	✓

The person assessed is immediately informed of all unacceptable activities (i.e., spaces lacking a Check marks, N/A and shown and informed of specific corrections.

Signature of Person Assessed ---Uma- Date 4/12/19.
Printed Name
Signature of Qualified Evaluator Maureen Bradley Date 4/12/19.
Printed Name

HYBRID PHARMA SOP

97 a Title: **Assessing Hand Hygiene and Garbing Related Practices of Compounding Personnel Form**

Hand Hygiene and Garbing Practices: The qualified evaluator will mark (x) each space for which the person being assessed has acceptably completed the described activity, prints N/A if the activity is not applicable to the assessment session or N/O if the activity was not observed.

Printed name and position/ title of person assessed: Uma

The person assessed is immediately informed of all unacceptable activities (i.e., spaces lacking a Check marks, N/A, or N/O) and shown and informed of specific corrections.

Signature of Evaluator Noreen Leadly Date: 4/5/19.

Signature of the Personnel evaluated: R. Uma Date: 4/5/19

HYBRID PHARMA SOP

97a. Hand Hygiene and Garbing Practices: Presents in a clean appropriate attire and manner. No street jackets allowed. Remove street shoe and wear lab shoes.	✓
Wears no cosmetics or jewelry (watches, rings, earrings, etc. piercing jewelry included) upon entry into prep/ staging areas.	✓
Brings no food or drinks into or stored in the ante-areas or buffer areas.	✓
Is aware of the line of demarcation separating clean and dirty sides and observes required activities.	✓
Dons shoe covers or designated clean-area shoes one at a time, plac ing the covered or designated shoe' on clean side of the line of demarcation, as appropriate.	✓
Dons beard cover if necessary. Dons head cover assuring that all hair and ears are covered.	NA
Dons face mask to cover bridge of nose down to include chin.	
Performs hand hygiene procedure by wetting hands and forearms and washing using soap and warm water for at least 30 seconds.	✓
Dries hands and forearms using lint-free towel or hand dryer.	✓
Selects the appropriate sized gown examining for any holes, tears, or other defects. Dons gown and ensures full closure.	✓
Disinfects hands again using a waterless alcohol-based surgical hand scrub with persistent activity and allows hands to dry thoroughly. before donning sterile gloves	✓
Dons appropriate sized sterile gloves ensuring that there is a tight fit with no excess glove material at the fingertips.	✓
in the direct compounding area (DCA) and after touching items or surfaces that may contaminate gloves.	✓
Removes PPE on the clean side of the ante-area. Removes gloves and performs hand hygiene.	✓
Removes gown and discards it, or hangs it on hook if it is to be reused within the same work day.	✓
Removes and discards mask, head cover, and beard cover (if used).	✓
Removes shoe covers or shoe one at a time, ensuring that uncovered foot is placed on the dirty side of the line of demarcation.	✓

HYBRID PHARMA SOP

Title: Assessing Cleaning and Disinfection Procedures: FORM 96a

Cleaning and Disinfection Practices:

The qualified evaluator will mark (×) each space for which the person being assessed has acceptably completed the described activity, prints N/A if the activity is not applicable to the assessment session or N/O if the activity was not observed.

Daily Tasks:

Prepares correct concentration of disinfectant solution according to Hybrid Pharma's SOP instructions.	✓
Uses appropriately labeled container for the dilution of the disinfectant.	✓
Documents disinfectant solution preparation.	✓
Follows garbing procedures when performing any cleaning activities.	✓
At the beginning of each shift, cleans all ISO Class 5 devices prior to compounding in the following order: walls, and work surface.	✓
Uses a lint free wipe soaked with sterile 70% IPA or other approved disinfectant solution and allows to dry completely.	✓
Removes all compounder components and cleans all ISO Class 5 areas as stated above at the end of each shift.	✓
Cleans all counters and easily cleanable work surfaces/ counters.	✓
Mops floors, using the mop, starting at the wall opposite the room entry door; mops floor surface in even strokes toward the operator. Moves carts as needed to clean entire floor surface. Use of a microfiber cleaning system is an acceptable alternative to mops.	✓
In the preparation/ staging room, cleans sink and all contact surfaces; cleans floor with a disinfectant solution or uses microfiber cleaning system.	✓

The person assessed is immediately informed of all unacceptable activities (i.e., spaces lacking a Check marks, N/A and shown and informed of specific corrections.

Signature of Person Assessed ---- R. Uma Date 8/24/18
Printed Name
Signature of Qualified Evaluator ---- Jeff Date 8/24/18
Printed Name Jeff Goldrich

APPROVED BY

HYBRID PHARMA SOP

Title: Assessing Cleaning and Disinfection Procedures: FORM 96b

The qualified evaluator will mark (x) each space for which the person being assessed has acceptably completed the described activity, prints N/A if the activity is not applicable to the assessment session or N/O if the activity was not observed.

Monthly Tasks:

Performs monthly cleaning on a designated week. Prepares a disinfectant solution as stated in approved list at Hybrid Pharma that is appropriate for the surfaces to be cleaned.	✓
Cleans buffer area and ante-area ceiling, walls, and storage shelving with a disinfectant solution and a mop or uses a microfiber cleaning system.	✓
Once ISO Class 5 area is clean, cleans compounding room ceiling, followed by walls and ending with the floor. Uses appropriate labeled mops or microfiber cleaning system.	✓
Cleans all buffer area storage shelves by removing contents and using a germicidal detergent soaked lint free wipes. Allows to dry prior to replacing contents , wipes with sterile 70% IPA to remove disinfectant residue. Uses new wipe as needed.	✓
Cleans all buffer area carts by removing contents and using germicidal detergent soaked lint free wipe, cleans all carts starting with the top shelf and top of post, working down to wheels. Cleans the under side of shelves in a similar manner. Uses a new wipe for each cart. Allows to dry. Wipes carts with sterile 70% IPA wetted lint-free wipe to remove any disinfectant residue. Uses new wipe as needed.	✓
Cleans buffer area chairs, the interior and exterior of trash bins, and storage bins using disinfectant solution soaked lint free wipe.	✓
Documents all cleaning activities as to who performed such activities with date noted.	✓

The person assessed is immediately informed of all unacceptable activities (i.e., spaces lacking a Check marks, N/A and shown and informed of specific corrections.

Signature of Person Assessed R. Uma Date 8/24/18
Printed Name
Signature of Qualified Evaluator [signature] Date 8/24/18
Printed Name Jeff Goldrich

APPROVED BY

97 a Title: **Assessing Hand Hygiene and Garbing Related Practices of Compounding Personnel Form**

Hand Hygiene and Garbing Practices: The qualified evaluator will mark (x) each space for which the person being assessed has acceptably completed the described activity, prints N/A if the activity is not applicable to the assessment sess1on or N/ O if the activity was not observed.

Printed name and position/title of person assessed: ----------

The person assessed is immediately informed of all unacceptable activities (i.e., spaces lacking a Check marks, N/A, or N/O) and shown and informed of specific corrections.

Signature of Evaluator [signature] Date: 8/24/18

Signature of the Personnel evaluated: [signature] Date: 8/24/18

UMA

APPROVED BY DATE:

97a. Hand Hygiene and Garbing Practices: Presents in a clean appropriate attire and manner. No street jackets allowed. Remove street shoe and wear lab shoes.	✓
Wears no cosmetics or jewelry (watches, rings, earrings, etc. piercing jewelry included) upon entry into prep/ staging areas.	✓
Brings no food or drinks into or stored in the ante-areas or buffer areas.	✓
Is aware of the line of demarcation separating clean and dirty sides and observes required activities.	✓
Dons shoe covers or designated clean-area shoes one at a time, placing the covered or designated shoe on clean side of the line of demarcation, as appropriate.	✓
Dons beard NA cover if necessary. Dons head cover assuring that all hair and ears are covered.	✓
Dons face mask to cover bridge of nose down to include chin.	✓
Performs hand hygiene procedure by wetting hands and forearms and washing using soap and warm water for at least 30 seconds.	✓
Dries hands and forearms using lint-free towel or hand dryer.	✓
Selects the appropriate sized gown examining for any holes, tears, or other defects. Dons gown and ensures full closure.	✓
Disinfects hands again using a waterless alcohol-based surgical hand scrub with persistent activity and allows hands to dry thoroughly. before donning sterile gloves	✓
Dons appropriate sized sterile gloves ensuring that there is a tight fit with no excess glove material at the fingertips.	✓
in the direct compounding area (DCA) and after touching items or surfaces that may contaminate gloves.	✓
Removes PPE on the clean side of the ante-area. Removes gloves and performs hand hygiene.	✓
Removes gown and discards it, or hangs it on hook if it is to be reused within the same work day.	✓
Removes and discards mask, head cover, and beard cover (if used).	✓
Removes shoe covers or shoe one at a time, ensuring that uncovered foot is placed on the dirty side of the line of demarcation.	✓

APPROVED BY [signature] DATE: 8/24/18

STATE OF FLORIDA

DEPARTMENT OF HEALTH

INVESTIGATIVE REPORT

Office: Area 10 – Fort Lauderdale	Date of Complaint: 12/28/2017	Case Number: 2017-23347

Subject: HYBRID PHARMA, LLC 1015 W Newport Ctr. Dr. #106-A Deerfield Beach, FL 33442 954-708-2771	Source: DEPARTMENT OF HEALTH/ISU/FT. LAUDERDALE 1400 W Commercial Blvd. Ft. Lauderdale, FL 33309 954-202-3250
Profession: Pharmacy	License Number and Status: PH29374; Clear
Related Case(s): 2017-23346	Period of Investigation and Type of Report: 01/31/2018 to 02/01/2018 - SUPPLEMENTAL I

Alleged Violation: SS 456.072(1)(d)(k)(dd); 465.023(1)(c); 465.016(1)(r), F.S 64B16-27.797; 64B16-27.300; 64B16-24.420, F.A.C

Synopsis: This Supplemental investigation is predicated upon the receipt of additional information which includes correspondence from EDWIN A. BAYO, Esq., on behalf of GOLDRICH, RPh (Exhibit S1-1).

Investigator's Note:

On 01/31/2018, this investigator received correspondence via US Mail from BAYO responding to the initial allegations on behalf of HYBRID PHARMA.

Investigator/Date: 02/01/2018 M. Boatwright Marsha Boatwright, LI-125 Investigation Specialist II	Approved By/Date: 02/01/2018 Pat Callahan Patricia Callahan, C.F.E Investigation Manager, LI-96

Distribution: HQ/ISU

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Grossman, Furlow & Bayó, LLC
ATTORNEYS AT LAW

RECEIVED
JAN 31 REC'D

January 23, 2018

Marsha Boatwright, Investigator
Florida Department of Health
Division of MQA
1400 W. Commercial Blvd.
Ft. Lauderdale, FL 33309

Re: Hybrid Pharma, LLC, DOH Case No. 2017-23347

Dear Investigator Boatwright:

As indicated in our letter dated January 3, 2018, please consider the following as our supplemental response to the above captioned matter.

The complaint states that our client failed to comply with sterile compounding requirements as stated in USP 797, and proceeds to point out several alleged deficiencies. The complaint also includes a concise list of the alleged deficiencies from Inspectors Monica Bower, R.Ph., and James Shepherd, R.Ph.

In response to the alleged deficiencies, enclosed with this letter is our client's response to the findings in question where our client received "NO" on their inspection report.

We hope that our client's letter sufficiently responds to the alleged deficiencies listed in the inspection report and demonstrates our client's continual compliance with applicable rules and regulations. Also, please consider this letter as our request, pursuant to subsection 456.073(10), F.S., for a complete copy of the investigative file at the conclusion of the investigation. Our client agrees to maintain the confidentiality of all documents provided pursuant to this request and further agrees to pay appropriate costs for the copies provided.

Please let me know if you have any questions or need for additional information to complete your investigation.

Sincerely,

Edwin A. Bayó

cc: Hybrid Pharma, LLC

Response to DOH Inspection Report, dated December 19, 2017

Inspection Report item in underline

DOH Inspector's comments in italics

9. A 0.2-µm certified sterilizing membrane filter is used that is chemically and physically compatible with the CSP. Filtration is completed rapidly without filter replacement. Sterilization method is verified to achieve sterility for the quantity and type of containers. [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Sterilization of High-Risk Level CSPs by Filtration]

Compounding record for Zinc sulfate 10mg/ml final volume of 300 ml was sterilized by filtration with a Baxter Supor 32 mm syringe filter. Manufacturer recommended volume for this filter is less than 150 ml.

RESPONSE: While the manufacturer lists 150 ml as a recommended volume for this filter, it does not give a maximum recommended volume. The manufacturer also fails to mention the conditions or criteria used to determine the "recommended" volume.

The volume any given filter can process and still maintain its integrity is based upon many factors including substrate viscosity, solubility, structure, pressure, purity, and size to name a few. The validation test performed at the end of every batch (known as bubble point or pressure holding test) is the determining factor when assessing a filters failure point.

We have not had any premature failure of the Supor 0.2 micron filter after processing 300ml of Zinc Sulfate.

Action Plan: Although no official maximum filtered volume is given for this filter, we will use 150ml as the maximum allowed volume going forward.

15. Dry heat depyrogenation is used to render glassware or containers, such as vials free from pyrogens as well as viable microbes. The description of the dry heat depyrogenation cycle and duration for specific load items is included in written documentation in the compounding facility. The effectiveness of the dry heat depyrogenation cycle is verified using endotoxin challenge vials (ECVs). [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY: Depyrogenation by Dry Heat]

Firm is using distilled water to rinse glassware not sterile water; SECOND ADVISORY.

Response to June 14, 2017 DOH Inspection Report:

All the non-sterile glassware is washed with tap water to remove any suspended particles, and then washed with distilled water in the cleaning process. Next, it **is rinsed with sterile water for injection**. We explained the cleaning procedure to the inspectors. We have many cases of sterile water for injection (Baxter product) in the inventory room within the pharmacy. We only take from inventory the necessary amount to use during the sterilization process.

Response to December 19, 2017 DOH Inspection Report:

The inspector claims again that we are using distilled water for the final rinse of glassware. **This is incorrect.** Distilled water is used in the cleaning process but not in the final rinse stage. Sterile water is transported from the storage room after being removed from its cardboard shipping containers. We do not store sterile water in the prep room. See on the next page the SOP regarding the procedure to wash glassware and vials prior to depyrogenation.

Hybrid Pharma SOP

Procedure to wash Glassware and Vials Prior to Depyrogenation.

We process glassware, vials and other containers to meet required endotoxin levels according to USP <85>. Cleaning, washing and drying is performed inside ISO 8/Class room. Glassware and vials used in the processing, storage, or packaging of pharmaceutical compounds are washed, dried and depyrogenated.

Washing of glassware
Materials Required:

- Distilled Water
- Sterile Water for Irrigation / Sterile Water for Injection
- Stainless Steel Sterilizing Trays
- Plastic bins

We use plastic storage containers or stainless steel trays to transfer bags of sealed sterile water for injection into clean room on a need to use basis. Large stock of Baxter brand Sterile Water is kept in supply room. After inspecting cardboard cases for damage they are placed in supply room from UPS delivery.

Shipping containers or boxes are not stored in the clean room. Quantity of sterile rinse water depends upon amount of glassware to be rinsed. Return only unopened bags of Sterile Water to supply room when finished. Discard opened but unused sterile water down sink.

Step1: Wash all glassware and vials with plenty of tap water and drain them to remove any dust particles. Repeat this procedure 3 times.
Step 2: The drained glassware from step 1 is washed with plenty of distilled water, make sure all the surfaces are cleaned. Repeat this process with Distilled water two times.
Step 3: The drained glassware from step 2 is rinsed with sterile water for Irrigation or Sterile water for Injection [SWI]
Step 4: Drain the glassware in the Stainless steel Sterilizing Trays and let them air dry. Once they are dry, store the vials in the plastic storage bins, labelled as Washed.

Instructions:

a. Do not perform any of these activities when any compounding activities are carried out in the room.
b. Make sure the sink and counter is clear of any dirty items before you begin the washing the glassware/ containers/vials.

22. On site: Membrane filtration is used if appropriate. (The technique of membrane filtration is used whenever the nature of the product permits; that is, for filterable aqueous preparations, for alcoholic or oily preparations, and for preparations miscible with, or soluble in, aqueous or oily solvents, provided these solvents do not have an antimicrobial effect in the conditions of the test.) Filters are rinsed according to USP<71>. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Sterility Testing]

The SOP the firm is using is the Pall MF (membrane filtration) technique for their sterility testing that does not match the procedure, also, the Nalgene sterile filter that was presented to inspectors indicates that it is for food and beverages and does not indicate it can be used for pharmaceutical product sterility tests; PROVIDE DOCUMENTATION THE DEVICE IS APPROPRIATE FOR USP <71> STERILITY TESTS

RESPONSE:

Hybrid Pharmacy is not using the "Pall filtration technique" (which was contained in a mislabeled folder). This was mistaken for our SOP. The SOP for sterility testing was filed in our FDA section. Hybrid was using Pall filters for sterility testing prior to upgrading to the Nalgene system. Please see enclosed SOP as **Exhibit 1**.

The Nalgene filters #145-2045 (in use since August 2017) are listed by ThermoFisher Scientific for Water Quality, Food and Beverage, and Pharmaceuticals. (See attached PDF Nalgene Filter.pdf)

USP<71> outlines the use of membrane filtration in regard to sterility testing.

We have met all the criteria described in "Membrane Filtration" (2009 USP/NF Pg. 83). The description and specifications of these filters are as follows:

1) Use membrane filters having a nominal pore size not greater the 0.45 micron whose effectiveness to retain microorganisms has been established.

We use 0.45 micron sterile filters whose effectiveness to retain microorganisms has been established.

2) Cellulose Nitrate is used as an example of filter composition when using aqueous, oily, and weakly alcoholic solutions.

The new Nalgene filters are composed of Cellulose Nitrate. The Nalgene filters #145-2045 are listed by ThermoFisher Scientific is listed to be used for pharmaceutical purposes, including raw ingredients (liquid and powder), Make-up Water, Rinse Water, and Final Product. See as **Exhibit 1a** ThermoFisher Scientific's product description.

114. Rev.1 Sterility test (Membrane Filtration Method) in finished sterile drug preparations

1.0 OBJECTIVE

The Objective of this SOP is to test for sterility of the Sterile drug products by Membrane filtration method and document the results.

2.0 SCOPE

This protocol is applicable for Sterility test of the finished pharmaceutical products. The sterility test will be conducted in accordance with the methods outlined in the current USP <71> [Harmonized Pharmacopeia Method/ 21 CFR 610.12.]

3.0 RESPONSIBILITIES

	Responsibilities	Name of the Department
1	Validation Protocol, Approval & Report	Quality Control

4.0 PRE-REQUISITES

1. Method Suitability Test or Bacteriostatic and Fungistatic Test

In order to efficiently conduct the sterility suitability test by Membrane Filtration method, ensure that the following requirements are fulfilled.

a. Validated Aseptic facility, an independent testing Facility to carry out the Sterility test validation
b. Follow the proper GMP procedure and share the procedure to develop proper method(s) to do the sterility test.
c. Method suitability follows the validated GMP protocol and Sterility test follows USP <71> protocol.
d. After the method suitability is done, perform the sterility test for the different batches of the same product as per USP <71>.

5. STERILITY TESTING.

a. Follow the strict protocols described in USP <71> and method suitability tests.
b. All Equipment to be used for Sterility test are qualified and operational SOP's established and followed.
c. All the equipment and culture media required for the sterility test should be sterile.

d. Trained personnel for conducting Sterility test

6.0 IDENTIFICATION OF CRITICAL CONTROL / MONITORING PARAMETER

Before proceeding for sterility test, following parameters are checked

a. Each lot of sterility test medium must be tested for its growth promoting qualities as provided by manufacturer.

b. During validation carry out environmental monitoring by settle plate (Plate Exposure) and Personnel monitoring by gloved finger dab.

7. TEST FOR ANTIMICROBIAL ACTIVITY /STERILITY TEST

Objectives: The test is performed to ensure that, the absence of Antimicrobial Activity in the finished sterile products under the experimental conditions.

Sample Procedure: For a batch of 200 vials of 10mL; 10 vials for testing

Step No	Product Control
1	Rinse the membrane with approx. 10 ml of sterile fluid D before starting the filtration under vacuum.
2	Select 10 vials randomly and pour half the content into a filter holder & start the filtration
3	Rinse the membrane three times with fluid D
4	Aseptically transfer the filter paper using sterile S.S. tweezer to sterile FTM
5.	Repeat step 1-3 using another sterile filter and aseptically transfer the filter paper using sterile S.S. tweezer to sterile TSB/SCDM
6	Incubate the TSB/SCDM glass containers at 20- 25°C and FTM glass bottles at 30-35°C for 14 days
7	After incubation observe the samples for growth and document the observation.
8	After 14 days incubation and Document the observation

Acceptance Criteria:

a. After incubation, observe all the negative control of each medium i.e. FTM and SCDM for absence of growth.

b. Observation: - Observe the samples for any evidence of microbial growth by means of turbidity. If evidence of microbial growth is observed in terms of turbidity or cloudy, the test article does not pass the sterility test unless it can be clearly demonstrated that the test is invalid for causes unrelated to the test article.

If no evidence of microbial growth is observed and the sample is clear for the incubation period of 14 days, the test article passes sterility test.

If a test article renders the media turbid so the presence or absence of microbial growth cannot be readily determined by visual examination, a portion (not less than 1mL) of the media will be transferred to a fresh container of the media on Day 14. The transfer solution will be incubated for not less than 4 days.

8.0 Reporting:

The final report will include but will not be limited to: the dates of test initiation and completion and the final test results.

9.0 PRECAUTION:

a. Personnel conducting sterility testing or associated aseptic manipulations should wear sterilized garments. Following the completion of the test, the personnel will gently press their gloved fingertips onto the surface of the TSA w L/PS plate. The glove plates will be aerobically incubated at 30^0C to 35^0C for 48-72 hours.

The BSC/LAFH will be wiped with an approved disinfectant immediately prior to testing.

b. All equipment, vessels and materials, which are used for sterility test, should be sterilized by autoclaving or by dry heat sterilization.

10. Independent Testing Lab-validation work

a. Validation tasks are to be carried out by trained personnel using techniques and equipment, which minimize the risk of accidental microbial contamination of the test and of the testing environment.
b. Validation tests should be conducted in sterile environment and positive control tests in Microbiological testing room under LAFH

11. Test Article Identification:

All the necessary documentation for the identification of the test article are documented in Form 122A, 122B, 122C and the dates are marked in the samples. The minimum number of articles to be used in relation to the number of articles in the batch and the minimum quantity to be used for each medium by USP 71 guidelines. Out of this 50% of the samples are reserved as retention sample, which will be used for any repeating of tests or other testing needed.

12. Compliance:

This study will be performed in accordance with applicable Good laboratory practices and follow USP 71 sterility test protocol.

13. **Testing Environment:**

All sterility tests will be performed in ISO 5 hood.

Personnel will be gowned as suitable for the testing environment. Sterile gloves, mask, goggles and sleeves are required in the ISO 5 hood. Sterile coverall suit, mask and goggles are required in ISO 7 suite.

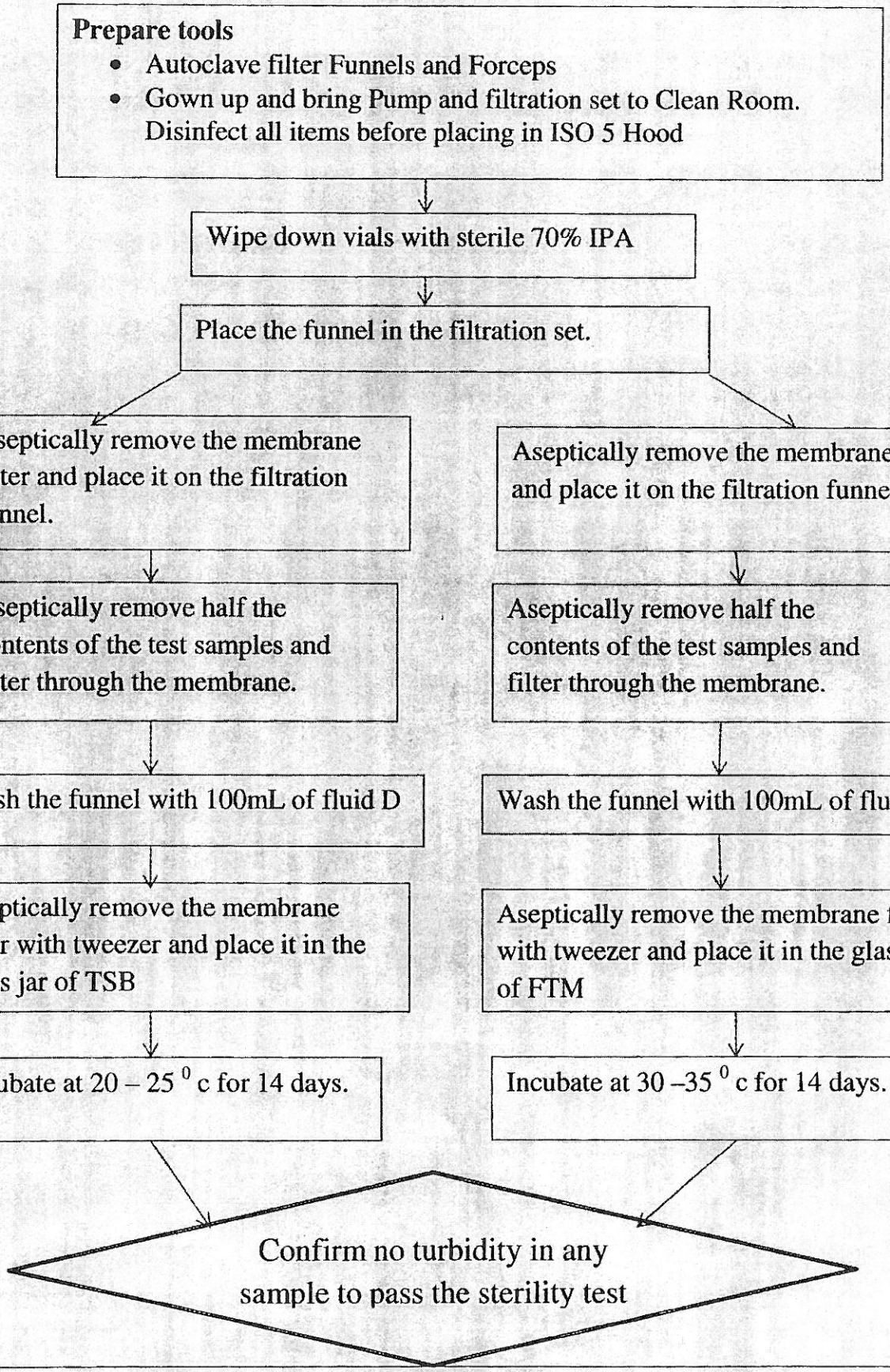
Settling plates will be placed in the hood during testing to confirm ISO 5 conditions were in effect during testing. Tryptic Soy Agar or Malt Extract Agar or equivalent settling plates will be opened during testing. When testing is complete TSA will be incubated for 48 – 72 hours, and MEA will be incubated 5 – 7 days.

Contact plates will sample surface of hood after testing, to confirm the surface of the Hood is sterile. TSA+ contact plates will be used to neutralize any residual disinfectant. TSA+ will be incubated for 48 – 72 hours.

Contact plates will also sample microbiology technician fingertips after testing, to ensure technician maintained aseptic technique. TSA+ plates will be incubated for 48 – 72 hours.

In case of a failing sample, the environmental monitoring results will be helpful in determining whether there was laboratory error.

USP <71> STERILITY TEST FLOW CHART



USP 71 STERILITY TEST:

Product Requirements: Minimum Quantity per Unit for Each Medium

Liquids	Minimum Quantity
< 1 mL	The whole contents of each container
1-40 mL	Half the contents of each container, but not less than 1mL
>40 - <100 mL	20 mL per container
>100 mL	10% of the contents of the container, but not less than 20 mL
Antibiotic Liquids	1 mL

Product Requirements: Minimum Quantity per Unit for Each Medium

Solids	Minimum Quantity
< 50 mg	The whole contents of each container
50 - <300 mg	Half the contents of each container, but not less than 50 mg
300 mg – 5 g	150 mg per container
>5 g	500 mg per container

Insoluble preparations, creams, and ointments to be suspended or emulsified - Use the contents of each container to provide not less than 200 mg

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Table 3. Minimum Number of Articles to be Tested in Relation to the Number of Articles in the Batch

Number of Items in the Batch*	Minimum Number of Items to be Tested for Each Medium (unless otherwise justified and authorized)**
Parenteral preparations	
Not more than 100 containers	10% or 4 containers, whichever is the greater
More than 100 but not more than 500 containers	10 containers
More than 500 containers	2% or 20 containers, whichever is less
*For large-volume parenterals	2% or 10 containers, whichever is less
Antibiotic solids	
Pharmacy bulk packages (<5 g)	20 containers
Pharmacy bulk packages (≥5 g)	6 containers
Bulks and blends	See *Bulk solid products*
Ophthalmic and other noninjectable preparations	
Not more than 200 containers	5% or 2 containers, whichever is the greater
More than 200 containers	10 containers
If the product is presented in the form of single-dose containers, apply the scheme shown above for preparations for parenteral use.	
Catgut and other surgical sutures for veterinary use	2% or 5 packages, whichever is the greater, up to a maximum total of 20 packages
Not more than 100 articles	10% or 4 articles, whichever is greater
More than 100, but not more than 500 articles	10 articles
More than 500 articles	2% or 20 articles, whichever is less
Bulk solid products	
Up to 4 containers	Each container
More than 4 containers, but not more than 50 containers	20% or 4 containers, whichever is greater
More than 50 containers	2% or 10 containers, whichever is greater

* If the batch size is unknown, use the maximum number of items prescribed.
** If the contents of one container are enough to inoculate the two media, this column gives the number of containers needed for both the media together.

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114A: Sterility Testing Experimental Procedure

Equipment/supplies/reagents:

Equipment:

- Filtration set
- Filter holders
- 47 mm filters
- Laminar Flow Hood
- Vacuum Supply
- Incubator (30 – 35°C)
- Incubator (20 – 25°C)
- ISO 5 Laminar Flow Hood
- Autoclave

Media:

- Tryptic Soy Broth (TSB)
- Fluid Thioglycolate Medium (FTM)
- Fluid D
- Tryptic Soy Agar (TSA)
- Tryptic Soy Agar plus lecithin and tween (TSA+)
- Malt Extract Agar

Supplies:

- Tweezers
- Sterile gloves
- Sterile sleeves
- Lab coat
- Hair net
- Safety glasses
- Face mask

1.0 Method

1.1 **Sample Quantity:**

1.1.1 Take the appropriate number of samples for test, depending upon batch size and unit dose size. The amount is determined by Table 3 in USP <71>. See Appendix 1.

1.1.2 The volume to be tested is dependent upon unit dose size. The amount is determined by Table 2 in USP <71>. See Appendix 2

1.2 STERILITY TEST PROCEDURE

1.2.1 All sterility tests will be performed in ISO 5 hood.

1.2.2 Personnel will be gowned as suitable for the testing environment. Sterile gloves, mask, goggles and sleeves are required in the ISO 5 hood. Sterile coverall suit, mask and goggles are required in ISO 7 suite.

1.2.3 Settling plates will be placed in the hood during testing to confirm ISO 5 conditions were in effect during testing. Tryptic Soy Agar or Malt Extract Agar or equivalent settling plates will be opened during testing. When testing is complete TSA will be incubated for 48 – 72 hours, and MEA will be incubated 5 – 7 days.

1.2.4 Contact plates will sample surface of hood after testing, to confirm the surface of the hood is sterile. TSA+ contact plates will be used to neutralize any residual disinfectant. TSA+ will be incubated for 48 – 72 hours.

1.2.5 Contact plates will also sample microbiology technician fingertips after testing, to ensure technician maintained aseptic technique. TSA+ plates will be incubated for 48 – 72 hours.

1.2.6 In case of a failing sample, the environmental monitoring results will be helpful in determining whether there was laboratory error.

1.3 **Membrane Filtration**:

1.3.1 Membrane filtration is performed on liquid samples that are readily filterable. It is the preferred method as it allows inhibitory compounds to pass through while trapping microbes on the surface of the filter.

1.3.2 Wrap filter funnels and autoclave at 121C for at least 20 minutes or use sterile filter funnels.

1.3.3 Spray the outside of the wrapped funnels with sterile 70% IPA and place wrapped funnels in the ISO 5 Hood.

1.3.4 Unwrap funnels and place on filtration set.

1.3.5 Using sterile tweezes, place sterile filter on filter funnel.

1.3.6 Wipe dry outside of sample containers (primary packaging) with sterile70% IPA.

1.3.7 Wipe dry outside of media bottles with sterile 70% IPA.

1.3.8 Turn on vacuum pump.

1.3.9 Filter adequate amount of sample through filter set. Sample must be removed aseptically. Products from syringes can be directly injected into funnel. Products in vials and bags may be removed from vial by sterile syringe.

1.3.10 Allow vacuum to drain the filter funnel through the filter.

1.3.11 Fill funnel with Fluid D, being sure to rinse side of funnel. The amount of Fluid D rinse will be dependent upon what was validated during method suitability. Wash the membrane not less than three times with the validated amount but do not exceed five 100 mL washes per filter.

1.3.12 Allow all of the Fluid D passes through the filter.

1.3.13 Using sterile forceps, aseptically remove the filter from the funnel and place in TSB or FTM. Product will be tested in both media – whether samples are split or whole samples are filtered will depend upon unit dose size. Refer to USP Table 2 in Appendix 2.

1.3.14 Incubate TSB for 14 days at 20 – 25°C, incubate FTM for 14 days at 30 – 35°C.

1.4 **Direct Inoculation:**

1.4.1 To be utilized for insoluble products that cannot be membrane filtered.

1.4.2 Transfer sample into culture medium so that the volume of the product is not more than 10% of the volume of the medium.

1.4.3 Samples will be transferred according to USP Table 2 in Appendix 2 and what has been validated according to method suitability.

1.4.4 Incubate TSB for 14 days at 20-25°C. Incubate FTM for 14 days at 30 – 35°C.

2.0 REFERENCES: US Pharmacopeia <71> Sterility Tests

Product	Testing lab Atlas Fluid D	Size of vial	Product volume filtered/Volume of FTM	Product volume filtered/Volume of FTM
Magnesium chloride 200mg/ml	Fluid D, 0.45 CN	50mL	250ml/ 100ml	250ml/ 100ml
HCG 11000 iu	Reconstitute with BS water	11mL	55ml/100ml	55ml/100ml
MIC	Fluid D, 0.45 CN	30mL	450mL/100ml	450mL/100ml
B12, MIC	Fluid D, 0.45 CN	30mL	450mL/100ml	450mL/100ml
Testosterone Cypionate 200mg/mL	Fluid D, 0.45 CN	10mL	50mL/100mL	50mL/100mL
Calcium Gluconate 10%	Fluid D, 0.45 CN	20mL	100mL/100mL	100mL/100mL
Sodium Bicarbonate 8.4%	Fluid D, 0.45 CN	50mL	250ml/ 100ml	250ml/ 100ml
Placebo	Fluid D, 0.45 CA	2mL	50mL/100mL	50mL/100mL
Cyanocobalamin 1mg/mL	Fluid D, 0.45 CN	30mL	450mL/100ml	450mL/100ml
Methyl cobalamin 1mg/mL	Fluid D, 0.45 CN	30mL	450mL/100ml	450mL/100ml
Glutathione	Fluid D, 0.45 CN	30mL	450mL/100ml	450mL/100ml

HYBRID PHARMA

HYBRID PHARMA ON-SITE STERILITY TESTING /MEMBRANE FILTRATION DOCUMENTATION FORM 122C_Rev.2

Batch details, Name of the drug, strength, Batch size, number of vials				vials used in sterility test	
During Sterility test ISO 5 Hood settle air Plates		Cfu Pass/ Fail		Start date	End Date
Negative Control		Cfu Pass/ Fail			
Post sterility test Personnel Gloved fingertip	LEFT Cfu Pass/ Fail	RIGHT Cfu Pass/ Fail	HOOD SURFACE Cfu Pass/ Fail	Incubation Temp. 30 -35^{0}C	
	Negative Control Cfu Pass/ Fail				
Details of Fluid D, USP	Details of the membrane, batch, expiry, manufacturer	Details of settle plate TSA to collect air in the LAFH W64 15X100mm	Details of TSA W/LEC &P80 P34		

Details of settle plate MEA to collect air in the LAFH 15X 100mm W28 Hardy

Cfu Pass/ Fail

Negative Cfu Pass/ Fail

000020

HYBRID PHARMA

Sterility Test Inspection Log TSB 20-25^0 C [68-77F] Incubator 1 Form 122A

Indicate X if cloudy or Turbid. For accelerated early release of the batch, follow it up on Day 1 to Day 14. If it is not monitored these days [holidays or missed] they shall be followed asap.

Broth Lot# Broth Expiry Date	U71TSB USP 100mL	Days of Inspection				Results		
		1	3	7	14	Pass	Fail	
Sample Lot #								Start Date
Negative Control								Finish Date

Sterility Test Inspection Log FTM 30 - 35^0 C Incubator 2 Form 122B

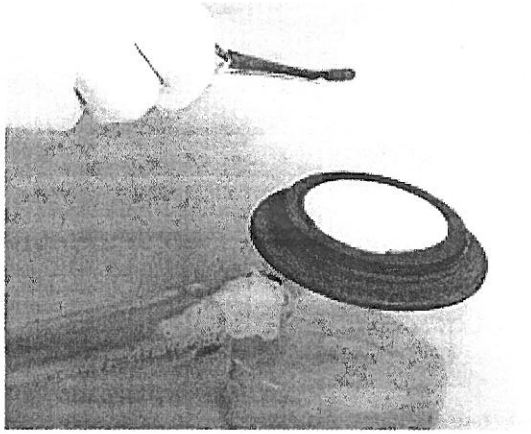
Broth Lot# Broth Expiry Date	U41	Days of Inspection				Results		
		1	3	7	14	Pass	Fail	
Sample Lot #								Start Date
Negative Control								Finish Date

CONFIDENTIAL

ThermoFisher
SCIENTIFIC

000022

Analytical Filtration



Reliable and consistent analytical filterware for microbiological quality control testing

When conducting analytical filtration in your lab, we understand that particle retention efficiency is critical to your research. Analytical filter units and filter funnels are often used in water quality testing to determine the microbial content of samples. Producing accurate results in this type of testing is especially dependent on the filter's performance in retaining microbes on the membrane.

We built our Nalgene analytical filterware products with all of this in mind. For over 50 years, we have provided precise, easy-to-use systems for the recovery of microorganisms and particles for QC testing and research. We provide sterile analytical filters, funnels and a wide array of reusable filters to support a variety of analytical filtration applications.

The most common applications for Nalgene Analytical Filtration products are for the Water Quality, Food and Beverage, and Pharmaceutical industries.

Water quality

- Waste Water
- Potable Water
- Recreational Water (Beaches, Lakes, etc)
- Swimming Pools

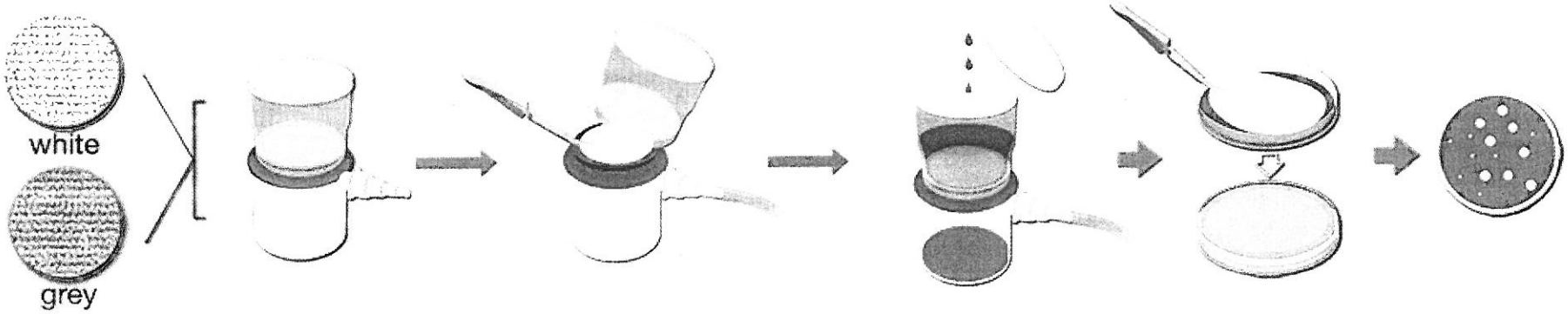
Food & beverage

- Wine
- Beer
- Milk
- Packaged Foods
- Fruit Juices

Pharmaceutical

- Raw Ingredients (liquid and powder)
- Make-up Water
- Rinse Water
- Final Product

Nalgene analytical system

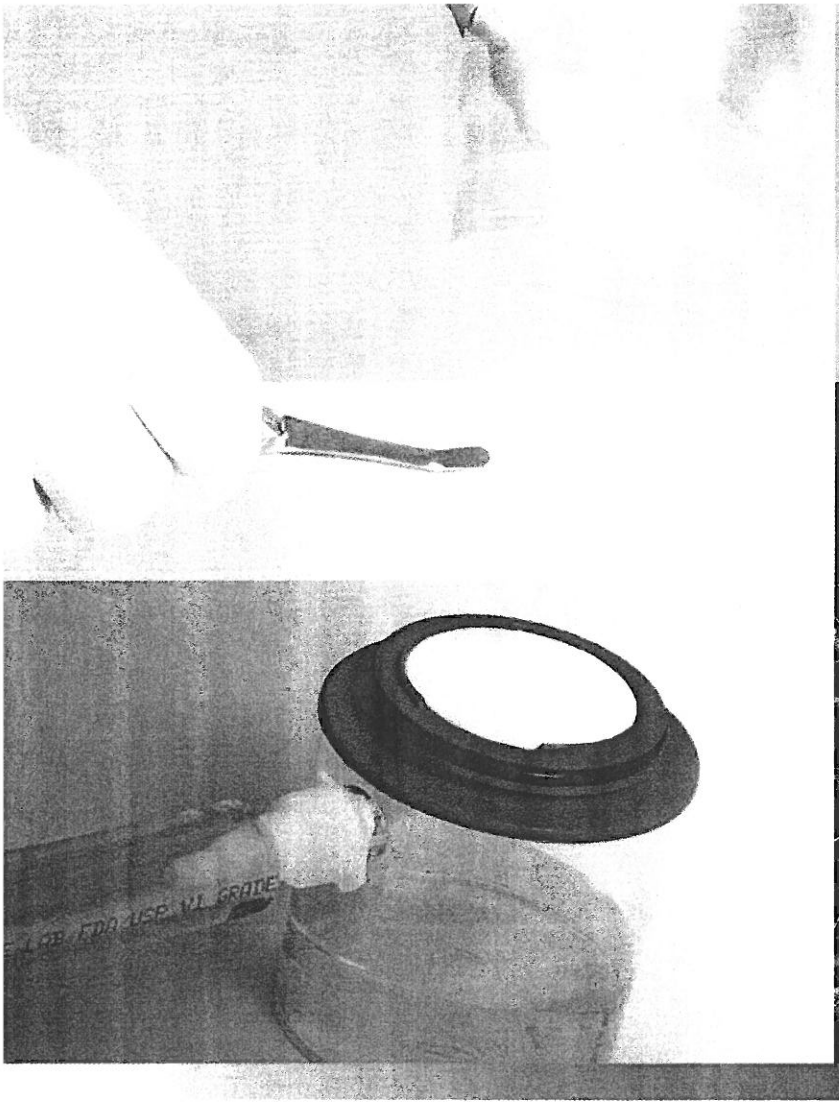


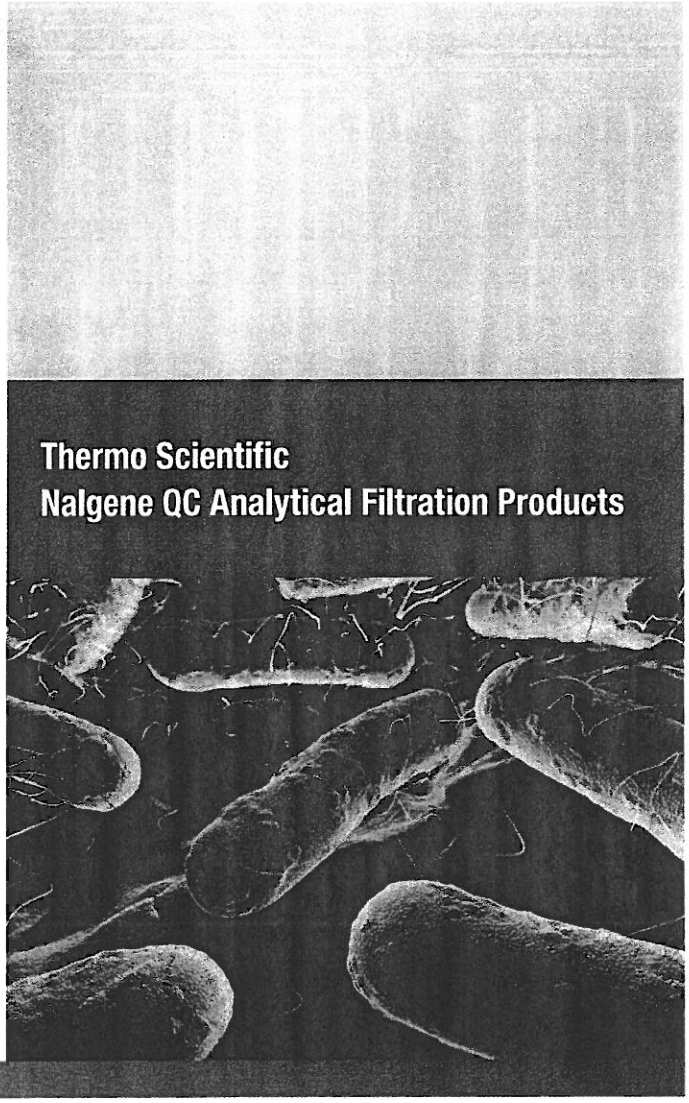
Step 1 : Select membrane

Select a membrane by color and pore size:

Color	Pore size	Challenge organism
White • Standard for microbiological analysis of water, wastewater, and bever	**0.2µm**	Small bacteria
Grey • For the maximum contrast between colonies and the filter without stai • Use to enumerate yeast and bacteria in beverages, wines, wastewate	**0.45µm**	Coliforms, fecal coliforms, Comm
	0.8µm	Yeasts, molds and fungi
	1.0µm	Yeasts, molds and fungi

Product selection





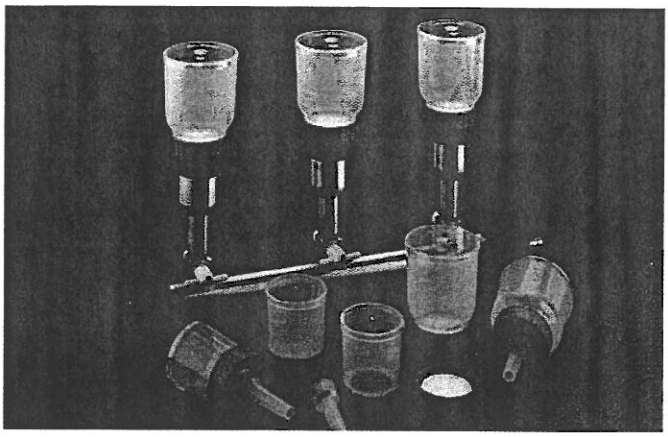
Ensuring reliable and repeatable microbiological quality control testing

Thermo SCIENTIFIC

000024

Hybrid uses #145-2045

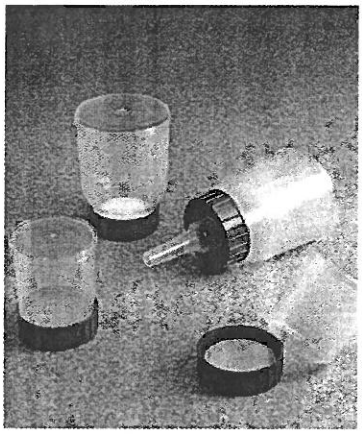
Disposable Analytical Filters



Single-use Nalgene® Filterware - ready when you are!

Our analytical filterware provides precise, easy-to-use systems for the recovery of microorganisms and particulates for QC testing and research.

- Disposable, easy-to-use, pre-assembled sterile filter units and funnels
- Easy-to-remove triton-free cellulose nitrate (CN) membranes
- The 0.2 µm CN membrane is suitable for sterility testing
- 0.45 µm CN gridded membrane is certified for water quality testing



Analytical Test Filter Funnels, Sterile

Low cost filter funnels feature white or gray CN membrane. Gray membrane turns black when wet. Upper separates easily from lower for convenient access to membrane. Adapter allows use with No.8 stopper (Cat.No.DS0396-0080) with filtering flask or manifold. 50 funnels and 6 adapters per case. 100 ml or 250 ml volume. Pass ISO 7704 recovery testing.

Cat. No.145	-0020	-0045	-2020	-2045
Upper cap., ml	100	100	250	250
Membrane dia., mm	47	47	47	47
Pore size, µm	0.2	0.45	0.2	0.45
Membrane color/grid	White/ none	White/ black	White/ none	White/ black

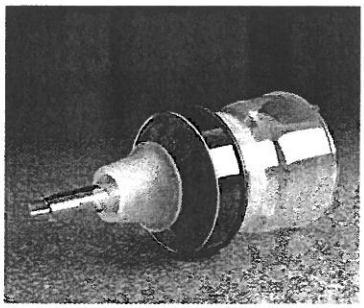
Cat. No.147	-0045	-2045
Funnel cap., ml	100	250
Membrane dia., mm	47	47
Pore size, µm	0.45	0.45
Membrane color/grid	Gray/black	Gray/black

Analytical Filter Units, Sterile

Filter units have wide polystyrene base for added stability on the bench.

150 ml capacity of units and funnels is ideal for beverage samples that may foam. Twist-off upper chamber provides easy access to 47 mm diameter membrane. Upper and lower chambers are graduated for quick volume checks. Easy-to-open bags. 72 units per case. Pass ISO 7704 recovery testing.

Cat. No. 130	-4020	-4045
Pore size, µm	0.2	0.45
Membrane color/grid	White/none	White/black



Analytical Filter Funnels, Sterile

For use with filter flasks or manifolds. 150 ml graduated chamber. Accomodates larger volumes as long as membrane continues to flow. Convenient snap away design with removable membrane. Each pack of 12 filters contains 1 vacuum gasket (DS0395-0708) to replace a stopper. 72 funnels per case. Pass ISO 7704 recovery testing.

Cat. No. 140	-4045
Funnel cap., ml	150
Membrane dia., mm	47
Pore size, µm	0.45
Membrane color/grid	White/black

Notation on June 14, 2017 DOH Inspection Report and Response:

27. On site: A USP<71> method suitability test has been done with appropriate inoculum, additives and rinses. [STERILITY TEST USP<71> : Method Suitability Test]

Method suitability is outsourced to WuVi AppTec in Marietta GA. Sterility testing is done in house. There is no documentation to demonstrate that the procedure for method suitability matches the procedure for sterility testing such as rinse solutions. No.

RESPONSE: We will synchronize with WuVi App Tec's procedure and switch from fluid A to fluid D. We will document the change. See attachment 27 [WUXi e-mail communication]

Notation on December 19, 2017 DOH Inspection Report and Response:

27. On site: A USP<71> method suitability test has been done with appropriate inoculum, additives and rinses. [STERILITY TEST USP<71> : Method Suitability Test]

Method suitability does not match method used for sterility tests. SECOND ADVISORY . Atlas labs conducts method suitability for HCG and uses bacteriostatic water to reconstitute the product , not SWFI ; SECOND ADVISORY Provide documentation that all rinses and methods used in the method suitability are alike ie; membrane filtration, inoculation, rinses, etc. FOR EACH PRODUCT THAT YOU TEST FOR STERILITY. The media you are using is TSB with lecithin and tween 20 and Fluid Thioglycollate that are manufactured by Hardy. Send documentation Atlas labs is using the same media and rinses for method suitability for EACH PRODUCT. No.

RESPONSE:

Atlas Labs uses bacteriostatic water for injection to reconstitute HCG and it becomes a multi dose vial. Hence diluting with bacteriostatic water for injection is the correct method. Here at Hybrid Sterility testing, we also reconstitute HCG with bacteriostatic water for injection.

As of The TSB media manufacturer Tryptic Soy Broth (TSB) with Lecithin and Tween® 80 are added to the formulation TSB to neutralize germicidal or disinfectant residues. Neutralization of these residues reduces their inhibitory effect which would ultimately result in the lowering of the microbial count. Instead using TSB, TSB modified with lecithin and tween 80 ensure a better result to pick up any minute microbial contamination.

We did the comparison study with TSB and TSB modified with lecithin and tween 80 for many of our product formulations and we did not see any difference. Understand the fact that, the method suitability is to evaluate the inhibitory effect on the growth of microbes by the drug product whereas the sterility testing is to see the growth of microbes if any contamination. The media plays a role. The TSB modified with Lec/Tween 80 is for Sterility test and the TSB is for the method suitability.

Please refer the Table 1, for the inoculums, the method, and the rinse fluid between the Method suitability test and the sterility test for all our products.

Table1

	Inoculum Media	Method	Rinse
Method Suitability Test	TSB	Membrane Filtration	Fluid D
Sterility Test	TSB	Membrane Filtration	Fluid D

Though the TSB w Lec/ Tween 80 is superior to TSB, we will continue to match TSB as in the suitability test going forward for all the drug products.

We provide the documentation that Atlas labs is also using the Hardy's TSB product as per their e-mail re-printed below.

-------- Original Message ---------
Subject: Followup on yesterday phone conversation From: "Kim Dix" <kim@atlasanalytical.com> Date: 12/22/17 9:48 am To: "drraja@hybridpharma.com" drraja@hybridpharma.com

Dr. Raja, Please send your 6 x 50mL 95% sterile alcohol vials for validation. We will do method suitability on the 6 target organisms in TBS and FTM. **With regards to Atlas preparation of TSB and FTM: we prepare according to manufacturer instructions: Hardy Criterion C7141 and C7501**. We growth promote prior to use to verify that media meets its intended use. Thanks, Kim Dix Quality Coordinator Atlas Analytical 8255 Commercial Way Weeki Wachee, FL 34613 (352) 610-4367 www.atlasanalytical.com Atlas Logo_JPEG

Additional Language from DOH Inspector in Item 27:

The media you are using is TSB with lecithin and tween 20 and Fluid Thioglycollate that are manufactured by Hardy. Send documentation Atlas labs is using the same media and rinses for method suitability for EACH PRODUCT.

RESPONSE:

Enclosed as **Exhibit 2** is the Certificate of Analysis, dated January 9, 2018, for Ethyl Alcohol 95% (Lot# Y171226) provided by Atlas Analytical. You will see that the materials used are the same. N.B All products produced in batches over 25 are produced under the protection of FDA 503B license. These products are compounded under CGMP with 503B exemptions.

ATLAS ANALYTICAL

CERTIFICATE OF ANALYSIS

Client:	Hybrid Pharma 1015 W Newport Center Dr #106a Deerfield Beach, FL 33442
Contact:	Dr. Raja Drraja@hybridpharma.com P (954) 708-2771
Atlas Sample ID No.:	17-2527
Atlas Report No.:	17-2527
Original Issue Date:	January 9, 2018
Test:	USP <71> Sterility: Method Suitability Test
Product Name:	Placebo Ethyl Alcohol, USP 95% qs.
Lot Number:	Y171226
Samples Tested:	6 vials with 50mL product in each were received. The entire contents of each vial was filtered through a 0.45µM filter and that filter was placed into 100 mL of growth medium (3 filters into TSB; 3 filters into FTM).
Test Materials:	Tryptic Soy Broth (TSB) Hardy Diagnostics Cat. No.: C7141 was prepared according to manufacturer's instructions and growth promoted with <100 cfu of microorganisms according to Atlas SOP 402.1. Turbidity in microorganism inoculated media confirmed growth. Uninoculated media served as a sterility control. Fluid Thioglycollate Medium (FTM) Hardy Diagnostics Cat. No.: C7501 was prepared according to manufacturer's instructions and growth promoted with <100 cfu of microorganisms according to Atlas SOP 402.1. Turbidity in microorganism inoculated media confirmed growth. Uninoculated media served as a sterility control. Fluid D was prepared using 1g of pancreatic digest of casein Hardy Diagnostics Cat. No.: C6531 and 1mL of Tween 80 (Polysorbate) per liter of distilled water. Fluid D was filter sterilized using a bottle-top sterile filtration unit. The 0.45µm cellulose acteate membrane filters used in the product enrichment were Advantec Item C045G047A individually wrapped sterile membranes.

This document is issued under the company's terms and conditions which were agreed upon during sample submission. Atlas Analytical Inc.'s liability regarding this analysis is limited to the cost of the tests associated with this Certificate of Analysis. The results are the property of the client listed above and Atlas Analytical Inc.

ATLAS ANALYTICAL

Method Summary:

In order for a USP <71> Sterility Test to be considered valid, the enrichment scheme used to recover contaminants must be shown to be able to recover various test species introduced to separate enrichments at low levels (<100 colony forming units). These enrichments are incubated for no more than five days at prescribed temperatures. Turbidity in the growth media is confirmation of growth and therefore validates the test.

Product Enrichment:

50 mL of product was filtered through a 0.45µM filter. The filter was rinsed with <100 cfu of test species suspended in 20mL Fluid D. The filter was rinsed with 80mL Fluid D and the filter was transferred to 100 mL of growth media. The type of medium was dependent on the test species as outlined below.

Results:

Tryptic Soy Broth	*Bacillus subtilis*	36 cfu	20° - 25°C	Yes
Tryptic Soy Broth	*Candida albicans*	42 cfu	20° - 25°C	Yes
Tryptic Soy Broth	*Aspergillus brasiliensis*	22 cfu	20° - 25°C	Yes
Fluid Thioglycollate Medium	*Clostridium sporogenes*	13 cfu	30° - 35°C	Yes
Fluid Thioglycollate Medium	*Staphylococcus aureus*	9 cfu	30° - 35°C	Yes
Fluid Thioglycollate Medium	*Pseudomonas aeruginosa*	20 cfu	30° - 35°C	Yes

Conclusion:

Filtering aliquots of 50 mL of Placebo Ethyl Alcohol, USP 95% and placing the filters in separate bottles of 100 mL of TSB and FTM is a valid method for confirming sterility of manufactured product.

Approved by:

Kim Dix

Kim Dix
Quality Assurance

This document is issued under the company's terms and conditions which were agreed upon during sample submission. Atlas Analytical Inc.'s liability regarding this analysis is limited to the cost of the tests associated with this Certificate of Analysis. The results are the property of the client listed above and Atlas Analytical Inc.

8255 Commercial Way · Weeki Wachee, FL 34613 · Phone (352) 610 4367

32. Endotoxin testing is conducted for High-risk level CSP's that are prepared in batches of more than 25 identical containers, or exposed longer than 12 hours at 2° to 8°, and 6 hours at warmer than 8°, before being sterilized or in multidose containers for administration to multiple patients. (excluding those for inhalation and ophthalmic administration) [FINISHED PREPARATION RELEASE CHECKS AND TESTS: Bacterial Endotoxin (Pyrogen) Testing]

Testosterone lot #171006a 2000 ml has not been tested for endotoxins.

Response:

The USP monograph for Testosterone Cypionate does not reference any endotoxin value requirement for this product.

The USP contains maximum allowable endotoxin levels for all official **water soluble** injectable products. The USP describes the methods used to determine these values. The USP does not list any method to test **oil soluble** products. The USP fails to list the maximum allowable endotoxin level for oil based injectable drugs, most notably *TESTOSTERONE CYPIONATE*.

While doing research into this we found some labs were doing endotoxin testing on Testosterone Cypionate utilizing their own unofficial methods. These methods all involve adding water to the oil and extracting solution from the water based layer after shaking. The hope is that the endotoxin will be drawn into the water layer and the extracted water layer would be free from oil contamination.

No validation of this method exists and is most likely the reason it is not mentioned in the USP <797>, <71>,<85> or any of the other references listed below.

The test methods refer to dilution with LAL Reagent Water. These methods work fine with water soluble drugs.

The USP gives **no guidance, methods or procedures** to determine endotoxin levels involving oil based preparations which can interfere with the gel clotting and photometric methods.

We do endotoxin testing for all water based batches as per USP <85>.

We have tested the Testosterone batch in question (lot# 171006A) using an unofficial water extraction method found common in many testing labs. It shows a sample value of <5.00 EU/mL which calculates into:

$$\frac{< 5.00\ \text{EU/mg}}{200\ \text{EU/ml}} = \textbf{<0.025 EU/mg} \quad \textbf{(PASS)}$$

Suggested limits for unlisted, unofficial drugs is calculated:

*Endotoxin Limit K = 5.0 EU/kg for parenteral drugs. For an average body weight of 70kg the endotoxin limit is 350EU. This value (0.05 EU/mg) is expressed in Endotoxin Units per mg of product. In order to convert this value to an endotoxin unit concentration per ml, multiply it (0.5EU/mg) by the product potency 10mg/ml. 10mg/ml x 0.05 EU/mg=0.5 EU/ml.

Common references which omit Testosterone Cypionate endotoxin information.

https://www.ashp.org/-/media/assets/policy-guidelines/docs/guidelines/compounding-sterile-preparations.ashx

http://www.pharmacopeia.cn/v29240/usp29nf24s0_c85.html

https://www.fda.gov/downloads/drugs/guidances/ucm310098.pdf

http://www.pharmacopeia.cn/v29240/usp29nf24s0_m81190.html

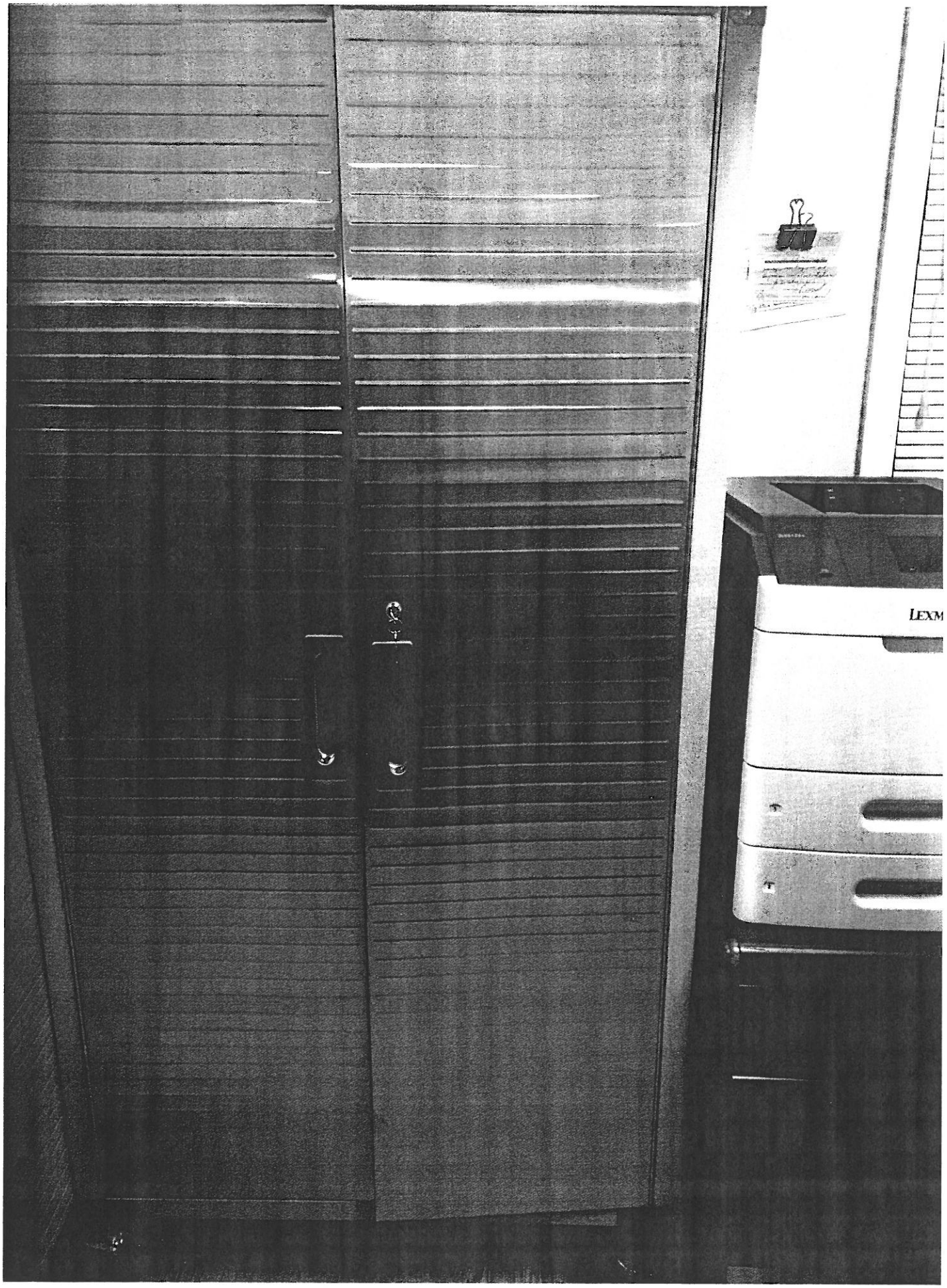
Action Plan: We will perform the water extraction endotoxin values on all future batches even though this method is not documented in any official documents.

46. Hazardous drugs are stored separately from other inventory in a manner to prevent contamination and personnel exposure. [HAZARDOUS DRUGS AS CSPs]

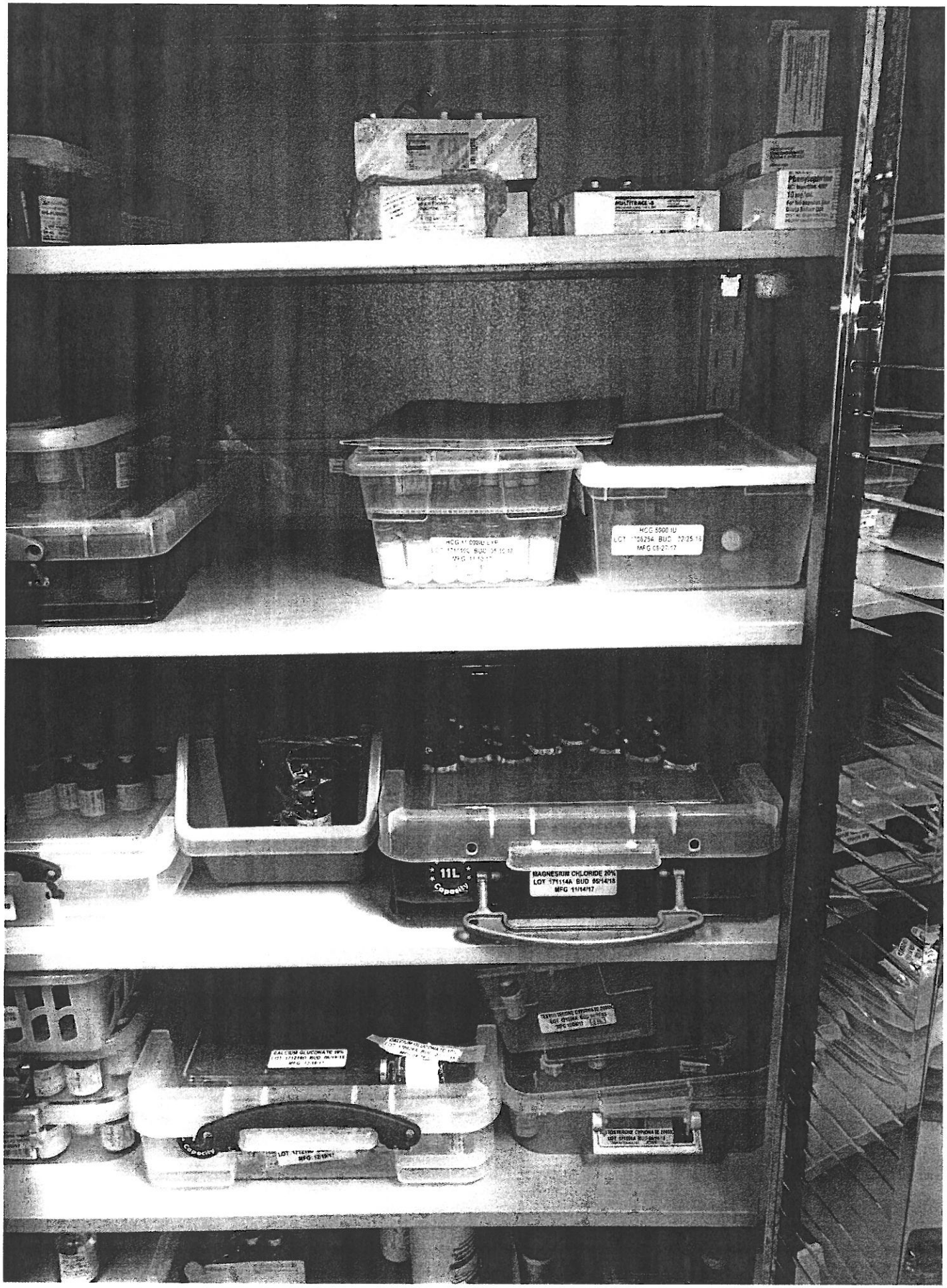
HCG stored in quarantine cabinet with nonhazardous drugs.

RESPONSE:

The HCG will not be stored in the quarantine cabinet. However, it should be noted that, during the time of the inspection, no HCG was stored in the quarantine cabinet. Instead, the HCG was kept in a different large metal storage cabinet. For some reason the inspector thought this cabinet was the quarantine cabinet. It is not, and never was, a quarantine cabinet. We have attached as **Exhibit 3** photos to illustrate. HCG is already contained in a plastic container with top fitting lid. It is important to note that Merck's commercial HCG has no warning or information about special storage conditions.


LEXM

11L
Capacity
MAGNESIUM CHLORIDE 20%
LOT 171114A BUD 05/14/18
MFG 11/14/17


11L
Capacity
MAGNESIUM CHLORIDE 20%
LOT 171114A BUD 05/14/18
MFG 11/14/17

HCG 11,000IU LYP
LOT: 171110C BUD: 05/10/18
MFG: 11/10/17
HCG
HCG 5000 IU
LOT: 170825A BUD: 02/25/18
MFG 08/27/17

51. Certification and testing of primary (LAFWs, BSCs, CAIs and CACIs) and secondary engineering controls (buffer and ante areas) have been performed by a qualified individual no less than every six months and whenever the device or room is relocated, altered, or major service to the facility is performed. Corrective action for deficiencies are documented. Certification procedures such as those outlined in the CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2006) are conducted under dynamic conditions. [ENVIRONMENTAL QUALITY AND CONTROL : Environmental Nonviable Particle Testing Program]

July 11, 2017 TMI; Ante ISO Class 7 , BR 1 (positive buffer room) ISO Class 7 , BR 2 (negative buffer room) ISO Class 7; ISO Class 7 PR (prep room); 1 X LFH ISO Class 5 TESTED UNDER AT REST CONDITIONS; 1 x BSC located in BR 2 however TMI reported the PEC is located in the lab which non viable particle counts were not collected on the BSC. There is no assurance this PEC is operating under clean ISO Class 5 standards.

RESPONSE:

All above = Ante ISO Class 7 , BR 1 (positive buffer room) ISO Class 7 , BR 2 (negative buffer room) ISO Class 7; ISO Class 7 PR (prep room); 1 X LFH ISO Class 5 WERE TESTED UNDER **DYNAMIC CONDITIONS** AS SHOWN BY CERTIFICATES.

The BSC certificate shows no particle count data, which is an oversite by TMI. Please see attached as **Exhibit 4** the TMI Certificates. They were instructed to do particle counts under dynamic conditions for both hoods. We did not catch the omission. We are however monitoring particle counts before every session with our own certified Bio-Test particle counter. We are finding 0 (zero) particles on every occasion. See video enclosed with this response, entitled "51 - video particle count bsc.mp4." TMI will re-certify the BSC on Jan 17th for official documentation, and the official documentation will be submitted in a supplemental response.

TMI

CERTIFICATION SERVICES

CLEANROOM CERTIFICATION
DYNAMIC WORKING CONDITION

PERFORMED FOR:
HYBRID PHARMA
015 W. NEWPORT CENTER DRIVE, STE 106A
DEERFIELD BEACH, FL. 33442

ROOM NUMBER:	AR	DATE CERTIFIED:	11 JUL 2017
SQUARE FOOTAGE:	24 SQ/FT		
CUBIC FOOTAGE:	192 CU/FT	NEXT DUE:	JAN 2018
NUMBER OF HEPAS:	1		
AMBIENT CONDITIONS:	73°F/48% RH	CERT #:	A2581292

HEPA FILTER VELOCITY DATA

AVG. FILTER FACE VELOCITY:	90 FPM
AVERAGE VELOCITY RANGE:	85-100 FPM
TOTAL MEASURED CFM:	2040 CFM
AIR CAHNGES PER HOUR:	637
CRITERIA MET?	YES

HEPA FILTER INTEGRITY TEST:

LEAK DETECTED?	NO	FILTER SIZE:	(2'X4')
LEAK REPAIRED?	NO		
FINAL PENETRATION:	< 0.01%	CRITERIA MET?	YES

ROOM PRESSURE PROFILE:

IN RELATION TO PR:	-0.045"H2O
IN RELATION TO BR :	-0.040"H2O
IN RELATION TO BR2 :	0.045"H2O
CRITERIA MET, >0.02"?	YES

Note: Refer to Appendixes A and B for sample locations and a list of equipment turned on during dynamic working conditions.

CLEANLINESS CLASSIFICATION

ALL DATA IS IN PARTICLES PER:		CUBIC METER	
CLASSIFICATION:	ISO 7	SAMPLE VOLUME :	28 L

ALL TESTS PERFORMED UNDER DYNAMIC CONDITIONS

ID	SAMPLE 1	SAMPLE 2	PARTICLE SIZE:
	593	371	5.0 µM

PARTICLE LIMITS: 2,930	CRITERIA MET?	YES

Note: Target Classification: ISO 7
Actual Classification: ISO 7

STANDARDS USED:

MANUFACTURER	MODEL #	SERIAL #	DUE DATE
ATI	2H	18710	14 DEC 2017
TSI	8375	90745037	21 OCT 2017
MET ONE	2400	010500133	20 SEP 2017

CERTIFIED BY: _____ DATE: 28 AUG 2017

REVIEWED BY: _____ DATE: 28 AUG 2017

TMI

CERTIFICATION SERVICES

CLEANROOM CERTIFICATION
DYNAMIC WORKING CONDITION

PERFORMED FOR:
HYBRID PHARMA
1015 W. NEWPORT CENTER DRIVE, STE 106A
DEERFIELD BEACH, FL. 33442

ROOM NUMBER:	AR	DATE CERTIFIED:	11 JUL 2017
SQUARE FOOTAGE:	24 SQ/FT		
CUBIC FOOTAGE:	192 CU/FT	NEXT DUE:	JAN 2018
NUMBER OF HEPAS:	1		
AMBIENT CONDITIONS:	73°F/48% RH	CERT #:	A2581292

HEPA FILTER VELOCITY DATA

AVG. FILTER FACE VELOCITY:	90 FPM
AVERAGE VELOCITY RANGE:	85-100 FPM
TOTAL MEASURED CFM:	2040 CFM
AIR CAHNGES PER HOUR:	637
CRITERIA MET?	YES

HEPA FILTER INTEGRITY TEST:

LEAK DETECTED?	NO	FILTER SIZE:	(2'x4')
LEAK REPAIRED?	NO		
FINAL PENETRATION:	< 0.01%	CRITERIA MET?	YES

ROOM PRESSURE PROFILE:

IN RELATION TO PR:	-0.045"H2O
IN RELATION TO BR :	-0.040"H2O
IN RELATION TO BR2 :	0.045"H2O
CRITERIA MET, >0.02"?	YES

Note: Refer to Appendixes A and B for sample locations and a list of equipment turned on during dynamic working conditions.

CLEANLINESS CLASSIFICATION

ALL DATA IS IN PARTICLES PER:		CUBIC METER	
CLASSIFICATION:	ISO 7	SAMPLE VOLUME :	28 L

ALL TESTS PERFORMED UNDER DYNAMIC CONDITIONS

ID	SAMPLE 1	SAMPLE 2	PARTICLE SIZE:
	6,492	6,158	0.5 µM

PARTICLE LIMITS: 352,000	CRITERIA MET?	YES

Note: Target Classification: ISO 7
Actual Classification: ISO 7

STANDARDS USED:

MANUFACTURER	MODEL #	SERIAL #	DUE DATE
ATI	2H	18710	14 DEC 2017
TSI	8375	90745037	21 OCT 2017
MET ONE	2400	010500133	20 SEP 2017

CERTIFIED BY: _____ DATE: 28 AUG 2017

REVIEWED BY: _____ DATE: 28 AUG 2017

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TMI
CERTIFICATION SERVICES

CLEANROOM CERTIFICATION
DYNAMIC WORKING CONDITION

PERFORMED FOR:
HYBRID PHARMA
1015 W. NEWPORT CENTER DRIVE, STE 106A
DEERFIELD BEACH, FL. 33442

ROOM NUMBER:	BR	DATE CERTIFIED:	11 JUL 2017
SQUARE FOOTAGE:	80 SQ/FT		
CUBIC FOOTAGE:	480 CU/FT	NEXT DUE:	JAN 2018
NUMBER OF HEPAS:	4		
AMBIENT CONDITIONS:	73 °F/48% RH	CERT #:	A2581295

HEPA FILTER VELOCITY DATA

AVG. FILTER FACE VELOCITY:	84 FPM
AVERAGE VELOCITY RANGE:	85-100 FPM
TOTAL MEASURED CFM:	7030 CFM
AIR CHANGES PER HOUR:	878
CRITERIA MET?	YES

HEPA FILTER INTEGRITY TEST:

LEAK DETECTED?	NO	FILTERS SIZE:	(2'x4')
LEAK REPAIRED?	NO		
FINAL PENETRATION:	< 0.01%	CRITERIA MET?	YES

ROOM PRESSURE PROFILE:

IN RELATION TO AR:	0.040"H2O
CRITERIA MET, >0.020"?	YES

Note: Refer to Appendixes A and B for sample locations and a list of equipment turned on during dynamic working conditions.

CLEANLINESS CLASSIFICATION

ALL DATA IS IN PARTICLES PER:		CUBIC METER	
CLASSIFICATION:	ISO 7	SAMPLE VOLUME :	28 L

ALL TESTS PERFORMED UNDER DYNAMIC CONDITIONS

ID	SAMPLE 1	SAMPLE 2	SAMPLE 3	SAMPLE 4	PARTICLE SIZE:
	3,376	2,930	3,301	7,420	0.5 µM

PARTICLE LIMITS: 352,000		CRITERIA MET?	YES

Note: Target Classification: ISO 7
Actual Classification: ISO 7

STANDARDS USED:

MANUFACTURER	MODEL #	SERIAL #	DUE DATE
ATI	2H	18710	14 DEC 2017
TSI	8375	90745037	21 OCT 2017
MET ONE	2400	010500133	20 SEP 2017

CERTIFIED BY: _____ DATE: 28 AUG 2017

REVIEWED BY: _____ DATE: 28 AUG 2017

TMI
CERTIFICATION SERVICES

CLEANROOM CERTIFICATION
DYNAMIC WORKING CONDITION

PERFORMED FOR:
HYBRID PHARMA
1015 W. NEWPORT CENTER DRIVE, STE 106A
DEERFIELD BEACH, FL. 33442

ROOM NUMBER:	BR	DATE CERTIFIED:	11 JUL 2017
SQUARE FOOTAGE:	80 SQ/FT		
CUBIC FOOTAGE:	480 CU/FT	NEXT DUE:	JAN 2018
NUMBER OF HEPAS:	4		
AMBIENT CONDITIONS:	73 °F/48% RH	CERT #:	A2581295

HEPA FILTER VELOCITY DATA

AVG. FILTER FACE VELOCITY:	84 FPM
AVERAGE VELOCITY RANGE:	85-100 FPM
TOTAL MEASURED CFM:	7030 CFM
AIR CHANGES PER HOUR:	878
CRITERIA MET?	YES

HEPA FILTER INTEGRITY TEST:

LEAK DETECTED?	NO	FILTERS SIZE:	(2'X4')
LEAK REPAIRED?	NO		
FINAL PENETRATION:	< 0.01%	CRITERIA MET?	YES

ROOM PRESSURE PROFILE:

IN RELATION TO AR:	0.040"H2O
CRITERIA MET, >0.020"?	YES

Note: Refer to Appendixes A and B for sample locations and a list of equipment turned on during dynamic working conditions.

CLEANLINESS CLASSIFICATION

ALL DATA IS IN PARTICLES PER:		CUBIC METER	
CLASSIFICATION:	ISO 7	SAMPLE VOLUME :	28 L

ALL TESTS PERFORMED UNDER DYNAMIC CONDITIONS

ID	SAMPLE 1	SAMPLE 2	SAMPLE 3	SAMPLE 4	PARTICLE SIZE:
	148	259	482	927	5.0 µM

PARTICLE LIMITS: 2,930	CRITERIA MET?	YES

Note: Target Classification: ISO 7
Actual Classification: ISO 7

STANDARDS USED:

MANUFACTURER	MODEL #	SERIAL #	DUE DATE
ATI	2H	18710	14 DEC 2017
TSI	8375	90745037	21 OCT 2017
MET ONE	2400	010500133	20 SEP 2017

CERTIFIED BY: _____ DATE: 28 AUG 2017

REVIEWED BY: _____ DATE: 28 AUG 2017

TMI
CERTIFICATION SERVICES

CLEANROOM CERTIFICATION
DYNAMIC WORKING CONDITION

PERFORMED FOR:
HYBRID PHARMA
1015 W. NEWPORT CENTER DRIVE, STE 106A
DEERFIELD BEACH, FL. 33442

ROOM NUMBER:	BR2	DATE CERTIFIED:	11 JUL 2017
SQUARE FOOTAGE:	78 SQ/FT		
CUBIC FOOTAGE:	624 CU/FT	NEXT DUE:	JAN 2018
NUMBER OF HEPAS:	1		
AMBIENT CONDITIONS:	73°F/48% RH	CERT #:	A2581286

HEPA FILTER VELOCITY DATA

AVG. FILTER FACE VELOCITY:	91 FPM
AVERAGE VELOCITY RANGE:	85-100 FPM
TOTAL MEASURED CFM:	1620 CFM
AIR CHANGES PER HOUR:	155
CRITERIA MET?	YES

HEPA FILTER INTEGRITY TEST:

LEAK DETECTED?	NO	FILTER SIZE:	(2'X4')
LEAK REPAIRED?	NO		
FINAL PENETRATION:	< 0.01%	CRITERIA MET?	YES

ROOM PRESSURE PROFILE:

IN RELATION TO AR:	0.045"H2O
CRITERIA MET, >0.02"?	YES

Note: Refer to Appendixes A and B for sample locations and a list of equipment turned on during dynamic working conditions.

CLEANLINESS CLASSIFICATION

ALL DATA IS IN PARTICLES PER:		CUBIC METER	
CLASSIFICATION:	ISO 7	SAMPLE VOLUME :	28 L

ALL TESTS PERFORMED UNDER DYNAMIC CONDITIONS

ID	SAMPLE 1	SAMPLE 2	PARTICLE SIZE:
	3,598	3,301	0.5 µM

PARTICLE LIMITS: 352,000	CRITERIA MET?	YES

Note: Target Classification: ISO 7
Actual Classification: ISO 6

STANDARDS USED:

MANUFACTURER	MODEL #	SERIAL #	DUE DATE
ATI	2H	18710	14 DEC 2017
TSI	8375	90745037	21 OCT 2017
MET ONE	2400	010500133	20 SEP 2017

CERTIFIED BY: _____ DATE: 28 AUG 2017

REVIEWED BY: _____ DATE: 28 AUG 2017

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TMI
CERTIFICATION SERVICES

CLEANROOM CERTIFICATION
DYNAMIC WORKING CONDITION

PERFORMED FOR:
HYBRID PHARMA
1015 W. NEWPORT CENTER DRIVE, STE 106A
DEERFIELD BEACH, FL. 33442

ROOM NUMBER:	BR2	DATE CERTIFIED:	11 JUL 2017
SQUARE FOOTAGE:	78 SQ/FT		
CUBIC FOOTAGE:	624 CU/FT	NEXT DUE:	JAN 2018
NUMBER OF HEPAS:	1		
AMBIENT CONDITIONS:	73°F/48% RH	CERT #:	A2581286

HEPA FILTER VELOCITY DATA

AVG. FILTER FACE VELOCITY:	91 FPM
AVERAGE VELOCITY RANGE:	85-100 FPM
TOTAL MEASURED CFM:	1620 CFM
AIR CHANGES PER HOUR:	155
CRITERIA MET?	YES

HEPA FILTER INTEGRITY TEST:

LEAK DETECTED?	NO	FILTER SIZE:	(2'X4')
LEAK REPAIRED?	NO		
FINAL PENETRATION:	<0.01%	CRITERIA MET?	YES

ROOM PRESSURE PROFILE:

IN RELATION TO AR:	0.045"H2O
CRITERIA MET, >0.02"?	YES

Note: Refer to Appendixes A and B for sample locations and a list of equipment turned on during dynamic working conditions.

CLEANLINESS CLASSIFICATION

ALL DATA IS IN PARTICLES PER:		CUBIC METER	
CLASSIFICATION:	ISO 8	SAMPLE VOLUME :	28 L

ALL TESTS PERFORMED UNDER DYNAMIC CONDITIONS

ID	SAMPLE 1	SAMPLE 2	PARTICLE SIZE:
	408	296	5.0 µM

PARTICLE LIMITS: 2,930	CRITERIA MET?	YES

Note: Target Classification: ISO 8
Actual Classification: ISO 8

STANDARDS USED:

MANUFACTURER	MODEL #	SERIAL #	DUE DATE
ATI	2H	18710	14 DEC 2017
TSI	8375	90745037	21 OCT 2017
MET ONE	2400	010500133	20 SEP 2017

CERTIFIED BY: _____ DATE: 28 AUG 2017

REVIEWED BY: _____ DATE: 28 AUG 2017

TMI
CERTIFICATION SERVICES

CLEANROOM CERTIFICATION
DYNAMIC WORKING CONDITION

PERFORMED FOR:
HYBRID PHARMA
1015 W. NEWPORT CENTER DRIVE, STE 106A
DEERFIELD BEACH, FL. 33442

ROOM NUMBER:	PR	DATE CERTIFIED:	11 JULY 2017
SQUARE FOOTAGE:	120 SQ/FT		
CUBIC FOOTAGE:	1440 CU/FT	NEXT DUE:	JAN 2018
NUMBER OF HEPAS:	2		
AMBIENT CONDITIONS:	73°F/48% RH	CERT #:	A2581288

HEPA FILTER VELOCITY DATA

AVG. FILTER FACE VELOCITY:	85 FPM
AVERAGE VELOCITY RANGE:	85-100 FPM
TOTAL MEASURED CFM:	9915 CFM
AIR CHANGES PER HOUR:	413
CRITERIA MET?	YES

HEPA FILTER INTEGRITY TEST:

LEAK DETECTED?	NO	FILTER SIZE:	(2'X4')
LEAK REPAIRED?	NO		
FINAL PENETRATION:	< 0.01%	CRITERIA MET?	YES

ROOM PRESSURE PROFILE:

IN RELATION TO EXTERIOR:	0.045"H2O
IN RELATION TO AR :	0.045"H2O
CRITERIA MET, >0.02"?	YES

Note: Refer to Appendixes A and B for sample locations and a list of equipment turned on during dynamic working conditions.

CLEANLINESS CLASSIFICATION

ALL DATA IS IN PARTICLES PER:		CUBIC METER	
CLASSIFICATION:	ISO 7	SAMPLE VOLUME :	28 L

ALL TESTS PERFORMED UNDER DYNAMIC CONDITIONS

ID	SAMPLE 1	SAMPLE 2	SAMPLE 3	SAMPLE 4	SAMPLE 5	PART. SIZE
	55,650	60,287	57,690	55,204	62,142	0.5µM

PARTICLE LIMITS: 352,000		CRITERIA MET?	YES

Note: Target Classification: ISO 7
Actual Classification: ISO 7

STANDARDS USED:

MANUFACTURER	MODEL #	SERIAL #	DUE DATE
ATI	2H	18710	14 DEC 2017
TSI	8375	90745037	21 OCT 2017
MET ONE	2400	010500133	20 SEP 2017

CERTIFIED BY: _____ DATE: 28 AUG 2017

REVIEWED BY: _____ DATE: 28 AUG 2017

TMI
CERTIFICATION SERVICES

CLEANROOM CERTIFICATION
DYNAMIC WORKING CONDITION

PERFORMED FOR:
HYBRID PHARMA
1015 W. NEWPORT CENTER DRIVE, STE 106A
DEERFIELD BEACH, FL. 33442

ROOM NUMBER:	PR	DATE CERTIFIED:	11 JULY 2017
SQUARE FOOTAGE:	120 SQ/FT		
CUBIC FOOTAGE:	1440 CU/FT	NEXT DUE:	JAN 2018
NUMBER OF HEPAS:	2		
AMBIENT CONDITIONS:	73°F/48% RH	CERT #:	A2581288

HEPA FILTER VELOCITY DATA

AVG. FILTER FACE VELOCITY:	85 FPM
AVERAGE VELOCITY RANGE:	85-100 FPM
TOTAL MEASURED CFM:	9915 CFM
AIR CHANGES PER HOUR:	413
CRITERIA MET?	YES

HEPA FILTER INTEGRITY TEST:

LEAK DETECTED?	NO	FILTER SIZE:	(2'X4')
LEAK REPAIRED?	NO		
FINAL PENETRATION:	< 0.01%	CRITERIA MET?	YES

ROOM PRESSURE PROFILE:

IN RELATION TO EXTERIOR:	0.045"H2O
IN RELATION TO AR :	0.045"H2O
CRITERIA MET, >0.02"?	YES

Note: Refer to Appendixes A and B for sample locations and a list of equipment turned on during dynamic working conditions.

CLEANLINESS CLASSIFICATION

ALL DATA IS IN PARTICLES PER:		CUBIC METER	
CLASSIFICATION:	ISO 7	SAMPLE VOLUME :	28 L

ALL TESTS PERFORMED UNDER DYNAMIC CONDITIONS

ID	SAMPLE 1	SAMPLE 2	SAMPLE 3	SAMPLE 4	SAMPLE 5	PART. SIZE
	816	1,372	519	593	408	5.0 µM

PARTICLE LIMITS: 2,930		CRITERIA MET?	YES

Note: Target Classification: ISO 7
Actual Classification: ISO 7

STANDARDS USED:

MANUFACTURER	MODEL #	SERIAL #	DUE DATE
ATI	2H	18710	14 DEC 2017
TSI	8375	90745037	21 OCT 2017
MET ONE	2400	010500133	20 SEP 2017

CERTIFIED BY: _____ DATE: 28 AUG 2017

REVIEWED BY: _____ DATE: 29 AUG 2017

TMI
CERTIFICATION SERVICES

LAMINAR FLOW HOOD CERTIFICATION

PERFORMED FOR:
HYBRID PHARMA
1015 W. NEWPORT CENTER DRIVE, STE 106A
DEERFIELD BEACH, FL. 33442

MANUFACTURER:	AIR SCIENCE	DATE CERTIFIED:	11 JULY 2017
MODEL:	LF-SERIES		
SERIAL NUMBER:	NSN	NEXT DUE:	JAN 2018
ID NUMBER:	LFH-1		
LOCATION:	BR	CERT #:	A2698720

HEPA FILTER VELOCITY DATA
(ALL READINGS ARE IN FEET PER MINUTE;)

82	88	93	96	94	83
82	92	87	99	96	84
80	96	89	100	92	82
84	91	90	100	86	83

AVERAGE VELOCITY:	89.5 FPM
AVERAGE VELOCITY CRITERIA:	80-100 FPM
DISTANCE OFF FACE OF HEPA:	12"
CRITERIA MET:	YES

CLEANLINESS CLASSIFICATION
AS PER: ISO 14644-1

ALL DATA IS IN PARTICLES PER:		CUBIC METER	
CLASSIFICATION:	ISO 5	SAMPLE VOLUME :	28.3 L

ALL TESTS PERFORMED UNDER DYNAMIC CONDITIONS

ID	SAMPLE 1	SAMPLE 2	SAMPLE 3
A	0	0	0
B	0	0	0
C	0	0	0
D	0	0	0

PARTICLE LIMITS: 3,520 | CRITERIA MET? YES

PARTICLE SIZE:	MEAN:	STD. DEVIATION:
0.5 µM	0.0	0.0

HEPA FILTER INTEGRITY TEST:

LEAK DETECTED?	NO	# OF FANS:	1
LEAK REPAIRED?	N/A	PAO CONCENTRATE:	100%
FINAL PENETRATION:	< 0.03%	CRITERIA MET?	YES

Note: Tested under Dynamic Conditions

STANDARDS USED:

MANUFACTURER	MODEL #	SERIAL #	DUE DATE
ATI	2H	18710	14 DEC 2017
MET ONE	A2400	010500133	20 SEP 2017
KANOMAX	A-044	07124	26 JAN 2018

CERTIFIED BY: _____ DATE: 2 Jan 2018

REVIEWED BY: _____ DATE: 2 Jan 2018

000046

TMI Certification Services

Biological Safety Cabinet Certification

Performed For:
Hybrid Pharma
1015 W. Newport Center Drive, STE 106A
Deerfield Beach, FL. 33442

Manufacturer:	Baker	Date Certified:	11 July 2017
Model:	SG 403TX		
Serial Number:	38687	Next Due:	JAN 2018
I.D. Number:	BSC-1		
Location:	BR-2	Cert #:	A2698726

Inflow Velocity Test

Method Used:	Direct	Width:	64"	Height:	30"	Area:	19.2 FT²
Sash Opening Dimensions:		Width:	60"	Height:	12"	Area:	7.2 FT²

Velocity Readings (FPM):

100	105	108	110	110	107	105	102	106	109

Have All Criteria Been Met? **Yes**

Note: Tested under Dynamic Conditions

Average Velocity:	106.2 FPM
Inflow Velocity Criteria:	100-110 FPM
Inflow Velocity Criteria Met:	YES

Downflow Velocity Test (Supply)

Readings Taken:	At Bottom of Sash	Style:	UNIFORM	Work Area Width:	64"	Depth:	30"	Size:	19.2 FT²

Individual Readings, FPM
(each must be within ±20% or ±16FPM of its avg., whichever is greater)

							Avg Downflow (FPM)	Tolerance Range (FPM):	Meets Criteria	All Criteria Meet?
77	77	74	75	73	77	79	76.0 FPM	73-80	YES	YES

HEPA Filter Leak Test

	Exhaust	Supply
PAO Concentration:	100%	100%
Leak Detected?	No	No
Leak Repaired?	No	No
Final Penetration:	<0.01%	<0.01%
Have All Criteria Been Met?	Yes	Yes

Standards Used:

Manufacturer	Model #	Serial #	Due Date
ATI	2H	18710	14 Dec 2017
Kanomax	A-044	07124	26 Jan 2018

Certified By: _____ Date: 2 Jan 2018

Reviewed By: _____ Date: 2 Jan 2018

000047

52. Primary engineering controls provide unidirectional (i.e., laminar) HEPA filtered air. Air pattern analysis via smoke studies are conducted at the critical site to demonstrate unidirectional airflow and sweeping action over and away from the product under dynamic conditions.[ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]

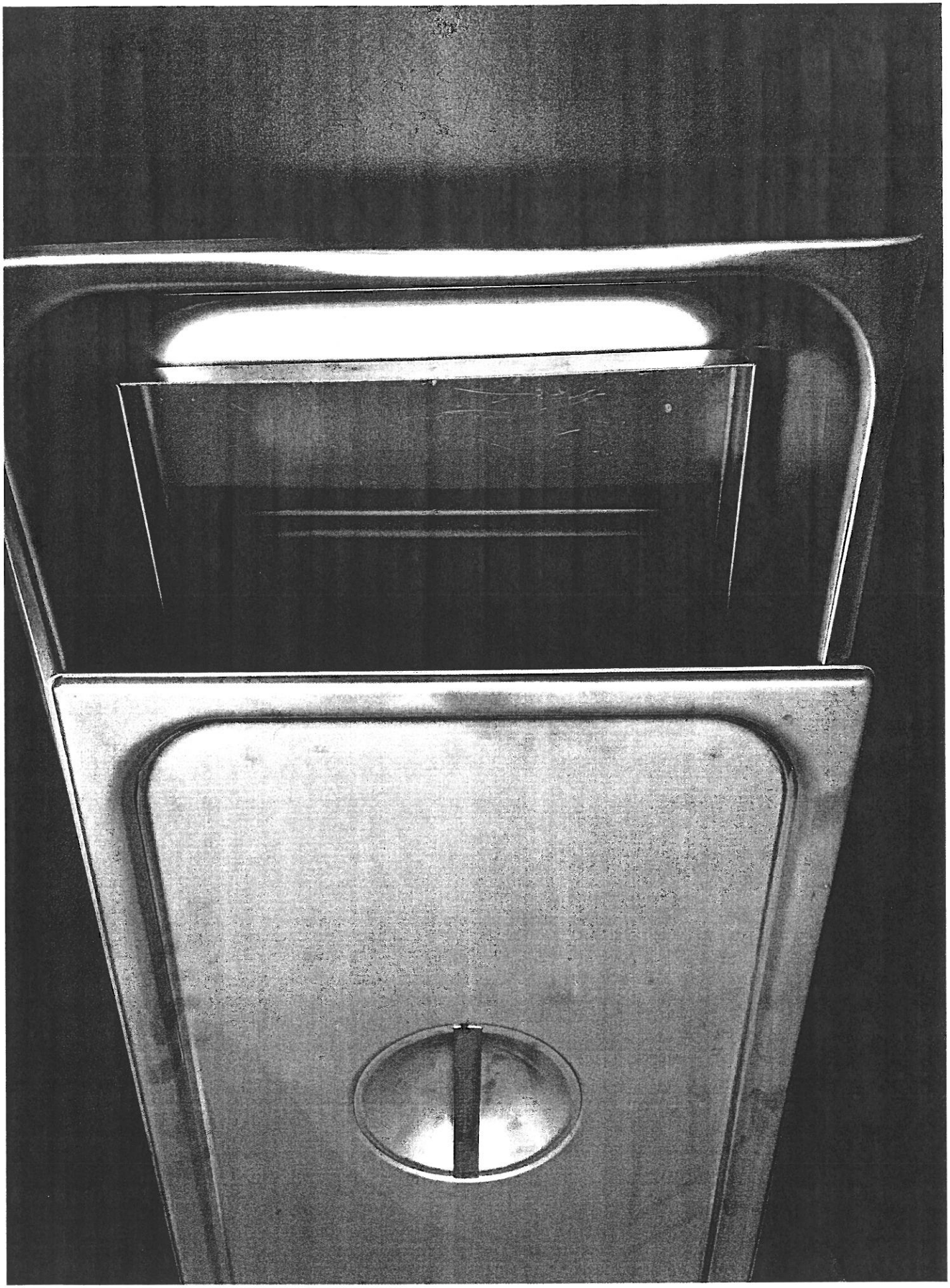
No smoke studies available at the time of inspection. PLEASE PROVIDE SMOKE STUDIES WITHIN 72 HOURS OF THIS INSPECTION. HCG IS A HAZARDOUS DRUG COMPOUNDED IN THE HD ROOM THEN TRANSFERRED TO THE LYOPHYLIZER THAT IS LOCATED IN THE POSITIVE CLEAN ROOM; PARTIALLY STOPPERED VIALS ARE BEING TRANSFERRED FROM ISO CLASS 5 PEC THROUGH ISO CLASS 7 TO THE LYOPHYLIZER.

RESPONSE:

Videos of smoke patterns for the BSC and area next to Lyophilizer have already been forwarded to the Department. It is also enclosed with this response.

The partially stoppered HCG vials are transported aseptically in a surgical stainless steel enclosure while inside the BSC. They are only reopened once they reach the area directly in front of the Lyophilizer. Attached as **Exhibit 5** are pictures of the stainless steel enclosures.

The video supplied clearly shows the air flow in the area around the lyophilizer is being directed downward as expected. The HEPA filter mounted in the ceiling directly above this area insures this flow.



58. Facility has pressure gauges or velocity meters to monitor the pressure differential or airflow between the buffer area and ante-area, and the ante-area and the general environment outside the compounding area. The results are reviewed and documented on a log at least daily or by a continuous recording device. The pressures differentials meet or exceed 5 Pa (0.02 inch water column (w.c.)). Alternatively, in facilities where low- and medium-risk level CS s are prepared, differential airflow Is maintained at a minimum velocity of 0.2 meter/second (40 fpm) across a line of demarcation between buffer area and ante-area. [ENVIRONMENTAL QUALITY AND CONTROL: Pressure Differential Monitoring]

Door connecting the general area to the ISO Class 7 prep area remained ajar through most of the inspection. Pressure gauge read +0.003"w.c..

RESPONSE:

We are not aware that this occurred, as we always keep the door closed. This door has spring loaded hinges that can be adjusted tighter. We will adjust the tension to overcome the pressure on the door.

63. The surfaces of ceilings, walls, floors, fixtures, shelving, counters, and cabinets in the buffer area are smooth, impervious, free from cracks and crevices, and non-shedding, thereby promoting cleanability, and minimizing spaces in which microorganisms and other contaminants may accumulate. [ENVIRONMENTAL QUALITY AND CONTROL: Facility Design and Environmental Controls]

positive clean room has protruding , rusted bolts sticking out of the upper left side of wall; there are multiple cracks on seam of wall in clean room.
SECOND ADVISORY.

Response to June 14, 2017 DOH Inspection Report:
The entire wall structure has been re-constructed with smooth cleanable surface. Protruding bolts have been capped with stainless steel. No exposed threads are present. The floor is not tile but rather vinyl which has 5 coats of clear epoxy.
N.B.

Buffer room has undergone 6 inspections by State Inspectors and complete FDA inspection. The "protruding bolts" are part of the room's construction and have never been questioned previously.

Response to December 19, 2017 DOH Inspection Report:
We have complied with the first advisory by totally reconstructing the ISO 7 buffer room. The walls were removed and replaced with smooth FRP (Fiber Reinforced Plastic) and stainless steel hardware. Protruding bolts were covered with stainless steel bolt covers.

The black hardware which inspector claims is rust has been painted over with white epoxy paint. These screws where most likely never removed when the walls were replaced from the plastic panels it was designed with. Unfortunately I never noticed these objects.

We hired a contractor to do the new construction and was lead to believe he could do the job correctly. Hybrid spent much time, effort, and money to comply with the first advisory. We will continue to comply with the states advisories.

68. An appropriate environmental sampling plan has been developed for airborne viable particles based on a risk assessment of compounding activities performed. Volumetric air sampling is conducted every six months and sites include locations within each ISO Class 5 environment and in the ISO Class 7 and 8 areas, and the areas at greatest risk of contamination (e.g., work areas near the ISO Class 5 environment, counters near doors, pass-through boxes). The plan includes sample locations, method of collection, frequency of sampling, volume of air sampled, and time of day as related to activity in the compounding area and action levels. [ENVIRONMENTAL QUALITY AND CONTROL : Environmental Viable Airborne Particle Testing Program—Sampling Plan]

Not available at the time of inspection

RESPONSE:

The SOPs are attached as **Exhibit 6**.

68 Title: Low Risk level CSPs with 12 hour or less BUD Environmental Viable Airborne Particle Testing Program

An appropriate environmental sampling plan has been developed for airborne viable particles based on a risk assessment of compounding activities performed including Low Risk, Medium risk, High risk as well Low risk with BUD less than 8 hours.

Volumetric air sampling is conducted (at a minimum) every six months and sites include locations within each ISO Class 5 environment and in the ISO Class 7 proximate to the ISO 5, that is our Buffer room designated area and the areas at greatest risk of contamination (e.g., work areas near the ISO Class 5 environment, counters near doors, ante-room). Air Sampling is done at counter level to simulate closest actual conditions.

Hybrid Pharma uses The A6® Viable Microbial Particle Sampler manufactured by EMLABS. And settle plates are also used.

Refer:

SOP 64 Title: Environmental Quality Control- Environmental viable Airborne Testing Program and Sampling Plan.

68a Title: Use of Settle plates for Environmental viable Micro organisms Monitoring

APPROVED BY: 4/1/15

68A Title: Use of Settle plates for Environmental viable Micro organisms Monitoring

Areas within the clean room where there is personnel activity or specific operations are carried out should also be subject to monitoring e.g. adjacent to bench areas where trays that have been passed into the clean room are held before being transferred into a clean air device.

Method of sampling:

Follow the specimen procedure for use and exposure of settle plates

1. Examine the plates for contamination prior to use.
2. Assemble the plates required and ensure that the correct information is written on the base of the plate (the part containing the media) with ink or other marker. Do not mark the lid of the plate, as there is always a possibility of lids coming off and being replaced on the incorrect sample plate.
3. The following details may be marked on each plate or recorded separately:

- operator who collected sample
- date and time of day sample taken
- area/location of sample
- position/sample number

4. Transfer the plates into the area/room/cabinet where they are to be exposed as outlined in the appropriate transfer procedure.

5. Enter the area to be tested by the appropriate procedure, if required.

6. Place the plates in the appropriate positions with the lids still on.

7. Raise lids to expose the surface of the medium, rest the lid on the very edge of the plate so that the entire agar surface is completely exposed. Take care not to put fingers on plates. Avoid passing anything over the top of plates being exposed, where possible.

APPROVED BY: 4/1/15

8. Leave settle plates exposed for the full work session. The exposure time should be recorded before sending the plates for incubation.

9. After exposure: Replace lids of plates. Swab areas where plates have been exposed with a suitable disinfectant (e.g. sterile IPA 70% solution) to remove any trace of media or condensation from the lids, which may contaminate the clean room. Remove from area/ room/ cabinet. Collect all plates exposed, and return to QA or microbiology for incubation. Ensure plates are secured in a suitable container , kept inverted and covered in bin.

9. Complete and enclose the necessary documentation. Write down the details of where settle plates are obtained and location collected from.

10. If refrigerated, the plates should be removed from the refrigerator half an hour before they are due to be exposed. Care should be taken to ensure that plates are used before the expiry date on the label.

11. Write down the details of how settle plates are returned to the Microbiology department, where used. Details of transport and any other arrangements should be described.

Incubation conditions: TSA plates at 20-25deg. C and MEA plates at 30 – 35 deg.C for 3- 5 days.

Results and reading of samples, Action levels Recommended action levels are given in **Table 1.:** Diameter 90mm, 4hr exposure.

Location	At rest (cfu)	Operational (cfu)
ISO 5	<1	5
ISO 7	5	50

Note 1: Values shown are average values. Individual settle plates may be exposed for less than 4 hours. If the settle plates are exposed for less than 4 hours, the action levels should be adjusted accordingly.

APPROVED BY: 4/1/15

70d. Title: Calculation of Minimum number of sampling points in Hybrid Pharma's Clean room_suite [Quality check not for certification].

Purpose: Calculate the sampling points to do Hybrid Pharma Clean Room Suite Environmental Monitoring (EM)

The Vertical Laminar Flowhood ISO class 5 hood or workstation is monitored within 6 inches of the critical exposure or aseptic manipulation site. The pharmacy maintains site-specific cleanroom diagrams that show sampling locations in compliance with ISO 14644-1:1999 standard (for sampling site determination) and the Hybrid Pharma EM program. Sample locations are chosen by calculating the minimum number of sampling point locations from the equation NL = √A so that the sample locations are evenly distributed throughout the cleanroom area and positioned at the height of the work activity. [Where NL = the minimum number of sampling sites and √A = square root of the area of the cleanroom in square meter (^{m2})]. The sampling diagram is approved by the QA Manager prior to implementation. Copies of the approved diagrams are maintained in the EM notebook.

Vertical Laminar Flow Hood =12 sq.ft = 1.11 sq.meters

Buffer Room Area = 120 sq.ft = 11.148 sq.metres

Ante Room Area = 24 sq.ft = 2.230 sq.metres

Staging /Preparation Room Area = 144 sq.ft = 13.378 sq.metres

One square foot is the equivalent to 0.09290304 square metres.

Locations	√A sq.m	The minimum number of sample points, NL
Vertical Laminar Flow Hood	√1.11	1
Buffer Room	√11.15	3
Ante Room	√2.23	1
Staging / Preparation Room	√13.38	4

APPROVED BY 4/1/13 **Date**

69. Evaluation of airborne microorganisms using volumetric collection methods in the controlled air environments is performed by properly trained individuals for all compounding risk levels. [ENVIRONMENTAL QUALITY AND CONTROL : Viable Air Sampling]

VAS using a general microbiological growth medium to support growth of bacteria has been used for the LFH only.

RESPONSE:

USP <797> Pharmaceutical Compounding – Sterile / Physical Tests Environmental Viable Airborne Particle Testing Program (From USP)

> A general microbiological growth medium such as Soybean-Casein Digest Medium shall be used to support the growth of bacteria. **Malt Extract agar** or some other media that support the growth of fungi shall be used in high risk level compounding environments.

We use **Malt Extract agar,** a more sensitive growth medium which supports the growth of fungi. The USP suggests that MEA should be used in high risk environment.

In addition, evaluation of airborne microorganisms using volumetric collection methods is performed in all of the controlled air environments. In support, attached as **Exhibit 7** is sampling data from 2016-2018, as well as the relevant SOPs, which show that all controlled air environments were evaluated and passed.

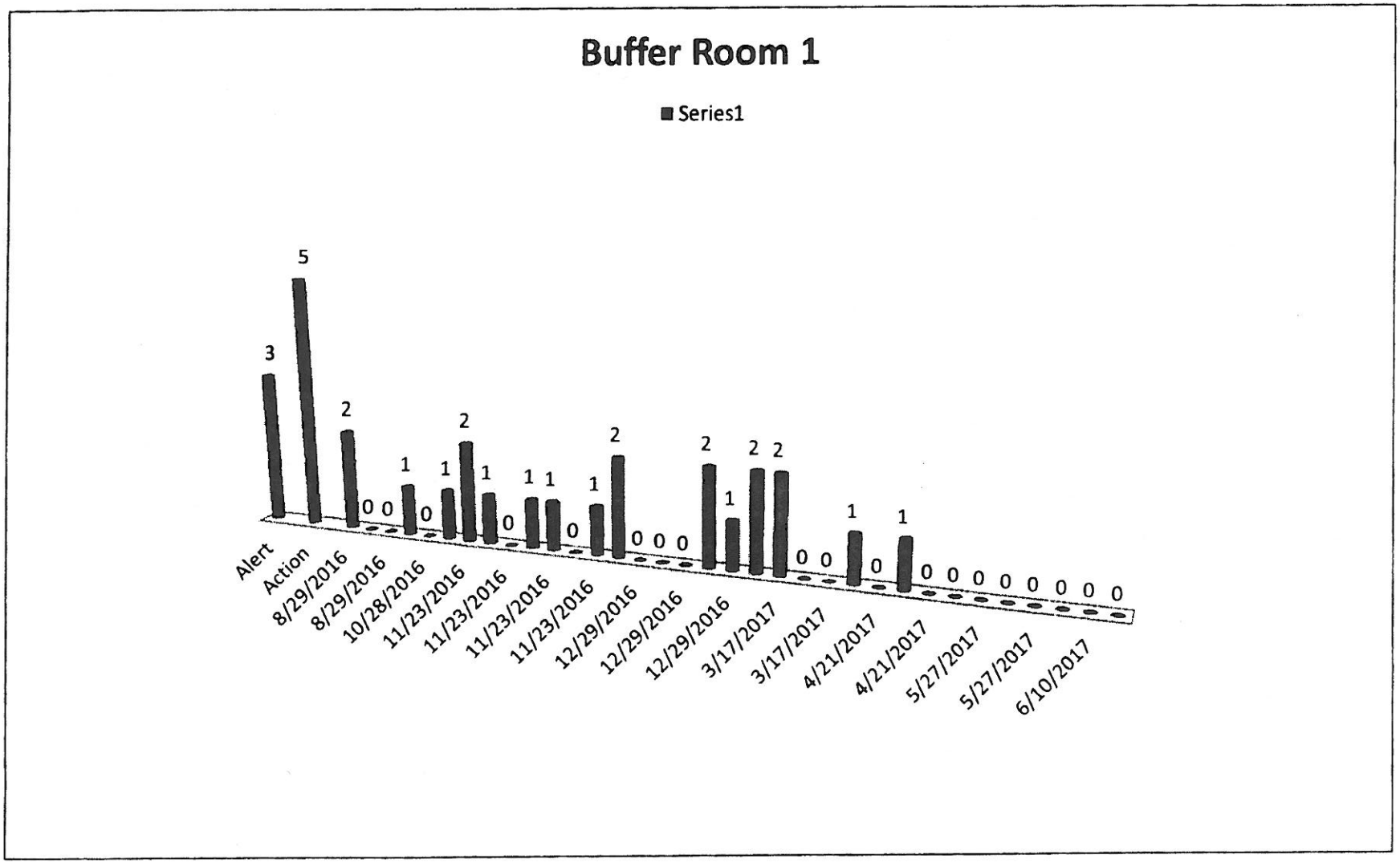
HYBRID PHARMA SOP **SAMPLING DATA FORM -FL 70 S-A Rev.1**

Air sampling Location	ISO/class	**Microbial Action Level REFERENCE**	12/31/16 MEA Air Sampler/ Settling plates	6/10/17 TSA Air Sampler/ Settling plates	7/10/17 MEA Air Sampler/ Settling plates	1/15/18 TSA Air Sampler/ Settling plates
		cfu/plate	cfu/plate	cfu/plate	cfu/plate	cfu/plate
HOOD ; BR1	5/ Class 100	>1	0	0	0	0
BUFFER ROOM 1	7/ Class 10,000	>10	0	0	0	0
HOOD , BR2	5/ Class 100	>1	0	0	0	0
BUFFER ROOM 2	7/ Class 10,000	>10	0	0	0	0
ANTE ROOM	7/ Class 10,000	>10	0	0	0	0
PREPARATION/ STAGING ROOM	8/Class 100,000	>100	0	0	0	0

			12/29/16	3/17/17	4/21/17	5/27/17	6/10/17	9/14/17
Surface Location	ISO/class	**Action Level REFERENCE**	SURFACE CONTACT	SURFACE CONTACT	SURFACE CONTACT	SURFACE CONTACT	SURFACE CONTACT	SURFACE CONTACT
		cfu/plate	cfu/plate	cfu/plate	cfu/plate	cfu/plate	cfu/plate	cfu/plate
HOOD , BR1	5/ Class 100	>3	0			0	0	0
BUFFER ROOM 1	7/ Class 10,000	>5	2		1	0	0	1
HOOD , BR2	5/ Class 100	>3	0			0	0	0
BUFFER ROOM 2	7/ Class 10,000	>5	3			2	0	1
SST#1	7/ Class 10,000	>5	1	0	1		0	
SST#2	7/ Class 10,000	>5	2	2			0	
SST#3 /ANTE	7/ Class 10,000	>5	2			2, 1	0	1
SST#5, BR1	7/ Class 10,000	>5					0	0
SST#6, BR2	7/ Class 10,000	>5		1			0	0
ANTE	7/ class10,000	>5					0	2
SST#4/ PREP	8/Class 100,000	>100	1			1, 2	0	
SINK COUNTER /PREP	8/Class 100,000	>100					0	
Prep Room					3	4	0	

1/2/18

Surface Location	ISO/class	Action Level REFERENCE	SURFACE CONTACT	SURFACE CONTACT	SURFACE CONTACT	SURFACE CONTACT	SURFACE CONTACT	SURFACE CONTACT	SURFACE CONTACT
		cfu/plate	cfu/plate	cfu/plate	cfu/plate	cfu/plate	cfu/plate	cfu/plate	cfu/plate
HOOD , BR1	5/ Class 100	>3	0						
BUFFER ROOM 1	7/ Class 10,000	>5	0						
HOOD , BR2	5/ Class 100	>3	0						
BUFFER ROOM 2	7/ Class 10,000	>5	2						
SST#1	7/ Class 10,000	>5	0						
SST#2	7/ Class 10,000	>5	0						
SST#3 /ANTE	7/ Class 10,000	>5	0						
SST#5, BR1	7/ Class 10,000	>5	0						
SST#6, BR2	7/ Class 10,000	>5	0						
Ante Room	7/class 10,000	75	3						
SST#4/ PREP	8/Class 100,000	>100	0						
SINK COUNTER /PREP	8/Class 100,000	>100	0, 1						


Buffer Room 1
Series1
3
5
2
0 0
1
0
1
2
1
0
1 1
0
1
2
0 0 0
2
1
2 2
0 0
1
0
1
0 0 0 0 0 0 0 0
Alert
Action
8/29/2016
8/29/2016
10/28/2016
11/23/2016
11/23/2016
11/23/2016
11/23/2016
12/29/2016
12/29/2016
12/29/2016
3/17/2017
3/17/2017
4/21/2017
4/21/2017
5/27/2017
5/27/2017
6/10/2017

Air sampling for viable airborne microorganisms: Location	Frequency
Settling plate air sampling in class ISO 5 Laminar Flow Hood	Once in 2 weeks
Settling plate air sampling in class ISO 5 Laminar Flow Hood [no compounding]	Once in a month
Settling plate air sampling in Raw material Weighing Station	Once in 6 months
Air samples in ISO 7area -Viable Microbial Particle Sampler	Once in 6 months
Air samples in ISO 8 Prep/ Staging Room - Viable Microbial Particle Sampler	Once in 6 months

When there is no compounding, maintain the Clean Room Suite by the regular approved Cleaning agents and Disinfectants.
All the above detailed sampling takes place after the compounding in the sterile room starts. The frequency of sampling depends on the activities, traffic, compounding in the Compounding Clean room suite.

70c Rev.2. Evaluation of the compounding environment quality by trend analysis and corrective action to control.

1.0 Objective: To ensure the corrective action to be taken for the result exceeding alert & action level followed by the collection and review of the sampling data.

2.0 Scope: This procedure is applicable to evaluate the environmental monitoring results of different area by trend analysis.

3.0 Procedure:

3.1 Distinguish the results in three categories as follows.

1. Normal level 2. Alert level 3. Action level

3.2 No action is required for results observed in normal level and below alert level category.

3.3 Consider the results, observed above normal level and below action level as alert level category.

3.3.1 On alert trend of results, initiate preventive action for any action level or critical results. Perform cleaning and disinfecting using the disinfectants in the Rotation consequently twice. If not, consider different disinfecting solutions

4.0 In action level results, a deviation report will be prepared and involved in deciding action to be taken.

4.1 Evaluate the results and decide that up to what extent and how much identification is relevant based on location. Identify all microorganisms found in the critical areas ISO 5 up to a level for determining the origin of the same.

4.2 Include the trend analysis report for evaluation of trend.

4.3 Frequency of trend analysis

	Frequency
Gloved Finger print and gown of personnel –microbial contamination working in ISO 5	Once in 6 months
Non-viable air samples in ISO 7 area	Once in 6 months

Surface sampling for viable microorganisms: Location	**Frequency**
Surface samples in class ISO 5 Laminar Flow Hood	Once in 2 weeks
Surface samples in class ISO 5 Laminar Flow Hood [no compounding]	Once in a month
Surface sample in ISO 7area	Once in quarter
Surface samples in ISO 8 Prep/ Staging Room	Once in quarter

70c. Rev.1 Evaluation of the compounding environment quality by trend analysis and corrective action to control.

1.0 Objective: To ensure the corrective action to be taken for the result exceeding alert & action level followed by the collection and review of the sampling data.

2.0 Scope: This procedure is applicable to evaluate the environmental monitoring results of different area by trend analysis.

3.0 Procedure:

3.1 Distinguish the results in three categories as follows.

1. Normal level 2. Alert level 3. Action level

3.2 No action is required for results observed in normal level and below alert level category.

3.3 Consider the results, observed above normal level and below action level as alert level category.

3.3.1 On alert trend of results, initiate preventive action for any action level or critical results. Perform cleaning and disinfecting using the disinfectants in the Rotation consequently twice. If not, consider different disinfecting solutions

4.0 In action level results, a deviation report will be prepared and involved in deciding action to be taken.

4.1 Evaluate the results and decide that up to what extent and how much identification is relevant based on location. Identify all microorganisms found in the critical areas ISO 5 up to a level for determining the origin of the same.

4.2 Include the trend analysis report for evaluation of trend.

4.3 Frequency of trend analysis

Location	Frequency
Surface samples and air samples in class ISO 5 Laminar Flow Hood [other than the conclusion of compounding]	Once in 2 weeks
Surface samples and air samples in class ISO 5 Laminar Flow Hood [no compounding]	Once in a month
Surface sample in ISO 7area	Once in a quarter
Finger print and gown of personnel working in ISO 5 and ISO 7 [other than the Day of Compounding]	Once in 6 months
Non-viable air samples in ISO 7 area	Once in 6 months
Viable air samples in ISO 7area	Once in 6 months
Surface samples and air samples in ISO 8 Ante & Prep/ Staging Room	Once in quarter

When there is no compounding, maintain the Clean Room Suite by the regular approved Cleaning agents and Disinfectants.

All the above detailed sampling takes place after the compounding in the sterile room. The frequency of sampling depends on the activities, traffic, compounding in the Compounding Clean room suite.

APPROVED BY: R. Uma 7/30/16.

QC.

Surface Location	ISO/class	**Action Level REFERENCE**	SURFACE CONTACT	SURFACE CONTACT	SURFACE CONTACT	SURFACE CONTACT
		cfu/plate	cfu/plate	cfu/plate	cfu/plate	cfu/plate
HOOD , BR1	5/ Class 100	>3				
HOOD , BR2	5/ Class 100	>3				
BUFFER ROOM 2	7/ Class 10,000	>5				
SST#1	7/ Class 10,000	>5				
SST#2	7/ Class 10,000	>5				
SST#3 /ANTE	7/ Class 10,000	>5				
SST#5, BR1	7/ Class 10,000	>5				
SST#6, BR2	7/ Class 10,000	>5				
BUFFER ROOM 1	7/ Class 10,000	>5				
SST#4/ PREP	8/Class 100,000	>100				
SINK COUNTER /PREP	8/Class 100,000	>100				

Air sampling Location	ISO/class	**Microbial Action Level REFERENCE**	Air Sampler/ Settling plates	Air Sampler/ Settling plates	Air Sampler/ Settling plates	Air Sampler/ Settling plates
		cfu/plate	cfu/plate	cfu/plate	cfu/plate	cfu/plate
HOOD , BR1	5/ Class 100	>1				
BUFFER ROOM 1	7/ Class 10,000	>10				
HOOD , BR2	5/ Class 100	>1				
BUFFER ROOM 2	7/ Class 10,000	>10				
ANTE ROOM	7/ Class 10,000	>10				
PREPARATION/ STAGING ROOM	8/Class 100,000	>100				

Hybrid Pharma SOP

67: Title: Volumetric air sampling in Clean Room Suite -High Risk Compounding Environment

1. **Test for Viable** that include

   a. Air (environmental)

1a. Viable Air sampling and testing required

- Once every six months
- When primary engineering control or surrounding area undergoes servicing
- Test must be volumetric, impaction preferred with total volume of 400 to 1000lit. (1000 lit. in ISO 5 areas highly recommended).
- **Gravimetric methods may be supplement volumetric methods, but cannot be the primary sampling method.**
- Use TSA or Soybean casein (SCD) digest agar for bacteria.

Use Malt extract Agar (MEA) or Sabouraud Dextrose (SDA) for Fungi;
This test is needed for only high risk sterile compounding.

Approved by **Date:** 8/1/18

76. Surfaces in the LAFWs, BSCs, CAIs, and CACIs are cleaned and disinfected frequently, including at the beginning of each work shift, before each batch preparation is started, every 30 minutes during continuous compounding periods of individual CSPs, when there are spills, and when surface contamination is known or suspected from procedural breaches. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]

Cleaning records do not show the BSC located in the hazardous clean room is being cleaned and/or disinfected.

RESPONSE:

Although the cleaning log was not updated to reflect the cleaning of the BSC, it was carried out without fail. The log has been revised to include this critical piece of equipment. See attached as **Exhibit 8** the updated Cleaning Maintenance Log.

Action Plan: Jeffrey Goldrich, R.Ph., will review all logs in the facility and check them all for accuracy, errors, and omissions.

Cleaning Maintenance Log: Biological Safety Cabinet/ Buffer Room 2. FORM 73A-Rev.1
Check Activity as completed

Month/ Year				Daily				Weekly	Monthly	Comments	By
Date	**Temp ^{0}F**	**% Humidity**	**Br "w.c Pressure**	**BSC**	**SST**	**Dry/ Wet mop Floor**	**Waste removal**	**Balance enclosure**	**Stationary cart walls/ ceiling**		
1.											
2.											
3.											
4.											
5.											
6.											
7.											
8.											
9.											
10.											
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25.											
26.											
27.											
28.											
29.											
30.											
31.											

HYBRID PHARMA

85. Shelving, walls, and ceilings in ante-areas and buffer areas are cleaned and disinfected at least monthly. [ENVIRONMENTAL QUALITY AND CONTROL: Cleaning and Disinfecting the Sterile Compounding Areas]

October cleaning logs reflect monthly cleaning was not done in hazardous clean room.

RESPONSE:

The cleaning schedule was affected by Hurricane Irma in September of 2017. We did 2 **extra** "Monthly" full room cleaning and disinfecting sessions, one of which should have been done 1 week later to qualify for October.

Action Plan: We will ensure the timings of the cleaning more closely relates to the physical calendar.

94. High Risk Media-fill tests that closely simulate the most challenging or stressful conditions encountered during compounding have been completed at least semiannually by compounding personnel. Media-filled vials are appropriately incubated for 14 days. [CSP MICROBIAL CONTAMINATION RISK LEVELS : High-Risk Level CSPs]

UR RPT last high risk media fill was conducted on 2.17.17

RESPONSE:

Umarani Rajalingam, R.P.T., has two recent media fill tests, the most recent having been performed on September 18, 2017. Attached as **Exhibit 9** are the assessments for Ms. Rajalingam.

PARTICIPANT NAME Uma. R DATE: _____

EVALUATOR NAME (R.PH.) Jeff Goldfield (Please Print)

LAFH
BRI

PROCESS VALIDATION EVALUATION CHECKLIST
VERTICAL LAMINAR AIRFLOW HOOD

(PLEASE PLACE A CHECK IN THE APPROPRIATE COLUMN WHILE OBSERVING PARTICIPANT PERFORMANCE: YES = 100% COMPLIANT NO = < 100% COMPLIANT)

PROCEDURE EVALUATED	YES	NO
Hood was turned on and let run for at least 30 minutes prior to preparation.	☑	☐
Did not wear jewelry, false nails, or long sleeves, etc. inside the hood.	☑	☐
Wore appropriate apparel as required by institution. (i.e. cap or scrubs)	☑	☐
Clean sterile gauze/sponge was used to clean hood with plenty of disinfectant.	☑	☐
Cleaned the IV pole first if applicable.	N/A ☐	☐
The sides of the hood were cleaned beginning at the top and starting in a downward motion from the back of the hood and working towards the front with overlapping strokes.	☑	☐
The back wall and inside of the glass shield were cleaned beginning at the top and working in a vertical downward motion with overlapping strokes.	☑	☐
The bottom of the hood was cleaned last, beginning with the back working towards the front moving horizontally from side to side with overlapping strokes.	☑	☐
Did not use spray bottles for cleaning.	☑	☐
Did not contaminate previously cleaned surfaces at any time during cleaning.	☑	☐
Lowered glass shield, so the opening was not more than 8 inches, prior to beginning sterile preparations.	☑	☐
All items placed in hood in a vertical fashion to prevent blocking of airflow.	☑	☐
No items were hung over other items, obstructing airflow.	☑	☐
Did not block airflow from HEPA filter with hands, or other objects inside hood during drug preparation manipulations.	☑	☐
Did not take hands out of hood or leave the hood during drug preparation manipulations.	☑	☐
Did not utilize outer 6 inches of hood opening or work too close to sides/back of hood during drug preparation manipulations.	☑	☐
Did not block air-intake grills at anytime.	☑	☐
Did not contaminate hood by coughing, sneezing, chewing gum, or excessive talking.	☑	☐

I certify on 1/8/18 (date) at Hybrid Pharma (evaluation site) that

Umavani Rajalingam (participant's name) is 100% competent at the above task.

EVALUATOR SIGNATURE: _____

000073

HYBRID PHARMA SOP

Title: Assessing Cleaning and Disinfection Procedures: FORM 96b
The qualified evaluator will mark (×) each space for which the person being assessed has acceptably completed the described activity, prints N/A if the activity is not applicable to the assessment session or N/O if the activity was not observed.

Monthly Tasks:

Performs monthly cleaning on a designated week. Prepares a disinfectant solution as stated in approved list at Hybrid Pharma that is appropriate for the surfaces to be cleaned.	Peridox RTU ✓
Cleans buffer area and ante-area ceiling, walls, and storage shelving with a disinfectant solution and a mop or uses a microfiber cleaning system.	✓
Once ISO Class 5 area is clean, cleans compounding room ceiling, followed by walls and ending with the floor. Uses appropriate labeled mops or microfiber cleaning system.	✓
Cleans all buffer area storage shelves by removing contents and using a germicidal detergent soaked lint free wipes. Allows to dry prior to replacing contents , wipes with sterile 70% IPA to remove disinfectant residue. Uses new wipe as needed.	✓
Cleans all buffer area carts by removing contents and using germicidal detergent soaked lint free wipe, cleans all carts starting with the top shelf and top of post, working down to wheels. Cleans the under side of shelves in a similar manner. Uses a new wipe for each cart. Allows to dry. Wipes carts with sterile 70% IPA wetted lint-free wipe to remove any disinfectant residue. Uses new wipe as needed.	✓
Cleans buffer area chairs, the interior and exterior of trash bins, and storage bins using disinfectant solution soaked lint free wipe.	✓
Documents all cleaning activities as to who performed such activities with date noted.	

The person assessed is immediately informed of all unacceptable activities (i.e., spaces lacking a Check marks, N/A and shown and informed of specific corrections.

Signature of Person ~~Assessed~~ --- Uma R Date 1/8/18
Printed Name
Signature of Qualified Evaluator --- Date 1/8/18
Printed Name Jeff Goldich

APPROVED BY

HYBRID PHARMA SOP

Title: Assessing Cleaning and Disinfection Procedures: FORM 96a

Cleaning and Disinfection Practices:

The qualified evaluator will mark (×) each space for which the person being assessed has acceptably completed the described activity, prints N/A if the activity is not applicable to the assessment session or N/O if the activity was not observed.

Daily Tasks:

Prepares correct concentration of disinfectant solution according to Hybrid Pharma's SOP instructions.	Peridox RTU
Uses appropriately labeled container for the dilution of the disinfectant.	Lot# GH3208062261 exp 03/2018
Documents disinfectant solution preparation.	✓
Follows garbing procedures when performing any cleaning activities.	✓
At the beginning of each shift, cleans all ISO Class 5 devices prior to compounding in the following order: walls, and work surface.	70% Sterile IPA
Uses a lint free wipe soaked with sterile 70% IPA or other approved disinfectant solution and allows to dry completely.	1 to 2 minutes
Removes all compounder components and cleans all ISO Class 5 areas as stated above at the end of each shift.	✓
Cleans all counters and easily cleanable work surfaces/ counters.	next to LAPH
Mops floors, using the mop, starting at the wall opposite the room entry door; mops floor surface in even strokes toward the operator. Moves carts as needed to clean entire floor surface. Use of a microfiber cleaning system is an acceptable alternative to mops.	N/A ✓
In the preparation/ staging room, cleans sink and all contact surfaces; cleans floor with a disinfectant solution or uses microfiber cleaning system.	Peridox RTU. ✓

The person assessed is immediately informed of all unacceptable activities (i.e., spaces lacking a Check marks, N/A and shown and informed of specific corrections.

Signature of Person ~~Assessed~~ ---------- Uma. R Date 1/8/18
Printed Name
Signature of Qualified Evaluator ---------- Date 1/8/18
Printed Name Jeff Goldich

APPROVED BY

HYBRID PHARMA

NAME: DATE:

Environmental Monitoring Competency Checklist	FORM 66

Reading Environmental Monitoring Samples Uma. R.
Selects the correct Environmental Sampling Form that corresponds with the samples being read.
Removes samples from the incubator in the time frame specified in established policy and procedure (TSA incubation should not be less than 48 but not greater than 72 hours. Fungal plate incubation should occur for a period of 5-7 days.
Document the date that samples are removed from the incubator to read.
Reads the plates one at a time counting the number of discrete colonu forming units (CFUs)on each plate
Documents the number of CFUs on each plate in the correct corresponding location on the Environmental Sampling Data Collection Form
After all the results for each plate are read and documented, compares the result to the established Action Limit Value for each location.
If any sample fails, the failing plate is marked fail with a black sharpie.
Immediately document any out of limit results, CFU # that exceed established Action Limits and save that plat/s to be sent for Speciation if applicable.
Review documentation form for those samples and once complete, files environmental monitoring Data collection Form.
Dispose the plates sealed in plastic bags

Evaluated By:
Date: 1/5/18, 1/8/18,

APPROVED BY DATE

HYBRID PHARMA

Environmental Monitoring Competency Checklist	FORM 66

NAME: Uma. R. DATE: 4/5/18

Viable Volumetric Air Sampling	
Air Samplers are taken at locations that are consistent with the established Environmental Monitoring Plan.	✓
Samples are taken using a procedure that is consistent with policy and procedure	✓
Air volume sampled is consistent with amounts specified in policy and procedure	✓
Surface sampling	
Contact plates are applied at locations that are consistent with the established Sampling Plan.	✓
Samples are taken using a procedure that is consistent with protocol.	✓
Cleans the area where the sample was taken to remove media residue using 70% sterile IPA and lint ~~free wipe~~ after sampling	✓
Incubation and post sampling Procedure	
Samples are handled in an aseptic manner which prevents accidental exposure outside of the selected sampling location	✓
Exposed samples are closed aseptically with tops secured to bottom with tape	✓
all closed samples are placed in a plastic bin and cover with the lid and removed from the controlled environment	✓
Documentation is completed immediately prior to placing the samples in the incubator.	✓
TSA samples are placed into the incubator in an inverted position. Fungal plates are placed right side up. ✓	✓

Evaluated By:
Date:

1/5/18

APPROVED BY DATE

HYBRID PHARMA

Environmental Monitoring Competency Checklist	FORM 66
SKILL NAME: Uma. R DATE: 1/5/18	
Describe the difference between viable and nonviable contamination and the role of each in a n Environmental Sampling Plan	
Articulates the purpose of an environmental sampling plan and what the data generated can be used to determine	
States the location of the facility's environmental sampling plan and data forms	
Describes Procedure for air, surface and personnel sampling	
Describes the actions to take in the event that any of the environmental monitoring plates that exceed established action limits	
Describes the process for particle control and particulate counts at the location and when particle counts must occur	
Describes the differential pressure measurements at the facility and correctly states established limits	
Gathers all supplies needed for environmental sampling including correct media, volumetric air sampler, tape, black sharpie pen, documentation forms, gloves, lint free wipes.	
Checks all media for packaging integrity and expiration dates. Note lot # and expiration dates as well as manufacturer and type on documentation forms	
Inspects each media unit to ascertain that there is no growth on the plates prior to beginning sampling.	
Cleans the outside of all containers and supplies before bringing into the clean room	
Labels each media unit using a sharpie identifying sample location per environmental monitoring plam, date and time taken, sampler's initials'	
Resanitize gloves and allow to dry. Resanitize gloves after every 5 plates.	
Discards plates if during transport or placement, the media unit is exposed or contaminated prior to or during sampling.	
Places media units and accompanying documentation into a cleaned plastic bin to go into cleanroom	

Evaluated By:
Date: 1/5/18

APPROVED BY DATE

HYBRID PHARMA

97 a Title: **Assessing Hand Hygiene and Garbing Related Practices of Compounding Personnel Form**

Hand Hygiene and Garbing Practices: The qualified evaluator will mark (x) each space for which the person being assessed has acceptably completed the described activity, prints N/A if the activity is not applicable to the assessment session or N/O if the activity was not observed.

Printed name and position/title of person assessed: ----Uma R.----

The person assessed is immediately informed of all unacceptable activities (i.e., spaces lacking a Check marks, N/A, or N/O) and shown and informed of specific corrections.

Signature of Evaluator Date: 11/10/17

Signature of the Personnel evaluated: Date: 11/10/17

APPROVED BY DATE 11/10/17

Appendix III. Sample Form for Assessing Hand Hygiene and Garbing Related Practices of Compounding Personnel

Printed name and position/title of person assessed: Uma R. Pharm Tech

Name of facility or location: Hybrid Pharma

Hand Hygiene and Garbing Practices: The qualified evaluator will mark (×) each space for which the person being assessed has acceptably completed the described activity, prints N/A if the activity is not applicable to the assessment session or N/O if the activity was not observed.

✓	Presents in a clean appropriate attire and manner.
✓	Wears no cosmetics or jewelry (watches, rings, earrings, etc. piercing jewelry included) upon entry into ante-areas
✓	Brings no food or drinks into or stored in the ante-areas or buffer areas.
✓	Is aware of the line of demarcation separating clean and dirty sides and observes required activities.
✓	Dons shoe covers or designated clean-area shoes one at a time, placing the covered or designated shoe on clean side of the line of demarcation, as appropriate.
N/A	Dons beard cover if necessary
✓	Dons head cover assuring that all hair is covered.
✓	Dons face mask to cover bridge of nose down to include chin.
✓	Performs hand hygiene procedure by wetting hands and forearms and washing using soap and warm water for at least 30 seconds.
✓	Dries hands and forearms using lint-free towel or hand dryer.
✓	Selects the appropriate sized gown examining for any holes, tears, or other defects.
✓	Dons gown and ensures full closure.
✓	Disinfects hands again using a waterless alcohol-based surgical hand scrub with persistent activity and allows hands to dry thoroughly. before donning sterile gloves
✓	Dons appropriate sized sterile gloves ensuring that there is a tight fit with no excess glove material at the fingertips.
✓	Examines gloves ensuring that there are no defects, holes, or tears.
✓	While engaging in sterile compounding activities, routinely disinfects gloves with sterile 70% IPA prior to work in the direct compounding area (DCA) and after touching items or surfaces that may contaminate gloves.
✓	Removes PPE on the clean side of the ante-area.
✓	Removes gloves and performs hand hygiene
✓	Removes gown and discards it, or hangs it on hook if it is to be reused within the same work day.
✓	Removes and discards mask, head cover, and beard cover (if used).
✓	Removes shoe covers or shoe one at a time, ensuring that uncovered foot is placed on the dirty side of the line of demarcation and performs hand hygiene again. (Removes and discards shoe covers every time the compounding area is exited).

The person assessed is immediately informed of all unacceptable activities (i.e., spaces lacking a Check marks, N/A, or N/O) and shown and informed of specific corrections.

R.U.	Uma. R	6/28/17
Signature of Person Assessed	Printed Name	Date
	Jeff Crabbick	6/28/17
Signature of Qualified Evaluator	Printed Name	Date

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97a. Hand Hygiene and Garbing Practices: Presents in a clean appropriate attire and manner. No street jackets allowed. Remove street shoe and wear lab shoes.	✓
Wears no cosmetics or jewelry (watches, rings, earrings, etc. piercing jewelry included) upon entry into prep/ staging areas.	✓
Brings no food or drinks into or stored in the ante-areas or buffer areas.	✓
Is aware of the line of demarcation separating clean and dirty sides and observes required activities.	✓
Dons shoe covers or designated clean-area shoes one at a time, placing the covered or designated shoe on clean side of the line of demarcation, as appropriate.	✓
Dons beard cover if necessary. Dons head cover assuring that all hair and ears are covered.	✓
Dons face mask to cover bridge of nose down to include chin.	✓
Performs hand hygiene procedure by wetting hands and forearms and washing using soap and warm water for at least 30 seconds.	✓
Dries hands and forearms using lint-free towel or hand dryer.	✓
Selects the appropriate sized gown examining for any holes, tears, or other defects. Dons gown and ensures full closure.	✓
Disinfects hands again using a waterless alcohol-based surgical hand scrub with persistent activity and allows hands to dry thoroughly. before donning sterile gloves	✓
Dons appropriate sized sterile gloves ensuring that there is a tight fit with no excess glove material at the fingertips.	✓
in the direct compounding area (DCA) and after touching items or surfaces that may contaminate gloves.	✓
Removes PPE on the clean side of the ante-area. Removes gloves and performs hand hygiene.	✓
Removes gown and discards it, or hangs it on hook if it is to be reused within the same work day.	✓
Removes and discards mask, head cover, and beard cover (if used).	✓
Removes shoe covers or shoe one at a time, ensuring that uncovered foot is placed on the dirty side of the line of demarcation.	✓

APPROVED BY JAL **DATE** 11/10/17

Process Validation Media Fill 150 x 50ml vials

10 J: High Risk – Media Fill Challenge Personnel's aseptic handling.
Name of the Person performing: Uma. R

Date: 6|22|17

METHOD: VALIDATION OF HIGH RISK PROCESS -weighing, measuring, mixing, dissolving, aseptic manipulation of the filtration process, dispensing, stoppering, capping.

TECHNIQUE/ PROCEDURE:

DISSOLUTION: stage 1

1. Weigh growth media TSB powder in scale 450.0gm -0.450 kg
2. Measure 1000ml in a graduated container
3. Transfer sterile water for injection [9000 ml] to a Glass container of size 10 litre without splashing. The sides mouths shall be half covered with screw caps or Aluminum foil.
4. Set up the Overhead stirrer. Speed -546 rpm for ---45- minutes
5. Turn on the stirring slowly using the knob. As a good swirling of liquid is seen, add TSB powder in the water and close the mouth with the aluminum foil. Allow for stirring to get a clear liquid. Keep sample solution at this stage 1 in sterile vial for positive control before filtration.
6. Set up the Pre sterilization to remove particulates as in 7a. In ISO 7 Work Bench.
7. **STERILIZATION: stage 2**

   a. stainless steel or plastic filter holder with 0.45 micron or 0.2micron filter, transfer tubes, transfer pump with positive pressure.

   Pump Details: Baxter Repeater Pump ✓

   Filter Details: Sterile PES 0.4 micron + 0.2 micron , 1" capsule Filter ✓

   Collect the filtered solution in depyrogenated 50ml clear vials set up in ISO Hood.

180 x 50ml vials
Process Validation Media fill

HYBRID PHARMA DOCUMENTATION CONTROL FORM FORM 75A

Batch details, Name of the drug, strength			Media Fill.		
Batch size and Vial size	ml, vials				
Details of settle plate TSA, collection time batch, expiry, manufacturer used to collect air in the LAFH Hardy 26ml USP W64			H17118 2017-08-16		
During Compounding ISO 5 Hood settle air Plates ✓	Ø Cfu	Pass/ Fail		Start date 6/22/17	End Date 6/26/17
Negative control ✓	Ø Cfu	Pass/ Fail			
Details of TSA W/LEC &P80 batch, expiry, manufacturer Temp: 30-35°C, Inc. 2 Hardy P34			H17094 2017-07-03		
Post Compounding Gloved fingertip Personnel: UR (UMK)	LEFT ✓ Ø Cfu Pass/ Fail	RIGHT ✓ Ø Cfu Pass/ Fail	HOOD SURFACE ✓ Ø Cfu Pass/ Fail	Start date 6/22/17	End Date 6/26/17
		Sleeve ✓ Ø Cfu Pass/ Fail	Negative control ✓ Ø Cfu Pass/ Fail		

000083

HYBRID PHARMA **MEDIA FILL TEMPLATE**

Process Validation: Media fill 220 x 1ml vial

10L: Low/Medium Risk – Media Fill Challenge Personnel's aseptic handling.

Name of the Person performing: Uma. R Date: 9/18/17

METHOD: VALIDATION OF HIGH RISK - measuring, aseptic manipulation of the filtration process, dispensing, stoppering, capping

TECHNIQUE/ PROCEDURE:

1. Measure 60ml of TSB w L & T20 at a time in sterile graduated cylinder accurately looking at lower meniscus of the water level.
2. Transfer TSB w L & T20 [60ml] to a beaker containing 180ml of Sterile water for injection.
3. Cover the beaker with the aluminum foil or glass cover and stir in a magnetic stirrer for 3 minutes at rpm 100.
4. Set up the filteration set either a or b
5. a. sterile 0.2 micron syringe filter, sterile 50ml syringes
   b. Sterile 0.2 micron Filter, Sterile transfer tubes, transfer pump
6. After filtration, dispense into sterile vials arranged in trays aseptically.
   Volume: (1ml) 2ml 5ml 10ml 30ml
   Stopper the vials without touching the open end of the vials and touching the inner surface of the stoppers using a depyrogenated tweezer.
7. Inspect visually and make sure the stoppers are sealed tight in by gently pressing using the fingers.
8. Cap the vials, label with date and initial and keep them in the plastic bin, cover them and submit it for microbiological evaluation.

Pipet 200-100 Wheaton Acu 82

Sterile 1000µl pipette tip Sorenson 10230T ; 15100702 30

Materials used: TSB / L / T20 ; U261 H17194 20171110

Filter: Supor 32mm 0.2µm Sterile # 93824642 Baxter 20176328 2020 02

Filter Integrity: use sterile water for injection through and measure the bubble point or Hold pressure Byb. Powd 53 psi (Pass) / Fail B

APPROVED BY

Materials used: Bubble Point Test value: 52 PSI

Sterile water for Injection: Baxter 03380013-06 #233684 05/31/2018 ✓

TSB powder: 106380A exp. 11/ 2017 Lab safety Corp. ✓

Tubes: Sterile Repeater Pump Fluid Transfer Tube set, Universal Spike Luer Lock, REF: H93811 1193584 2019- 10-31 ✓

Sterile Filter: MDI Asepticap KS-PES capsule Filter, 1" Type: DKS-S [0.4MICRON +0.2MICRON] Sterile DK4286E 2018-07 ✓

stoppers autoclaved: Steam Sterilizer at 121°C for 30 minutes, Sterigage 2020 06314 2020 06 ✓ Pass

Glasswares , vials, beakers, graduated jars, depyrogenated:

Using dry heat Oven, Lindberg/Blue U01F305604-WF, cert. Due: 03/ 2018

Temp: 250° C, 30 min ✓

Positive Control Stage 1 ---- 5 x 50ml vials

Number of Vials [Stage 2] made: ---- 175 x 50ml vials

Temperature Incubation: [Temp. 20 -25 ° C,] 25°C

Incubation Time for 14 Days

Start Date: 6/22/'17 End Date: 7/6/17

Pass : If positive is turbid and all the filtered solution clear.

Fail: If positive is turbid/ cloudy and filtered solution negative vials shows any turbidity.

Pass ① positive control is turbid
② All filtered vials/solution is clear

Fail: ① positive control is turbid
② Any filtered vials/solution is also turbid

HYBRID PHARMA **MEDIA FILL TEMPLATE**

For positive control: Dissolve the TSB powder in Sterile water for injection and pour in few vials for observation. TSB powder 1.089gm in 30ml SWI and 2ml in each vials stoppered (5vials)

Sterile water for Injection: Baxter Y237552 6/30/'18

TSB powder: 17094 3/20/2020 Criterion ; Hardy

Tubes, stoppers autoclaved? ----------, AC248 ----------

Glasswares , vials, beakers, graduated jars, depyrogenated? using dry heat Oven. Temp: 250°c ; 30min DPLB130 ; DPLB129 ; DPLB128

Number of Vials made: ~~463~~ x 2ml Positive Control 5 x 2ml

Temperature of the Biological Incubator used: [Temp. 20 -25 °C,] (68-77F) at Room Temperature 73 - 75F

Incubation Time for 14 Days

Start Date: 9/18/17 End Date: 10/2/17

PASS

3. Positive control samples are turbid ✓ 5 vials
4. All the filtered solution in vials : clear. ✓ 74F

Pass B 10/2/17

FAIL

3. Positive control samples are turbid.
4. Any filtered solution in vials is also turbid.

Details of Post Media Fill Gloved Fingertip evaluation

P34	Left Fingertips	Right Fingertips	Name of Personnel	Date Start
H 17205 20171022	0 Cfu Pass/ Fail	0 Cfu Pass/ Fail	Uma. R	9/18/17

B 9/21/17

BR. Temp 72F Humidity 36%.

BRI diff. pressure 0.05" w.c

ISO 5 Hood Pressure Gauge 0.5" w.c

APPROVED BY 10/2/17

HYBRID PHARMA **MEDIA FILL TEMPLATE**

Process Validation; Media Fill 463 X 2ml vials

10K: Low/Medium Risk – Media Fill Challenge Personnel's aseptic handling. 463 vials X 2ml.

Name of the Person performing: Uma. R Date: 9/18/17

METHOD: VALIDATION OF HIGH RISK - measuring, aseptic manipulation of the filtration process, dispensing, stoppering, capping

TECHNIQUE/ PROCEDURE:

1. Measure 100ml of TSB w L & T20 at a time in sterile graduated cylinder accurately looking at lower meniscus of the water level.
2. Transfer TSB w L & T20 [900ml] to a beaker .
3. Cover the beaker with the aluminum foil or glass cover.
4. Set up the filteration set either a,b or c
5. a. sterile 0.2 micron syringe filter, sterile 20ml syringes
   b. stainless steel filter holder with 0.2micron filter, transfer tubes, transfer pump.
   (c. Sterile 0.2 micron Filter, Sterile transfer tubes, transfer pump) ✓
6. After filtration, dispense into sterile vials arranged in trays aseptically.
   Volume: (2ml) 5ml 10ml 30ml
   Stopper the vials without touching the open end of the vials and touching the inner surface of the stoppers using a depyrogenated tweezer.
7. Inspect visually and make sure the stoppers are sealed tight in by gently pressing using the fingers.
8. Cap the vials, label with date and initial and keep them in the plastic bin, cover them submit it for microbiological evaluation.

Materials used: TSB W L/T20; U261 H17194, 2017-11-10

Filter: MDI 50mm Sterile Aseptiqap 0.2µm filter RS PES IK1296L 201901

Filter Integrity: use sterile water for injection through and measure the bubble ✓ point or Hold pressure 52 psi. (Pass)/ Fail

APPROVED BY 16/2/17

STERILIZATION: is carried out under ISO 5 Hood.

a. Sterile Filter Details: 1" capsule Filter PES
b. Transfer tubes: Sterile
c. Dose pump Details: Baxter Pump set up at Medium speed 9.

8. After filtration , dispense 50.5 ml through the sterile 0.2 micron filter into sterile and depyrogenated vials.
9. Stopper the vials without touching the open end of the vials or touching the inner surface of the stoppers using Tweezer and press with sterile gloved finger tips. Move the stoppered vial trays to ISO 7 work bench.
10. Finish the ISO 5 hood work by taking a surface sample in a TSA L/PS, gloved finger tip samples for both left and right hands of the operator/s. Operator disposes the gloves after sampling and changes into new gloves.
11. Crimp Cap the vials in ISO 7 bench, and keep them in the plastic bin, cover them submit it for microbiological evaluation, label with date and initial.

NOTES:

Particle Counts: /min/ft^3 5
Temperature: 74F
Humidity: 36%.
Differential Pressure: BRI 0.05" w.c
ISO 5 Hood Pressure Gauge: 0.5" w.c
ACTIVITES INTERRUPTIONS:
NUMBER OF EXITS AND ENTRIES TO BUFFER ROOM. One exit during mixing
OTHER ACTIVITIES INSIDE THE BUFFER ROOM One exit + entry during stoppering

HYBRID PHARMA **MEDIA FILL TEMPLATE**

For positive control: Dissolve the TSB powder in Sterile water for injection and pour in few vials , stopper & caps them for observation. 1gm in 30ml SWI in five vials @ 1ml ea

Sterile water for Injection: Baxter Y237552 6/30/18

TSB powder: Hardy ; Criterion ; 17094 3/20/2020

Stoppers autoclaved: Steam Sterilizer at 121^{0}C for 30 minutes, Sterigage 2020 06314 2020 06 AC248

Glasswares , vials, beakers, graduated jars, depyrogenated: DPLB 128, 129, 130.

Using dry heat Oven, Lindberg/Blue U01F305604-WF, cert. Due: 03/ 2018

Temp: 250^0 C, 30 min

Number of Vials made: 220x1ml Positive Control ---- 5 vials @ 1ml

Incubation Temperature [Temp. 20 -25 ^{0}C, 68-77F]

Incubation Time for 14 Days Room temperature 78-75 F

Start Date: 9/18/'17 End Date: 10/2/'17

PASS

5. Positive control samples are turbid
6. All the filtered solution in vials clear. clear 74 F Room temp. Pass, B 10/2/

FAIL

5. Positive control samples are turbid.
6. Any filtered solution in vials is also turbid.

APPROVED BY 10/2/17

HYBRID PHARMA **MEDIA FILL TEMPLATE**

Details of Post Media Fill Gloved Fingertip evaluation

P34 TSA/L &T80	Left Fingertips	Right Fingertips	Name of Personnel	Date Start
H 17205 2017 1022	0 Cfu Pass/ Fail	0 Cfu Pass/ Fail	Uma.R	9/18/17

E 9/21/17

NOTES:

Particle Counts: 2/ft³/min

Temperature: 72F

Humidity: 36%

Differential Pressure: BR1 0.05"to.c

ISO 5 Hood Pressure Gauge: 0.5"to.c

ACTIVITES INTERRUPTIONS:

NUMBER OF EXITS AND ENTRIES TO BUFFER ROOM. No exit after is started to dispense after sterile filteration.

APPROVED BY

95. Documentation indicates compounding personnel have successfully completed didactic training, passed written competency assessments, undergone skill assessment using observational audit tools (hand hygiene, garbing, aseptic technique) and media-fill testing annually or semiannually (high risk) and before any compounding personnel begin to prepare CSPs . [ENVIRONMENTAL QUALITY AND CONTROL: Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures]

JG RPh is overdue for all visual assessments.

RESPONSE:

Jeffrey Goldrich, R.Ph., is not overdue on his visual assessments. Attached as **Exhibit 10** are the visual assessments for Mr. Goldrich, performed on June 29, 2017, as well as on January 8, 2018.

Action Plan: Add all assessments on repeating calendar.

98. Compounding personnel and other personnel responsible for cleaning routinely undergo performance evaluation of proper hand hygiene, garbing, and all applicable cleaning and disinfecting procedures conducted by a qualified aseptic compounding expert. Visual observation of hand hygiene, garbing and cleaning is documented and maintained to provide a permanent record and long-term assessment of personnel competency. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures]

JG Rph is assessing UR RPT and is overdue for all visual assessments.

RESPONSE: See response to number 95.

HYBRID PHARMA SOP

Title: Assessing Cleaning and Disinfection Procedures: FORM 96a

Cleaning and Disinfection Practices:

The qualified evaluator will mark (x) each space for which the person being assessed has acceptably completed the described activity, prints N/A if the activity is not applicable to the assessment session or N/O if the activity was not observed.

BR2

Daily Tasks:

Prepares correct concentration of disinfectant solution according to Hybrid Pharma's SOP instructions.	✓
Uses appropriately labeled container for the dilution of the disinfectant.	✓
Documents disinfectant solution preparation.	✓
Follows garbing procedures when performing any cleaning activities.	✓
At the beginning of each shift, cleans all ISO Class 5 devices prior to compounding in the following order: walls, and work surface.	✓
Uses a lint free wipe soaked with sterile 70% IPA or other approved disinfectant solution and allows to dry completely.	✓
Removes all compounder components and cleans all ISO Class 5 areas as stated above at the end of each shift.	✓
Cleans all counters and easily cleanable work surfaces/ counters.	✓
Mops floors, using the mop, starting at the wall opposite the room entry door; mops floor surface in even strokes toward the operator. Moves carts as needed to clean entire floor surface. Use of a microfiber cleaning system is an acceptable alternative to mops.	✓
In the preparation/ staging room, cleans sink and all contact surfaces; cleans floor with a disinfectant solution or uses microfiber cleaning system.	✓

The person assessed is immediately informed of all unacceptable activities (i.e., spaces lacking a Check marks, N/A and shown and informed of specific corrections.

Signature of Person Assessed ---- Jeff Date 1/8/18
Printed Name Jeff Goldrich
Signature of Qualified Evaluator ---- Date 1/8/18
Printed Name Uma. R

APPROVED BY

HYBRID PHARMA SOP

Title: Assessing Cleaning and Disinfection Procedures: FORM 96b
The qualified evaluator will mark (×) each space for which the person being assessed has acceptably completed the described activity, prints N/A if the activity is not applicable to the assessment session or N/O if the activity was not observed.

Monthly Tasks: BR2

Performs monthly cleaning on a designated week. Prepares a disinfectant solution as stated in approved list at Hybrid Pharma that is appropriate for the surfaces to be cleaned.	✓
Cleans buffer area and ante-area ceiling, walls, and storage shelving with a disinfectant solution and a mop or uses a microfiber cleaning system.	✓
Once ISO Class 5 area is clean, cleans compounding room ceiling, followed by walls and ending with the floor. Uses appropriate labeled mops or microfiber cleaning system.	✓
Cleans all buffer area storage shelves by removing contents and using a germicidal detergent soaked lint free wipes. Allows to dry prior to replacing contents , wipes with sterile 70% IPA to remove disinfectant residue. Uses new wipe as needed.	✓
Cleans all buffer area carts by removing contents and using germicidal detergent soaked lint free wipe, cleans all carts starting with the top shelf and top of post, working down to wheels. Cleans the under side of shelves in a similar manner. Uses a new wipe for each cart. Allows to dry. Wipes carts with sterile 70% IPA wetted lint-free wipe to remove any disinfectant residue. Uses new wipe as needed.	✓
Cleans buffer area chairs, the interior and exterior of trash bins, and storage bins using disinfectant solution soaked lint free wipe.	✓
Documents all cleaning activities as to who performed such activities with date noted.	✓

The person assessed is immediately informed of all unacceptable activities (i.e., spaces lacking a Check marks, N/A and shown and informed of specific corrections.

Signature of Person Assessed ---------- Date 1/8/18
Printed Name Jeff Gobbi
Signature of Qualified Evaluator ---------- Date 1/8/18
Printed Name

APPROVED BY

HYBRID PHARMA SOP

for Jeff Goldrich

97a. Hand Hygiene and Garbing Practices: Presents in a clean appropriate attire and manner. No street jackets allowed. Remove street shoe and wear lab shoes.	✓
Wears no cosmetics or jewelry (watches, rings, earrings, etc. piercing jewelry included) upon entry into prep/ staging areas.	✓
Brings no food or drinks into or stored in the ante-areas or buffer areas.	✓
Is aware of the line of demarcation separating clean and dirty sides and observes required activities.	✓
Dons shoe covers or designated clean-area shoes one at a time, placing the covered or designated shoe on clean side of the line of demarcation, as appropriate.	✓
Dons beard cover if necessary. Dons head cover assuring that all hair and ears are covered.	✓
Dons face mask to cover bridge of nose down to include chin.	✓
Performs hand hygiene procedure by wetting hands and forearms and washing using soap and warm water for at least 30 seconds.	✓
Dries hands and forearms using lint-free towel or hand dryer.	✓
Selects the appropriate sized gown examining for any holes, tears, or other defects. Dons gown and ensures full closure.	✓
Disinfects hands again using a waterless alcohol-based surgical hand scrub with persistent activity and allows hands to dry thoroughly. before donning sterile gloves	✓
Dons appropriate sized sterile gloves ensuring that there is a tight fit with no excess glove material at the fingertips.	✓
in the direct compounding area (DCA) and after touching items or surfaces that may contaminate gloves.	•
Removes PPE on the clean side of the ante-area. Removes gloves and performs hand hygiene.	✓
Removes gown and discards it, or hangs it on hook if it is to be reused within the same work day.	✓
Removes and discards mask, head cover, and beard cover (if used).	✓
Removes shoe covers or shoe one at a time, ensuring that uncovered foot is placed on the dirty side of the line of demarcation.	✓

APPROVED BY [signature] DATE: 1/8/18

97 a Title: **Assessing Hand Hygiene and Garbing Related Practices of Compounding Personnel Form**

Hand Hygiene and Garbing Practices: The qualified evaluator will mark (x) each space for which the person being assessed has acceptably completed the described activity, prints N/A if the activity is not applicable to the assessment sess1on or N/ O if the activity was not observed.

Printed name and position/title of person assessed: ----Jeffrey G

The person assessed is immediately informed of all unacceptable activities (i.e., spaces lacking a Check marks, N/A, or N/O) and shown and informed of specific corrections.

Signature of Evaluator B Date: 1/8/18

Signature of the Personnel evaluated: Date: 1/8/18

APPROVED BY DATE:

PARTICIPANT NAME Jeff Goldich DATE: 1/8/18

EVALUATOR NAME (R.PH.) Uma. R (Please Print)

PROCESS VALIDATION EVALUATION CHECKLIST
VERTICAL LAMINAR AIRFLOW HOOD

BSC

(PLEASE PLACE A CHECK IN THE APPROPRIATE COLUMN WHILE OBSERVING PARTICIPANT PERFORMANCE: YES = 100% COMPLIANT NO = < 100% COMPLIANT)

PROCEDURE EVALUATED	YES	NO
Hood was turned on and let run for at least 30 minutes prior to preparation.	☑	☐
Did not wear jewelry, false nails, or long sleeves, etc. inside the hood.	☑	☐
Wore appropriate apparel as required by institution. (i.e. cap or scrubs)	☑	☐
Clean sterile gauze/sponge was used to clean hood with plenty of disinfectant.	☑	☐
Cleaned the IV pole first if applicable.	NA	☐
The sides of the hood were cleaned beginning at the top and starting in a downward motion from the back of the hood and working towards the front with overlapping strokes.	☑	☐
The back wall and inside of the glass shield were cleaned beginning at the top and working in a vertical downward motion with overlapping strokes.	☑	☐
The bottom of the hood was cleaned last, beginning with the back working towards the front moving horizontally from side to side with overlapping strokes.	☑	☐
Did not use spray bottles for cleaning.	☑	☐
Did not contaminate previously cleaned surfaces at any time during cleaning.	☑	☐
Lowered glass shield, so the opening was not more than 8 inches, prior to beginning sterile preparations.	☑	☐
All items placed in hood in a vertical fashion to prevent blocking of airflow.	☑	☐
No items were hung over other items, obstructing airflow.	☑	☐
Did not block airflow from HEPA filter with hands, or other objects inside hood during drug preparation manipulations.	☑	☐
Did not take hands out of hood or leave the hood during drug preparation manipulations.	☑	☐
Did not utilize outer 6 inches of hood opening or work too close to sides/back of hood during drug preparation manipulations.	☑	☐
Did not block air-intake grills at anytime.	☑	☐
Did not contaminate hood by coughing, sneezing, chewing gum, or excessive talking.	☑	☐

I certify on 1/8/18 (date) at Hybrid Pharma (evaluation site) that

Jeff Goldich (participant's name) is 100% competent at the above task.

EVALUATOR SIGNATURE: R. Uma 1/8/18

HYBRID PHARMA

Environmental Monitoring Competency Checklist	FORM 66
SKILL NAME: Jeff Gotthold DATE: 1/8/18	
Describe the difference between viable and nonviable contamination and the role of each in a n Environmental Sampling Plan	
Articulates the purpose of an environmental sampling plan and what the data generated can be used to determine	
States the location of the facility's environmental sampling plan and data forms	
Describes Procedure for air, surface and personnel sampling	
Describes the actions to take in the event that any of the environmental monitoring plates that exceed established action limits	
Describes the process for particle control and particulate counts at the location and when particle counts must occur	
Describes the differential pressure measurements at the facility and correctly states established limits	
Gathers all supplies needed for environmental sampling including correct media, volumetric air sampler, tape, black sharpie pen, documentation forms, gloves, lint free wipes.	
Checks all media for packaging integrity and expiration dates. Note lot # and expiration dates as well as manufacturer and type on documentation forms	
Inspects each media unit to ascertain that there is no growth on the plates prior to beginning sampling.	
Cleans the outside of all containers and supplies before bringing into the clean room	
Labels each media unit using a sharpie identifying sample location per environmental monitoring plam, date and time taken, sampler's initials'	
Resanitize gloves and allow to dry. Resanitize gloves after every 5 plates.	
Discards plates if during transport or placement, the media unit is exposed or contaminated prior to or during sampling.	
Places media units and accompanying documentation into a cleaned plastic bin to go into cleanroom	

Evaluated By: B
Date: 1/8/18

APPROVED BY DATE

HYBRID PHARMA

NAME: Jeff Goldrick DATE: 1/8/18

Environmental Monitoring Competency Checklist	FORM 66

Reading Environmental Monitoring Samples
Selects the correct Environmental Sampling Form that corresponds with the samples being read.
Removes samples from the incubator in the time frame specified in established policy and procedure (TSA incubation should not be less than 48 but not greater than 72 hours.Fungal plate incubation should occur for a period of 5-7 days.
Document the date that samples are removed from the incubator to read.
Reads the plates one at a time counting the number of discrete colonu forming units (CFUs)on each plate
Documents the number of CFUs on each plate in the correct corresponding location on the Environmental Sampling Data Collection Form
After all the results for each plate are read and documented, compares the result to the established Action Limit Value for each location.
If any sample fails, the failing plate is marked fail with a black sharpie.
Immediately document any out of limit results, CFU # that exceed established Action Limits and save that plat/s to be sent for Speciation if applicable.
Review documentation form for those samples and once complete, files environmental monitoring Data collection Form.
Dispose the plates sealed in plastic bags

Evaluated By: B
Date: 1/8/18

APPROVED BY DATE

HYBRID PHARMA

for Jeff Gotlich

Environmental Monitoring Competency Checklist	FORM 66

NAME: **DATE:**

Viable Volumetric Air Sampling	
Air Samplers are taken at locations that are consistent with the established Environmental Monitoring Plan.	✓
Samples are taken using a procedure that is consistent with policy and procedure	✓
Air volume sampled is consistent with amounts specified in policy and procedure	✓
Surface sampling	
Contact plates are applied at locations that are consistent with the established Sampling Plan.	✓
Samples are taken using a procedure that is consistent with protocol.	✓
Cleans the area where the sample was taken to remove media residue using 70% sterile IPA and lint free wipe	✓
Incubation and post sampling Procedure	
Samples are handled in an aseptic manner which prevents accidental exposure outside of the selected sampling location	✓
Exposed samples are closed aseptically with tops secured to bottom with tape	✓
all closed samples are placed in a plastic bin and cover with the lid and removed from the controlled environment	✓
Documentation is completed immediately prior to placing the samples in the incubator.	✓
TSA samples are placed into the incubator in an inverted position. Fungal plates are placed right side up.	✓

Evaluated By: B
Date: 1/5/18

APPROVED BY **DATE**

Appendix III. Sample Form for Assessing Hand Hygiene and Garbing Related Practices of Compounding Personnel 6/29/17

Printed name and position/title of person assessed: Jeff Cobbick R.Ph.

Name of facility or location: Hybrid Pharma

Hand Hygiene and Garbing Practices: The qualified evaluator will mark (×) each space for which the person being assessed has acceptably completed the described activity, prints N/A if the activity is not applicable to the assessment session or N/O if the activity was not observed.

- ✓ Presents in a clean appropriate attire and manner.
- ✓ Wears no cosmetics or jewelry (watches, rings, earrings, etc. piercing jewelry included) upon entry into ante-areas.
- ✓ Brings no food or drinks into or stored in the ante-areas or buffer areas.
- ✓ Is aware of the line of demarcation separating clean and dirty sides and observes required activities.
- ✓ Dons shoe covers or designated clean-area shoes one at a time, placing the covered or designated shoe on clean side of the line of demarcation, as appropriate.
- ✓ Dons beard cover if necessary
- ✓ Dons head cover assuring that all hair is covered.
- ✓ Dons face mask to cover bridge of nose down to include chin.
- ✓ Performs hand hygiene procedure by wetting hands and forearms and washing using soap and warm water for at least 30 seconds.
- ✓ Dries hands and forearms using lint-free towel or hand dryer.
- ✓ Selects the appropriate sized gown examining for any holes, tears, or other defects.
- ✓ Dons gown and ensures full closure.
- ✓ Disinfects hands again using a waterless alcohol-based surgical hand scrub with persistent activity and allows hands to dry thoroughly, before donning sterile gloves
- ✓ Dons appropriate sized sterile gloves ensuring that there is a tight fit with no excess glove material at the fingertips.
- ✓ Examines gloves ensuring that there are no defects, holes, or tears.
- ✓ While engaging in sterile compounding activities, routinely disinfects gloves with sterile 70% IPA prior to work in the direct compounding area (DCA) and after touching items or surfaces that may contaminate gloves.
- ✓ Removes PPE on the clean side of the ante-area.
- ✓ Removes gloves and performs hand hygiene
- ✓ Removes gown and discards it, or hangs it on hook if it is to be reused within the same work day.
- ✓ Removes and discards mask, head cover, and beard cover (if used).
- ✓ Removes shoe covers or shoe one at a time, ensuring that uncovered foot is placed on the dirty side of the line of demarcation and performs hand hygiene again. (Removes and discards shoe covers every time the compounding area is exited).

The person assessed is immediately informed of all unacceptable activities (i.e., spaces lacking a Check marks, N/A, or N/O) and shown and informed of specific corrections.

Signature of Person Assessed	Jeff Cobbick	6/29/17
	Printed Name	Date
Signature of Qualified Evaluator	Uma. R	6/29/17.
	Printed Name	Date

Copyright 2007 The United States Pharmacopeial Convention *All Rights Reserved.*

101. Labels of CSPs contain name and address of pharmacy, correct names and amounts or concentrations of ingredients, total volumes, beyond-use dates, storage conditions, and route(s) of administration. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Identity and Strength Verification of Ingredients]

DECA Ultra lot 171113A BUD 12/28/17 label does not include Benzyl Benzoate as an ingredient in the final product, however it is listed in the compounded worksheet.

RESPONSE:

Inactive ingredient Benzyl Benzoate was inadvertently left off label.

Action Plan: All labels are to be double checked by at least 2 qualified personnel.

118. Compounding records are properly maintained. [FAC 64B16-28.140(4)]

Zinc Sulfate 10mg/ml lot 171113C BUD 12/28/17 states SWI was used in compounding the CSP however label states bacteriostatic water for injection;

Response:

Sterile Water for Injection was used in compounding. The label states "Bacteriostatic Water for injection." The Batch Sheet states " Benzyl alcohol 0.9% and Sterile Water for injection." It is important to note that Benzyl alcohol 0.9% and Sterile Water together are commonly known as Bacteriostatic water for injection.

See the below description of Bacteriostatic Water from Hospira, Inc., available online here: https://www.drugs.com/pro/bacteriostatic-water-for-injection.html

Bacteriostatic water (Water) injection, solution
[HOSPIRA, INC.]

Multiple-dose Plastic Vial Rx only

DESCRIPTION

The following preparation is designed solely for parenteral use only after addition of drugs that require dilution or must be dissolved in an aqueous vehicle prior to injection.

Bacteriostatic Water for Injection, USP is a sterile, nonpyrogenic preparation of water for injection containing 0.9% (9 mg/mL) of benzyl alcohol added as a bacteriostatic preservative. It is supplied in a multiple-dose container from which repeated withdrawals may be made to dilute or dissolve drugs for injection. The pH is 5.7 (4.5 to 7.0).

Water for Injection, USP is chemically designated H2O.

The semi-rigid vial is fabricated from a specially formulated polyolefin. It is a copolymer of ethylene and propylene. The safety of the plastic has been confirmed by tests in animals according to USP biological standards for plastic containers. The container requires no vapor barrier to maintain the proper labeled volume.

STATE OF FLORIDA

DEPARTMENT OF HEALTH

INVESTIGATIVE REPORT

Office: Area 10-Ft. Lauderdale	Date of Complaint: 12/28/2017	Case Number: 2017-23347

Subject: HYBRID PHARMA, LLC 1015 W Newport Ctr. Dr. #106-A Deerfield Beach, FL 33442 954-708-2771	Source: DEPARTMENT OF HEALTH/ISU/FT. LAUDERDALE 1400 W Commercial Blvd. Ft. Lauderdale, FL 33309 954-202-3250
Profession: Pharmacy	License Number and Status: PH29374; Clear
Related Case(s): 2017-23346	Period of Investigation and Type of Report: 12/29/2017 to 01/04/2018 - FINAL

Alleged Violation: SS 456.072(1)(d)(k)(dd); 465.023(1)(c); 465.016(1)(r), F.S 64B16-27.797; 64B16-27.300; 64B16-24.420, F.A.C

Synopsis: This investigation is predicated on the receipt of a complaint submitted by the DEPARTMENT OF HEALTH/ISU/FT. LAUDERDALE (Exhibit #1), in regards to HYBRID PHARMA, LLC, located at 1015 W Newport Ctr. Dr. #106-A, Deerfield Beach, FL 33442. Alleges that on 12/19/2017, DOH Senior Pharmacist MONICA BOWER, RPh, accompanied by JAMES SHEPHERD, RPh conducted a routine sterile compounding (SSCP) inspection at HYBRID PHARMA. During the inspection the facility was found to have multiple SSCP deficiencies including failure to conduct sterility testing with an appropriate filter, failure to conduct endotoxin testing for High risk level CSP's, failure to render glassware or other non-sterile containers free from pyrogens or viable microbes, etc.

☒ Yes ☐ No Subject Notification Completed?
☐ Yes ☒ No Subject Responded?
☐ Yes ☒ No Patient Notification Completed? N/A
☒ Yes ☐ No Above referenced licensure checked in database/LEIDS?
☐ Yes ☒ No Board certified? Name of Board: Date:
Specialty:

Law Enforcement N/A
☐ Notified Date:
☐ Involved Agency:

☒ Yes ☐ No Subject represented by an attorney?
Attorney information: Edwin A. Bayo
2022-2 Raymond Diehl Rd.
Tallahassee, FL 32308
850-385-1314

Investigator/Date: 01/04/2018 M. Boatwright Marsha Boatwright, LI-125 Investigation Specialist II	Approved By/Date: 01/04/2018 Pat Callahan Patricia Callahan, LI-96 Investigation Manager

Distribution: HQ/ISU

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3. Copy of Previous Inspection Forms, SSCP dated 05/27/2015, 09/04/2015, 06/15/2017 & 12/27/2017 20-51
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5. Records collected by BOWER 54-97
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INVESTIGATIVE DETAILS

INTERVIEW OF MONICA BOWER/JIM SHEPHERD, RPh (Source/Witness)
DOH/MQA Senior Pharmacist
1400 W Commercial Blvd. Suite 130
Ft. Lauderdale, FL 23309
954-829-0371

On 12/29/2017, this investigator interviewed MONICA BOWER, RPh & JAMES SHEPHERD, RPh via conference call. BOWER stated she was accompanied by SHEPHERD while conducting a SSCP inspection at HYBRID PHARMA, located at 1015 W Newport Ctr. Dr. #106-A, Deerfield Beach, FL 33442. BOWER stated while conducting the inspection she noticed the pharmacy was still performing the same way they did during the last inspection with all the high risk products. BOWER stated no change had been made with the deficiencies that were noted on the last inspection. There were a lot of structural and sterility testing issues. BOWER stated if these high risk products are not compounded correctly they can cause infection, shock, or even death in people.

BOWER stated only two people conduct sterile compounding at HYBRID, technician UMARANI RAJALINGHAM (RPT 45465) & JEFF GOLDRICH (PS27855). BOWER stated she does not believe the pharmacy manager, GOLDRICH, conducts any sterile compounding because RAJALINGHAM was the person gathering the paperwork, answering all the questions and conducting the sterility testing, GOLDRICH was not involved. SHEPHERD stated it was very difficult to get any paperwork from the staff without having to ask multiple times.

BOWER stated HYBRID conducted its own sterility testing, in which it was being done improperly. BOWER noted that the filters being used to conduct the sterility test were food and beverage filters, not for pharmaceutical products.

SHEPHERD stated the filters are not approved for the drug testing process and there is no ability to prove that no microbes are entering or growing. SHEPHERD stated the sterility testing HYBRID is conducting is not valid and sterile assurance is not known with the testing they are conducting.

BOWER stated the RAJALINGHAM could not produce any smoke studies to show HEPA filtered air is being swept over compounded products to prevent contamination. BOWER stated there was no particle count being conducted; no medium to support bacteria in ISO-classified areas and they had no assurance the compounds were without the presence of bacteria.

Both BOWER & SHEPHERD stated they did not ask for a corrective plan from the pharmacy manager, GOLDRICH, because these were the same issues from the previous inspection (Exhibit #3). It was stated that GOLDRICH did not have an explanation for the deficiencies. BOWER and SHEPHERD stated that GOLDRICH does not like to take direction and always has some type of “pushback” when they try to tell him the things that are being done incorrectly.

INVESTIGATORS NOTE:

On 01/02/2018, this investigator contacted HYBRID PHARMA and spoke with GOLDRICH, who stated he would not be responding to the allegations personally and that he and the pharmacy will be represented by an attorney. This investigator advised GOLDRICH to have his attorney to send a letter of representation (Exhibit #4).

CASE SUMMARY

CONFIDENTIAL

Case No: 201723346
Please use this number in all correspondence with the Department concerning this matter.

RESPONDENT INFORMATION

License: 27855 Profession: 2201 Pharmacist
Name: JEFFREY S GOLDRICH
Address: 7427 SHELLRIDGE TER
LAKE WORTH, FL 33467
Home Phone: 561-247-1944

SOURCE OF INFORMATION

Name: Department of Health/ISU/Ft Lauderdale
Address: 1400 W. Commercial Blvd
Fort Lauderdale, FL 33309
Home Phone: 954-829-0371

REPORTED INFORMATION

Receive Date: 12/28/2017 Source Code: 5 Form Code: 2
Responsible Party: ha179 Status Code: 10
Classification Code: Incident Date: 12/19/2017

Patient Name:

Possible Code(s): 18 , 15

Summary:
Possible violation of SS 456.072(1)(d)(k)(dd); 465.023(1)(c); 465.016(1)(r), F. S., through Rule 64B16-27.797; 64B16-27.300; 64B16-27.420, F.A.C., violate Statutes/Rules; fail to perform legal obligations, CQI Policy & Procedures & Quarterly Meetings, Pharmacy Tech Properly Identified, Environmental Quality and Control ---

Received internally generated complaint indicating on 12/9/15 a routine inspection was conducted at Hybrid Pharma, LLC (PH29374), located at 1015 W. Newport Center Drive, #106-A, Deerfield Beach, FL 33442.Hybrid holds a SSCP pharmacy permit. During the inspection the following discrepancies were noted: the sterilizing membrane filter is used that is chemically and physically compatible with the CSP; distilled water to rinse glassware not sterile water; subject is using the Pall MF membrane filtration technique for the sterility testing that does not match the procedure; method suitability does not match method used for sterility tests; testosterone lot #17 has not been tested for endotoxins, etc. The subject (PS 27855) is the listed PDM of the Pharmacy.

Analyzed by Sherra W Mears - ha179

DOH-Form200

201723346-179

ealth Care Provider Complaint

This infomation MUST be completed to investigate your complaint, as we correspond via U.S. mail. Incomplete forms CANNOT be processed.

Florida Statutes 456.073, Disciplinary proceeding: (1) The department, for the boards under its jurisdiction, shall cause to be investigated any complaint that is filed before it if the complaint is in writing, signed by the complainant, and legally sufficient. *If an investigation of any subject is undertaken, the Department will furnish to the subject or the subject's attorney a copy of the complaint or document that resulted in the initiation of the investigation.*

Health Care Provider Information:

Name: Goldrich (Last) Jeff (First) (M.I.) Pharmacist (Profession) PS27855 (License Number)

Address: 1015 W Newport Ctr Drive #106-A (Number & Street) Deerfield Beach (City) FL (State) 33342 (Zip)

Phone number(s): _____ Website: _____

Complainant Information:

Your Name: Florida Dept. of Health/ MQA/ ISU/ Ft. Lauderdale (Last / First / M.I.)

Address: 1400 W Commercial Blvd (Number & Street) Ft. Lauderdale (City) FL (State) 33309 (Zip)

Home Phone: _____ Work Phone: _____ Best Time to Call: _____

Patient Information:

Name: _____ (Last / First / M.I.)

Address: _____ (Number & Street / City / State / Zip)

Phone Number: : _____ Date of birth: _____

Your relationship to the patient:

☐ Parent ☐ Son/Daughter ☐ Spouse ☐ Brother/Sister ☐ Friend ☐ Legal Guardian ☒ Other

Please provide documentation indicating your appointment as the Legal Authority/Guardianship or Personal Representative

The department does not in esti ate complaints re ardin the amount char ed or a procedure bro en or missed appointments customer ser ice bedside manner rudeness pro essionalism or personality conflicts.

What is the reason for your complaint? Please check all that apply.

☐ Quality of care	☐ Unlicensed	☐ Misfilled prescription	☐ Patient abandonment/neglect
☐ Misdiagnosis	☐ Abuse	☐ Impaired provider	☐ Failure to release patient records
☐ Substance abuse	☐ Sexual contact	☐ Inappropriate prescribing	☒ Other SSCP Inspection
☐ Advertising	☐ Insurance fraud	☐ Excessive test/treatment	

Date of Incident: 12-19-2017

000006

If the incident involved criminal conduct contact local law enforcement; have you contacted local law enforcement?
Yes No

If yes, name of contact: _____, date: _____, case number: _____

Agency Name: _____

Providers ho Treated You A ter the ncident se a separate sheet i necessary

Name: _____
Last First M.I.

Address: _____
Number & Street City State Zip

Name: _____
Last First M.I.

Address: _____
Number & Street City State Zip

Pro ide a complete description o the complaint report
nclude acts details dates locations etc (Who, what, when and where)

Attach copies of medical records, correspondence, contracts and any other documents that will help support your complaint. Failure to attach records will delay the investigation. (Attach additional sheets if necessary).

See Attached.
li127

lorida Statutes alse icial Statements: hoe er no in ly ma es a alse statement in ritin ith the intent to mislead a public ser ant in the per ormance o his or her o icial duty shall be uilty o a misdemeanor o the second de ree

Signature: Monica Bower Rph Date: 12-28-2017
(Required to file complaint)

000007

A T R AT N R R AS PAT NT N R AT N

To: Any and All Treating Health Care Practitioners or Facilities:
This authorization meets the requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA Privacy Law) found at 45 CFR, Part 164.

This document authorizes any and all licensed health care practitioners, including but not limited to: physicians, nurses, therapists, social workers, counselors, dentists, chiropractors, podiatrists, optometrists, hospitals, clinics, laboratories, medical attendants and other persons who have participated in providing any health care or service to me, to discuss any communication, whether confidential or privileged, and to provide full and complete patient reports and records justifying the course of treatment including but not limited to: patient histories, x-rays, examination and test results, HIV, mental health, drug abuse treatment, psychiatric and psychological records, reports or information prepared by other persons that may be in your possession and all financial records, to the Department of Health (or any official representative of the Department) pursuant to Section 456.057, Florida Statutes.
This document provides full authorization to the Department of Health (or any official representative of the Department) to use any of the aforementioned reports and information for reproduction, investigation or other use for licensure or disciplinary actions and civil, criminal or administrative proceedings, as needed by the Department and may be subject to re-disclosure by the recipient and may no longer be protected by the federal privacy laws and regulation.
By signing below, the patient understands, acknowledges and authorizes the Department to release their identity and medical records to law enforcement and other regulatory agencies in appropriate circumstances at the Department's discretion.

A photocopy of this document is as sufficient as the original.

I understand that this authorization may be revoked upon my written request except to the extent that action has already been taken on this authorization.

Patient Name (Print): _____ Signature: _____

D.O.B.: _____ SSN: _____ Date: _____

Name of Authorized Person Other than Patient (Print): _____

Signature of Authorized Person Other than Patient: _____

Witness Name (Print): _____ Witness Signature: _____

DOH USE ONLY
Reference Number

_____-_____
000008

Unlicensed Practice

Please fill out this form with information regarding individuals engaging in unlicensed activity.

What is your relationship to the subject? _____

How did you become aware of the alleged unlicensed practice? _____

When did you become aware of the alleged unlicensed practice? _____

Location of alleged unlicensed practice: _____

Time and date of treatment or incident: _____

If payment was made, how was subject paid? _____

Does the subject or subject's business accept Medicaid? _____

Does the subject or subject's business accept Medicare? _____

Physical description of subject:

Race: _____ Sex: _____ Height: _____ Weight: _____ Eye Color: _____

Description of Vehicle:

Year: _____ Make: _____ Model: _____ Tag No: _____ Color: _____

_____

_____

Names and addresses of patients/victims/witnesses aware of your complaint:

Name: _____ Address: _____

Name: _____ Address: _____

Names of other subjects/licensees at the same location or business: _____

_____

Please return completed complaint form to:

Consumer Services Unit
4052 Bald Cypress Way, Bin C-75
Tallahassee, FL 32399-3275

Email: mqa.consumerservices@flhealth.gov

Fax: (850) 488-0796

STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES
INV797-Sterile Compounding

File # 21375
Insp # 153486

NAME	PERMIT NUMBER	DATE OF INSPECTION
HYBRID PHARMA, LLC	29374	12/19/2017
DOING BUSINESS AS		
STREET ADDRESS 1015 W NEWPORT CTR DR #106-A	**TELEPHONE #**	**EXT**
CITY DEERFIELD BEACH	**COUNTY** BROWARD	**STATE/ZIP** FL/33442

Additional Information

Business Operation Hours

M-T-W-TH-F Y	Weekly Hours 10am-6pm
Monday Y	Tuesday N
Wednesday N	Thursday N
Friday N	Saturday N
Sunday N	

Registered Pharmacist / Intern / Tech

License # PS27855	Licensee Name Jeff Goldrich
License Type Registered Pharmacists	
License # RPT45465	Licensee Name Umarani Rajalingham
License Type Pharmacy Tech	

ACS Manager

Optional Information

Basic License Data - PSD

DEA Reg # FH4258706	

INV797 - Sterile Compounding

LOW RISK

1. Low risk CSP's are properly identified: Aseptic manipulations within an ISO Class 5 environment using three or fewer sterile products and no more than two entries into any container. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Low-Risk Level CSPs]	
2. Low Risk CSP's, in absence of passing sterility test, stored not more than 48 hours at controlled room temperature, 14 days at cold temperature, or 45 days in solid frozen state at -25° to -10° or colder. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Low-Risk Level CSPs]	
3. Low Risk CSP's with 12 hour BUD are properly identified and comply with all four specific criteria. 1. PEC in Segregated Compounding area 2. Away from windows, doors , high traffic areas 3. Hygiene & garbing required, sinks not adjacent to PEC. 4. Cleaning & Disinfecting, Personnel training, Competency evaluation, Garbing, Aseptic work practices, Viable and non-viable environmental sampling apply. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Low-Risk Level CSPs]	

MEDIUM RISK

4. Medium Risk CSP's are properly identified: Aseptic manipulations within an ISO Class 5 environment using prolonged and complex mixing and transfer, more than three sterile products and entries into any container, and pooling ingredients from multiple sterile products to prepare multiple CSPs. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Medium-Risk Level CSPs]	
5. Medium Risk CSP's, In absence of passing sterility test, stored not more than 30 hours at controlled room temperature, 9 days at cold temperature, or 45 days in solid frozen state at -25° to -10° or colder. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Medium-Risk Level CSPs]	

HIGH RISK

6. Presterilization procedures for high-risk level CSPs, such as weighing and mixing, are completed in no worse than an ISO Class 8 environment. [ENVIRONMENTAL QUALITY AND CONTROL : Placement of Primary Engineering Controls Within ISO Class 7 Buffer Areas]	N/A
7. High Risk CSP's are properly identified: Confirmed presence of nonsterile ingredients and devices, or confirmed or suspected exposure of sterile ingredients for more than one hour to air quality inferior to ISO Class 5 before final sterilization. [CSP MICROBIAL CONTAMINATION RISK LEVELS : High-Risk Level CSPs]	Yes

8. High Risk CSP's, in absence of passing sterility test are not stored more than 24 hours at controlled room temperature, 3 days at cold temperature, or 45 days in solid frozen state at -25° to -10° or colder. [CSP MICROBIAL CONTAMINATION RISK LEVELS : High-Risk Level CSPs]	Yes
9. A 0.2-µm certified sterilizing membrane filter is used that is chemically and physically compatible with the CSP. Filtration is completed rapidly without filter replacement. Sterilization method is verified to achieve sterility for the quantity and type of containers. [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Sterilization of High-Risk Level CSPs by Filtration] *Compounding record for Zinc sulfate 10mg/ml final volume of 300 ml was sterilized by filtration with a Baxter Supor 32 mm syringe filter. Manufacturer recommended volume for this filter is less than 150 ml.*	No
10. Sterilization method used has documentation that acceptable strength and purity of ingredients and integrity of containers is maintained. [CSP MICROBIAL CONTAMINATION RISK LEVELS : High-Risk Level CSPs]	N/A
11. The manufacturer recommended filter integrity (e.g., bubble point) test is performed and documented for all sterilizing filters after filtering CSPs. [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Sterilization of High-Risk Level CSPs by Filtration]	Yes
12. Autoclave cycle has been verified using appropriate biological indicators. Solutions are passed through a 1.2-µm or smaller filter into final containers to remove particulates before sterilization. [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Sterilization of High-Risk Level CSPs by Steam]	Yes
13. Dry heat ovens used for sterilization have filtered forced air. Only those items that will be damaged by steam are sterilized by dry heat. [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Sterilization of High-Risk Level CSPs by Dry Heat] *No sterilization of CSP's through dry heat*	N/A
14. The description of dry heat sterilization conditions and duration for specific CSPs is included in written documentation in the compounding facility. The effectiveness of dry heat sterilization is verified using appropriate biological indicators and other confirmation. [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Sterilization of High-Risk Level CSPs by Dry Heat]	N/A
15. Dry heat depyrogenation is used to render glassware or containers, such as vials free from pyrogens as well as viable microbes. The description of the dry heat depyrogenation cycle and duration for specific load items is included in written documentation in the compounding facility. The effectiveness of the dry heat depyrogenation cycle is verified using endotoxin challenge vials (ECVs). [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Depyrogenation by Dry Heat] *Firm is using distilled water to rinse glassware not sterile water ; SECOND ADVISORY.*	No
16. Sterility testing is completed for all High-risk level CSPs prepared in batches of more than 25 identical containers, or exposed longer than 12 hours at 2° to 8°, and 6 hours at warmer than 8° before being sterilized. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Sterility Testing]	Yes

USP <71> STERILITY TESTING (Outsourced)

17. Outsourced sterility testing results indicate that it is compliant with USP<71>. A method not described in the USP may be used if validation demonstrates that the alternative is at least as effective and reliable. [STERILITY TEST USP<71>]	
18. Outsourced: The number of articles tested are appropriate according to USP<71>. [STERILITY TEST USP<71> : Number of Articles to Be Tested]	
19. Outsourced: The volume/quantity tested is according to USP<71>. [STERILITY TEST USP<71> : Number of Articles to Be Tested]	
20. Outsourced: A USP<71> method suitability test has been done with appropriate inoculum, additives and rinses. [STERILITY TEST USP<71> : Method Suitability Test]	
21. Outsourced: Sterility testing reports are reviewed and appropriate actions taken and documented. [FINISHED PREPARATION RELEASE CHECKS AND TESTS]	

USP <71> STERILITY TESTING

22. On site: Membrane filtration is used if appropriate. (The technique of membrane filtration is used whenever the nature of the product permits; that is, for filterable aqueous preparations, for alcoholic or oily preparations, and for preparations miscible with, or soluble in, aqueous or oily solvents, provided these solvents do not have an antimicrobial effect in the conditions of the test.) Filters are rinsed according to USP<71>. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Sterility Testing] *The SOP the firm is using is the Pall MF (membrane filtration) technique for their sterility testing that does not match the procedure, also, the Nalgene sterile filter that was presented to inspectors indicates that it is for food and beverages and does not indicate it can be used for pharmaceutical product sterility tests; PROVIDE DOCUMENTATION THE DEVICE IS APPROPRIATE FOR USP <71> STERILITY TESTS*	No
23. On site: Direct inoculation is done only when membrane filtration cannot be carried out. Volume to be inoculated does not exceed 10% of the culture media volume. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Sterility Testing]	N/A
24. On site: The number of articles tested are appropriate according to USP<71>. [STERILITY TEST USP<71> : Number of Articles to Be Tested]	Yes
25. On site: The volume/quantity tested is according to USP<71>. [STERILITY TEST USP<71> : Number of Articles to Be Tested]	Yes
26. On site: A growth promotion test has been done on the media with the 5 specified organisms (not more than 100 CFU) according to USP<71>. [STERILITY TEST USP<71> : Growth Promotion Test of Aerobes, Anaerobes, and Fungi]	N/A
27. On site: A USP<71> method suitability test has been done with appropriate inoculum, additives and rinses. [STERILITY TEST USP<71> : Method Suitability Test] *Method suitability does not match method used for sterility tests. SECOND ADVISORY . Atlas labs conducts method suitability for HCG and uses bacteriostatic water to reconstitute the product , not SWFI ; SECOND ADVISORY Provide documentation that all rinses and methods used in the method suitability are alike ie; membrane filtration, inoculation, rinses, etc. FOR EACH PRODUCT THAT YOU TEST FOR STERILITY. The media you are using is TSB with lecithin and tween 20 and Fluid Thioglycollate that are manufactured by Hardy. Send documentation Atlas labs is using the same media and rinses for method suitability for EACH PRODUCT*	No
28. On site: TSB or SCD is incubated at 20-25 C for 14 days (2 incubators present). [STERILITY TEST USP<71> : Culture Media and Incubation Temperatures]	Yes
29. On site: FTM is incubated at 30-35 C for 14 days (2 incubators present). [STERILITY TEST USP<71> : Culture Media and Incubation Temperatures]	Yes
30. On site: Sterility testing is documented including lot numbers and expiration dates of media. [FINISHED PREPARATION RELEASE CHECKS AND TESTS]	Yes
31. On site: Sterility testing reports are reviewed and appropriate actions taken and documented. [FINISHED PREPARATION RELEASE CHECKS AND TESTS]	Yes

ENDOTOXIN TESTING

32. Endotoxin testing is conducted for High-risk level CSP's that are prepared in batches of more than 25 identical containers, or exposed longer than 12 hours at 2° to 8°, and 6 hours at warmer than 8°, before being sterilized or in multidose containers for administration to multiple patients. (excluding those for inhalation and ophthalmic administration) [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Bacterial Endotoxin (Pyrogen) Testing] *Testosterone lot #171006a 2000 ml has not been tested for endotoxins.*	No

33. Endotoxin testing process indicates that it is compliant with USP<85>. [BACTERIAL ENDOTOXINS TEST USP<85>]	Yes
34. High Risk CSP's are within allowable limits for bacterial endotoxins. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Bacterial Endotoxin (Pyrogen) Testing]	Yes

IMMEDIATE USE COMPOUNDING

35. Immediate-use compounding complies with all six specified criteria. 1. Low-risk sterile nonhazardous products or diagnostic radiopharmaceutical products from the manufacturers' original containers. Anti-neoplastics shall not be prepared as immediate-use CSPs because they are hazardous drugs. 2. Unless required for the preparation, the compounding procedure is a continuous process not to exceed 1 hour. 3. During preparation, aseptic technique is followed and, if not immediately administered, the finished CSP is under continuous supervision to minimize the potential for contact with nonsterile surfaces, introduction of particulate matter or biological fluids, mix-ups with other CSPs, and direct contact of outside surfaces. 4. Administration begins not later than 1 hour following the start of the preparation of the CSP. 5. Unless immediately and completely administered by the person who prepared it or immediate and complete administration is witnessed by the preparer, the CSP shall bear a label listing patient identification information, the names and amounts of all ingredients, the name or initials of the person who prepared the CSP, and the exact 1-hour BUD and time. 6. If administration has not begun within 1 hour following the start of preparing the CSP, the CSP shall be promptly, properly, and safely discarded. [IMMEDIATE-USE CSPs]	N/A

SINGLE/MULTIPLE DOSE CONTAINER BUD

36. Beyond-use date does not exceed 28 days for multiple-dose containers after initial opening or entry, unless specified otherwise by the manufacturer. [SINGLE-DOSE AND MULTIPLE-DOSE CONTAINERS]	N/A
37. Beyond-use time does not exceed 6 hours for closure sealed single-dose containers in ISO Class 5 or cleaner air after initial opening or entry, unless specified otherwise by the manufacturer. [SINGLE-DOSE AND MULTIPLE-DOSE CONTAINERS]	N/A
38. Beyond-use time does not exceed 1 hour for closure sealed single-dose containers after being opened or entered in worse than ISO Class 5 air. [SINGLE-DOSE AND MULTIPLE-DOSE CONTAINERS]	N/A
39. Single-dose ampules are discarded immediately after use. [SINGLE-DOSE AND MULTIPLE-DOSE CONTAINERS]	N/A

HAZARDOUS DRUGS

40. A pressure indicator is installed and differential pressures are monitored and documented daily for hazardous buffer room. [HAZARDOUS DRUGS AS CSPs]	Yes
41. Hazardous drug buffer room is at least 0.01 inch water column negative pressure with 30 ACPH of HEPA filtered air. [HAZARDOUS DRUGS AS CSPs]	Yes
42. At least 0.01 inch water column negative pressure and 12 air changes per hour in non-cleanrooms in which CACIs are located. FAC: USP Chapter 797 requires that: "When closed-system vial-transfer devices (CSTDs) (i.e., vial-transfer systems that allow no venting or exposure of hazardous substance to the environment) are used, they shall be used within an ISO Class 5 environment of a BSC or CACI. The use of the CSTD is preferred because of their inherent closed system process. In facilities that prepare a low volume of hazardous drugs, the use of two tiers of containment (e.g., CSTD within a BSC or CACI that is located in a non-negative pressure room) is acceptable." For purpose of said provision, a "low volume of hazardous drugs" is defined as less than 40 doses per month. [HAZARDOUS DRUGS AS CSPs]	N/A
43. Personnel compounding hazardous drugs wear appropriate personal protective equipment. [HAZARDOUS DRUGS AS CSPs]	Yes
44. Hazardous drugs are handled with caution at all times using appropriate chemotherapy gloves during receiving, distribution, stocking, inventorying, preparing for administration, and disposal. Spill kits are available. [HAZARDOUS DRUGS AS CSPs]	Yes
45. Hazardous drugs are prepared in an ISO Class 5 environment (BSC or CACI) with protective engineering controls in place, following aseptic practices specified for the appropriate contamination risk levels. [HAZARDOUS DRUGS AS CSPs]	Yes
46. Hazardous drugs are stored separately from other inventory in a manner to prevent contamination and personnel exposure. [HAZARDOUS DRUGS AS CSPs] *HCG stored in quarantine cabinet with non hazardous drugs.*	No
47. Access to hazardous drug preparation areas is limited to authorized compounding personnel. [HAZARDOUS DRUGS AS CSPs]	Yes
48. Annual documentation of hazardous drug training of personnel regarding storage, handling, containment techniques and disposal of hazardous drugs is available. [HAZARDOUS DRUGS AS CSPs]	Yes
49. Compounding personnel of reproductive capability have confirmed in writing that they understand the risks of handling hazardous drugs. [HAZARDOUS DRUGS AS CSPs]	Yes
50. Facility maintains appropriate disposal containers for all hazardous waste. [HAZARDOUS DRUGS AS CSPs]	Yes

FACILITY DESIGN AND CERTIFICATION

51. Certification and testing of primary (LAFWs, BSCs, CAIs and CACIs) and secondary engineering controls (buffer and ante areas) have been performed by a qualified individual no less than every six months and whenever the device or room is relocated, altered, or major service to the facility is performed. Corrective action for deficiencies are documented. Certification procedures such as those outlined in the CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2006) are conducted under dynamic conditions. [ENVIRONMENTAL QUALITY AND CONTROL : Environmental Nonviable Particle Testing Program] *July 11, 2017 TMI ; Ante ISO Class 7 , BR 1 (positive buffer room) ISO Class 7 , BR 2 (negative buffer room) ISO Class 7; ISO Class 7 PR (prep room) ; 1 X LFH ISO Class 5 TESTED UNDER AT REST CONDITIONS; 1 x BSC located in BR 2 however TMI reported the PEC is located in the lab which non viable particle counts were not collected on the BSC . There is no assurance this PEC is operating under clean ISO Class 5 standards.*	No
52. Primary engineering controls provide unidirectional (i.e., laminar) HEPA filtered air. Air pattern analysis via smoke studies are conducted at the critical site to demonstrate unidirectional airflow and sweeping action over and away from the product under dynamic conditions.[ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls] *No smoke studies available at the time of inspection. PLEASE PROVIDE SMOKE STUDIES WITHIN 72 HOURS OF THIS INSPECTION. HCG IS A HAZARDOUS DRUG COMPOUNDED IN THE HD ROOM THEN TRANSFERRED TO THE LYOPHYLIZER THAT IS LOCATED IN THE POSITIVE CLEAN ROOM; PARTIALLY STOPPERED VIALS ARE BEING TRANSFERRED FROM ISO CLASS 5 PEC THROUGH ISO CLASS 7 TO THE LYOPHYLIZER.*	No
53. The primary engineering controls are placed within a buffer area in such a manner as to avoid conditions that could adversely affect their operation. The PEC is placed out of the traffic flow and in a manner to avoid disruption from the HVAC system and room cross drafts. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
54. All HEPA filters are leak tested after installation and every six months thereafter. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes

ISOLATORS

55. CAIs are proven to maintain ISO Class 5 air when particle counts are sampled 6 to 12 inches upstream of critical site exposure areas during performance of normal inward and outward transfer of materials, and compounding manipulations when such CAIs are located in air quality worse than ISO Class 7. [ENVIRONMENTAL QUALITY AND CONTROL : Placement of Primary Engineering Controls Within ISO Class 7 Buffer Areas]	
56. Adequate recovery time for isolators to achieve ISO Class 5 air quality is allowed after material transfer before and during compounding operations. [ENVIRONMENTAL QUALITY AND CONTROL : Placement of Primary Engineering Controls Within ISO Class 7 Buffer Areas]	
57. Personnel garbing requirements are followed for CAIs unless manufacturer provides written documentation based on validated testing that any components of PPE are not required to maintain sterility of CSPs. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	

FACILITY DESIGN AND CERTIFICATION (Secondary Engineering Controls)

58. Facility has pressure gauges or velocity meters to monitor the pressure differential or airflow between the buffer area and ante-area, and the ante-area and the general environment outside the compounding area. The results are reviewed and documented on a log at least daily or by a continuous recording device. The pressures differentials meet or exceed 5 Pa (0.02 inch water column (w.c.)). Alternatively, in facilities where low- and medium-risk level CSPs are prepared, differential airflow is maintained at a minimum velocity of 0.2 meter/second (40 fpm) across a line of demarcation between buffer area and ante-area. [ENVIRONMENTAL QUALITY AND CONTROL : Pressure Differential Monitoring] *Door connecting the general area to the ISO Class 7 prep area remained ajar through most of the inspection. Pressure gauge read +0.003"w.c..*	No
59. Clean rooms for nonhazardous and nonradioactive CSPs are supplied with HEPA filtered air that enters from ceilings with return vents low on walls, and that provides not less than 30 air changes per hour or qualifies for exception in 64B16-27.797(4)(c). [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
60. Activities and tasks carried out within the buffer area are limited to only those necessary when working within a controlled environment. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
61. Only the furniture, equipment, supplies, and other material required for the compounding activities to be performed are brought into the buffer room. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
62. Surfaces and essential furniture in buffer rooms or zones and clean rooms are nonporous, smooth, non-shedding, impermeable, cleanable, and resistant to disinfectants. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
63. The surfaces of ceilings, walls, floors, fixtures, shelving, counters, and cabinets in the buffer area are smooth, impervious, free from cracks and crevices, and non-shedding, thereby promoting cleanability, and minimizing spaces in which microorganisms and other contaminants may accumulate. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls] *positive clean room has protruding , rusted bolts sticking out of the upper left side of wall; there are multiple cracks on seam of wall in clean room. SECOND ADVISORY.*	No
64. Ceiling tiles are caulked around each perimeter and to walls to seal them to the support frame. The exterior lens surface of ceiling lighting fixtures is smooth, mounted flush, and sealed. All other penetrations through the ceiling or walls are sealed. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
65. The buffer area does not contain sources of water (sinks) or floor drains. Work surfaces are constructed of smooth, impervious materials, such as stainless steel or molded plastic, so that they are easily cleaned and disinfected. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
66. Storage shelving, counters, cabinets and carts/casters in the buffer area are smooth, impervious, free from cracks and crevices, non-shedding, non-porous, cleanable, and disinfectable. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
67. When devices (e.g., computers and printers) and objects (e.g., carts and cabinets) are placed in buffer areas, air quality is verified by particle counts on certification. [ENVIRONMENTAL QUALITY AND CONTROL : ISO Class 5 Air Sources, Buffer Areas, and Ante-Areas]	Yes

QUALITY AND CONTROL

68. An appropriate environmental sampling plan has been developed for airborne viable particles based on a risk assessment of compounding activities performed. Volumetric air sampling is conducted every six months and sites include locations within each ISO Class 5 environment and in the ISO Class 7 and 8 areas, and the areas at greatest risk of contamination (e.g., work areas near the ISO Class 5 environment, counters near doors, pass-through boxes). The plan includes sample locations, method of collection, frequency of sampling, volume of air sampled, and time of day as related to activity in the compounding area and action levels. [ENVIRONMENTAL QUALITY AND CONTROL : Environmental Viable Airborne Particle Testing Program—Sampling Plan] *Not available at the time of inspection*	No
69. Evaluation of airborne microorganisms using volumetric collection methods in the controlled air environments is performed by properly trained individuals for all compounding risk levels. [ENVIRONMENTAL QUALITY AND CONTROL : Viable Air Sampling] *VAS using a general microbiological growth medium to support growth of bacteria has been used for the LFH only.*	No
70. Volumetric air sampling using malt extract agar (MEA) or some other media that supports the growth of fungi is used in high-risk level compounding environments. [ENVIRONMENTAL QUALITY AND CONTROL : Growth Media]	Yes
71. For low-risk level CSPs with 12-hour or less BUD, air sampling is performed at locations inside the ISO Class 5 environment and other areas that are in close proximity to the ISO class 5 environment. [ENVIRONMENTAL QUALITY AND CONTROL : Viable Air Sampling]	N/A
72. The number of discrete colonies of microorganisms is counted and reported as colony-forming units (cfu) and documented on an environmental monitoring form. Counts from air monitoring are transformed into cfu/cubic meter of air and evaluated for adverse trends. [ENVIRONMENTAL QUALITY AND CONTROL : Incubation Period]	Yes
73. Surface sampling is accomplished in all ISO classified areas on a periodic basis using TSA contact plates with lecithin and polysorbate 80 and/or swabs and is done at the conclusion of compounding. [ENVIRONMENTAL QUALITY AND CONTROL : Surface Cleaning and Disinfection Sampling and Assessment]	Yes
74. Sampling data is collected and reviewed on a periodic basis as a means of evaluating the overall state of control of the compounding environment. [ENVIRONMENTAL QUALITY AND CONTROL : Action Levels, Documentation and Data Evaluation]	Yes
75. Competent microbiology personnel are consulted if an environmental sampling consistently shows elevated levels of microbial growth. If any mold, yeast, coagulase positive staphylococcus, or gram negative rods are detected immediate remediation and investigation into the cause and source was conducted. [ENVIRONMENTAL QUALITY AND CONTROL : Action Levels, Documentation and Data Evaluation]	N/A
76. Surfaces in the LAFWs, BSCs, CAIs, and CACIs are cleaned and disinfected frequently, including at the beginning of each work shift, before each batch preparation is started, every 30 minutes during continuous compounding periods of individual CSPs, when there are spills, and when surface contamination is known or suspected from procedural breaches. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas] *Cleaning records do not show the BSC located in the hazardous clean room is being cleaned and/or disinfected.*	No
77. Cleaning and disinfecting occurs before compounding is performed. Items are removed from all areas to be cleaned, and surfaces are cleaned by removing loose material and residue from spills, e.g., water-soluble solid residues are removed with Sterile Water and low-shedding wipes. This shall be followed by wiping with a residue-free disinfecting agent, such as sterile 70% IPA, which is allowed to dry before compounding begins. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes

78. Cleaning and disinfecting agents and methods of application are in accordance with written SOPs and followed by custodial and/or compounding personnel. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
79. Cleaning materials, such as wipes, sponges, and mops, are non-shedding, preferably composed of synthetic micro fibers, and dedicated to use in the buffer area, ante-area, and segregated compounding areas and are not removed from these areas except for disposal. If cleaning materials are reused (e.g., mops), there are procedures based on manufacturer recommendations that ensure that the effectiveness of the cleaning device is maintained and repeated use does not add to the bioburden of the area being cleaned. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
80. Supplies and equipment removed from shipping cartons are wiped with a suitable disinfecting agent (e.g., sterile 70% IPA). [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
81. Disinfectant sprayed or wiped on a surface to be disinfected is allowed to dry, and during this time the item is not be used for compounding purposes. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
82. Sterile 70% IPA pads are used to disinfect the sterile entry points of packages and devices. Wetted gauze pads or other particle-generating material are not appropriate. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes

QUALITY AND CONTROL (Secondary Engineering Controls)

83. Work surfaces in ISO Class 7 and 8 areas and segregated compounding areas are cleaned at least daily. IPA (70% isopropyl alcohol) remains on surfaces to be disinfected for at least 30 seconds before such surfaces are used to prepare CSPs. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
84. Floors in ISO Class 7 and 8 areas are mopped daily by trained personnel at a time when no aseptic operations are in progress using approved agents and procedures described in written SOP's. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
85. Shelving, walls, and ceilings in ante-areas and buffer areas are cleaned and disinfected at least monthly. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas] *October cleaning logs reflect monthly cleaning was not done in hazardous clean room.*	No

PERSONNEL CLEANSING, GARBING & COMPETENCY EVALUATION

86. Personnel preparing CSP's are free from rashes, sunburn, weeping sores, conjunctivitis, and active respiratory infections. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	Yes
87. Compounding personnel remove personal outer garments; cosmetics; artificial nails; hand, wrist, and body jewelry that can interfere with the fit of gowns and gloves; and visible body piercing above the neck. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	Yes
88. Facility has adequate supplies to meet PPE requirements of USP<797>. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	Yes
89. Garbing and hand hygiene are accomplished in the ante-area in order of dirtiest to cleanest: shoes or shoe covers, head and facial hair covers, face mask, fingernail cleansing, hand and forearm washing and drying; non-shedding gown. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	Yes
90. Sterile gloves are donned in the buffer room/isolator after hand cleansing with an alcohol-based product with persistent activity and hands are allowed to dry. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	Yes
91. Gloves are routinely disinfected with sterile 70% IPA after contacting nonsterile objects. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	Yes
92. Personnel repeat garbing and hand hygiene after they are exposed to direct contact contamination or worse than ISO Class 8 air. Gowns may be hung in the anteroom and reused during the same workshift. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	Yes
93. Low/Medium Risk media-fill tests that closely simulate the most challenging or stressful conditions encountered during compounding are completed at least annually by compounding personnel. Media-filled vials are appropriately incubated for 14 days. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Medium-Risk Level CSPs]	N/A
94. High Risk Media-fill tests that closely simulate the most challenging or stressful conditions encountered during compounding have been completed at least semiannually by compounding personnel. Media-filled vials are appropriately incubated for 14 days. [CSP MICROBIAL CONTAMINATION RISK LEVELS : High-Risk Level CSPs] *UR RPT last high risk media fill was conducted on 2.17.17.*	No
95. Documentation indicates compounding personnel have successfully completed didactic training, passed written competency assessments, undergone skill assessment using observational audit tools (hand hygiene, garbing, aseptic technique) and media-fill testing annually or semiannually (high risk) and before any compounding personnel begin to prepare CSPs . [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures] *JG RPh is overdue for all visual assessments.*	No
96. Compounding personnel who fail written tests, observational audits, or whose media-fill test vials have one or more units showing visible microbial contamination, are reinstructed and re-evaluated by expert compounding personnel to ensure correction of all aseptic work practice deficiencies. Corrective action is documented. Compounding personnel pass all evaluations prior to resuming compounding of sterile preparations. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures]	N/A
97. Other cleaning personnel performing cleaning and disinfecting procedures (e.g. environmental) are thoroughly trained in proper hand hygiene, and garbing, cleaning, and disinfection procedures by a qualified aseptic compounding expert. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures]	N/A
98. Compounding personnel and other personnel responsible for cleaning routinely undergo performance evaluation of proper hand hygiene, garbing, and all applicable cleaning and disinfecting procedures conducted by a qualified aseptic compounding expert. Visual observation of hand hygiene, garbing and cleaning is documented and maintained to provide a permanent record and long-term assessment of personnel competency. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures] *JG Rph is assessing UR RPT and is overdue for all visual assessments.*	No
99. Immediately after the compounder completes the hand hygiene and garbing procedure, the evaluator collects a gloved fingertip and thumb sample from both hands of the compounder onto appropriate agar plates. The plates are incubated at 30-35° for 2–3 days. All compounding personnel have successfully completed an initial competency evaluation and gloved fingertip/thumb sampling procedure (0 cfu) no less than three times before initially being allowed to compound CSPs for human use. [ENVIRONMENTAL QUALITY AND CONTROL : Gloved Fingertip Sampling]	Yes
100. Re-evaluation of glove fingertip testing onto appropriate agar plates (Trypticase soy agar (TSA) with lecithin and polysorbate 80) for all compounding personnel occurs at least annually for low- and medium-risk level CSPs and semiannually for high-risk level CSPs before being allowed to continue compounding CSPs. Gloves shall not be disinfected with sterile 70% IPA prior to testing. The cfu action level is based on the total number of cfu on both gloves and not per hand. [ENVIRONMENTAL QUALITY AND CONTROL : Gloved Fingertip Sampling]	Yes

VERIFICATION

101. Labels of CSPs contain name and address of pharmacy, correct names and amounts or concentrations of ingredients, total volumes, beyond-use dates, storage conditions, and route(s) of administration. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Identity and Strength Verification of Ingredients] *DECA Ultra lot 171113A BUD 12/28/17 label does not include Benzyl Benzoate as an ingredient in the final product, however it is listed in the compounded worksheet.*	No
102. Facility has documentation that procedures have been followed to ensure sterility, purity, correct identities and amounts of ingredients, and stability. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Inspection of Solution Dosage Forms and Review of Compounding Procedures]	Yes
103. CSP's are visually inspected for abnormal particulate matter and color, and intact containers and seals. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Inspection of Solution Dosage Forms and Review of Compounding Procedures]	Yes
104. Beyond Use Dates are assigned using direct stability-indicating assays or authoritative literature that supports the assigned BUD. [STORAGE AND BEYOND-USE DATING : Determining Beyond-Use Dates]	Yes
105. Storage time of assembled bag and vial systems are according to the manufacturer recommendations. (eg Minibag plus, Addvantage, Add-ease) [STORAGE AND BEYOND-USE DATING : Proprietary Bag and Vial Systems]	N/A

DISPENSING/DISTRIBUTION

106. Facility has written procedures for proper packaging, storage, and transportation conditions to maintain sterility, quality, purity, and strength of CSPs. [MAINTAINING STERILITY, PURITY, AND STABILITY OF DISPENSED AND DISTRIBUTED CSPs :]	
107. Modes of transport are used that maintain appropriate temperatures and prevent damage to CSPs. [MAINTAINING STERILITY, PURITY, AND STABILITY OF DISPENSED AND DISTRIBUTED CSPs : Packaging and Transporting CSPs]	
108. Facility provides a multiple component formal training program to ensure patients and caregivers understand the proper storage, handling, use, and disposal of CSPs. [PATIENT OR CAREGIVER TRAINING]	

POLICY/PROCEDURE

109. Written procedures detail cleaning and disinfecting the sterile compounding areas including cleansers, disinfectants, and non-shedding wipe and mop materials. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
110. A written procedure is in place for cleaning and disinfecting the Direct Compounding Areas. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
111. Facility has written procedures to verify correct identity, quality, amounts, and purities of ingredients used in CSPs. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Identity and Strength Verification of Ingredients]	Yes
112. Policies address packaging to maintain physical integrity, sterility, stability, and purity of CSPs. [MAINTAINING STERILITY, PURITY, AND STABILITY OF DISPENSED AND DISTRIBUTED CSPs : Packaging and Transporting CSPs]	Yes
113. Written standard procedures describe means for patients to ask questions and report concerns and adverse events with CSPs, and for compounding pharmacists to correct and prevent future problems. [PATIENT MONITORING AND ADVERSE EVENTS REPORTING]	Yes

RADIOPHARMACEUTICALS

114. Facility has appropriate primary engineering controls and radioactivity containment and shielding. Location of primary engineering controls permitted in ISO Class 8 controlled environment. [RADIOPHARMACEUTICALS AS CSPs]	
115. Radiopharmaceuticals prepared as low-risk level CSPs with 12-hour or less BUD are prepared in a segregated compounding area. Segregated compounding area is designated with a line of demarcation. [RADIOPHARMACEUTICALS AS CSPs]	
116. Technetium-99m/Molybdenum-99 generators are eluted in ISO Class 8 conditions. [RADIOPHARMACEUTICALS AS CSPs]	

MISCELLANEOUS

117. Facility engaged in office use sterile compounding for human use is registered with FDA as an outsourcing facility. [FAC 64B16-27.700 (3)(g]	Yes
118. Compounding records are properly maintained. [FAC 64B16-28.140(4)] *Zinc Sulfate 10mg/ml lot 171113C BUD 12/28/17 states SWI was used in compounding the CSP however label states bacteriostatic water for injection;*	No
119. When compounding activities require the manipulation of a patient's blood-derived or other biological material, the manipulations are clearly separated from routine material-handling procedures and equipment used in CSP preparation activities, and they are controlled by specific standard operating procedures in order to avoid any cross-contamination. [ENVIRONMENTAL QUALITY AND CONTROL : Placement of Primary Engineering Controls Within ISO Class 7 Buffer Areas]	N/A

SPECIAL PARENTERAL ENTERAL & EXTENDED SCOPE

120. Pharmacy technicians properly identified and supervised. [64B16-27.420, F.A.C.]	
121. Medication properly labeled. [465.0255, F.S.] [64B16-28.108, F.A.C.]	
122. Expired medications removed from the shelves. [64B16-28.110, F.A.C.]	
123. CQI Policy and Procedures and quarterly meetings. [766.101, F.S.] [64B16-27.300, F.A.C.]	
124. Prescriptions have the date dispensed and dispensing pharmacists. [893.04(1)(c) 6, F.S.] [64B16-28.140(3)(b), F.A.C.]	
125. Pharmacy maintains patient profile records. [64B16-27.800, F.A.C.]	
126. All controlled substance prescriptions contain information required. [893.04, F.S.]	
127. Prescriptions for controlled substances are on counterfeit-proof prescription pads or blanks purchased from a Department-approved vendor and the quantity and date meet the requirements of [456.42(2), F.S.].	
128. Controlled substance inventory taken on a biennial basis and available for inspection. [893.07(1)(a), F.S.]	
129. DEA 222 order forms properly completed. [893.07, F.S.]	
130. Controlled substance records and Rx information in computer system is retrievable. [21CFR 1306.22] [64B16-28.140, F.A.C.]	
131. Controlled substance records maintained for 4 years. [465.022(12)(b), F.S.]	
132. Certified daily log OR printout maintained. [21CFR 1306.22(b)(3)] [64B16-28.140(3)(b), F.A.C.]	

133. Pharmacy is reporting to the PDMP within 7 days of dispensing controlled substance. [893.055(4), F.S.]	
134. Pharmacy maintains invoices documenting that medicinal drugs were obtained from a Florida licensed distributor. 499.005 (14)	

Remarks:

Routine High risk SSCP inspection conducted with Umarani Rajalingam RPT and Jeff Goldrich Rph PDM.

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge. I have received a copy of the Licensee Bill of Rights.

Inspector Signature:

Date:12/19/2017

Representative:

Jeff Goldrich

Date:12/19/2017

On December 19, 2017, Senior Pharmacists Monica Bower and James Shepherd conducted a routine SSCP inspection at Hybrid Pharmacy (PH29374) located at 1015 W Newport CTR DR #106-A; Deerfield Beach, FL 33442. Jeffrey Goldrich PDM (PS27855) and Umarani Rajalingam RPT (RPT45465) were present for the inspection. The following deficiencies were found:

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22. **FAILURE to conduct USP <71> sterility testing for high risk CSP's with an appropriate filter**: Sterility tests are conducted onsite using a sterile filter that is not indicated to be used for pharmaceutical products, but for food and beverage. THIS MAY RESULT IN A FALSE NEGATIVE STERILITY RESULT, LEADING TO THE DISPENSING OF POSSIBLE CONTAMINATED CSP'S (Compounded Sterile Products). THERE IS A LACK OF STERILITY ASSURANCE.

23. **FAILURE to have appropriate method suitability for high risk CSP's:** Firm outsources their method suitability for sterility testing but uses TSB with L&T for their media for sterility test. The method suitability done by the contract lab is plain TSB This practice does not harmonize the growth media for dispensed CSP's, hence there is no assurance the growth media Hybrid is using for sterility testing is capable of microbial growth. THIS MAY RESULT IN A FALSE NEGATIVE STERILITY RESULT, LEADING TO THE DISPENSING OF POSSIBLE CONTAMINATED CSP'S.*****THIS IS THEIR SECOND ADVISORY******

32. **FAILURE to conduct endotoxin testing for High risk level CSP's**: A batch of testosterone , 2000ml , has not been tested for endotoxins (pyrogens that can cause fever, shock or death).

9. **FAILURE to sterilize high risk CSP's through filtration without disruption**: Specifications for filters used for sterilization indicate the maximum volume to be filtered is exceeded in the compounding process. THIS MAY RESULT IN MEMBRANE FAILURE AND COMPROMISE THE INTEGRITY OF THE FILTER USED TO STERILIZE CSP'S.

52. **FAILURE to demonstrate PEC's provide unidirectional HEPA filtered air through smoke studies**: Two PEC's (laminar flow hood and BSC) could not be shown to demonstrate HEPA filtered clean air is unidirectional and is capable of sweeping particles away from the critical sites during aseptic processing. THERE IS NO ASSURANCE CLEAN AIR IS PREVENTING CONTAMINATION OF CSP'S DURING ASEPTIC PROCESS.

51. **FAILURE to certify the PEC (primary engineering control) is ISO Class 5 certified under CETA Cag 003-2006 guidelines**: Non -viable particles for the BSC (Biological Safety Cabinet) were not counted. The PEC is used to compound and sterilize CSP's and there is NO ASSURANCE the hood does not exceed the maximum number of airborne particles that can potentially be introduced into the final sterile product. ****THIS PHARMACY COMPOUNDS LYOPHYLIZED CSP'S. THERE IS NO SMOKE STUDY TO ENSURE THE STERILIZED FINISHED PRODUCT IS TRANSFERRED THROUGH AN ISO CLASS 5 ZONE WITH UNIDIRECTIONAL AIRFLOW FROM THE PEC TO THE LYOPHYLIZER ****** THIS IS THEIR SECOND ADVISORY*****

15. **FAILURE to render glassware or other non-sterile containers free from pyrogens as well as viable microbes:** Pharmacy is using distilled water to rinse glassware, NOT sterile water. ***THIS IS THEIR SECOND ADVISORY***

58. **FAILURE to maintain required pressure of +0.02"w.c. between the ISO Class 7 ante area and general non classified area:** The door connecting the unclassified space to the ISO Class 7 prep room

was left ajar during the entire inspection resulting in a drop of pressure, thus allowing dirty air enter the prep room.

69. **FAILURE to evaluate airborne microorganisms in the controlled air environments:** Pharmacy conducts their own VAS (viable airborne sampling) and has not used general microbiological growth medium (TSA) to support the growth of bacteria. THIS DOES NOT ENSURE THE PEC's AND SEC's are free from pathogenic microorganisms or the classified environments does not exceed USP <797> actionable CFU levels.

94. **FAILURE to qualify compounding personnel through training and aseptic technique:** Media fill that is required to be done for all compounding personnel is overdue. THIS DOES NOT ENSURE CRITICAL STEPS DURING ASEPTIC PROCESS ARE BEING DONE WITHOUT INTRODUCING MICROORGANISMS INTO THE FINAL CSP.

95. **FAILURE to qualify compounding personnel through visual assessments:** Personnel that are qualifying other compounding operators are overdue on all visual assessments. These include cleaning/disinfecting the PEC's and SEC's (secondary engineering controls- rooms), aseptic technique (compounding) and hand hygiene and garbing (putting on sterile gloves and garb in the proper order).

118. **FAILURE to properly maintain compounding records:** Compounding records and CSP label have conflicting documented ingredients.

63. **FAILURE to maintain buffer room free from cracks, crevices and are smooth:** There are protruding metal bolts located in the buffer room where aseptic compounding is done. Some of these metal protrusions are visibly rusted. ***THIS IS THEIR SECOND ADVISORY***

76. **FAILURE to clean and disinfect BSC frequently**, including at the beginning of each work shift, before each batch, every 30 minutes, when there are spills, and when there is known contamination: There are no records of cleaning the BSC.

77**. FAILURE to perform monthly cleaning on walls and ceilings in ante areas and buffer areas:** Records show monthly cleaning in the ante room, hazardous drug room and positive clean room was not done.

THIS INSPECTION IS EVIDENT OF THE FIRMS REFUSAL TO CORRECT PAST DEFICIENCES THAT RESULTED IN SOME OF THE SAME DEFICIENCIES. THIS INDICATES THAT THERE IS A LACK OF COMPLIANCE IN PLACE TO KEEP THEIR PATIENTS AND THE PUBLIC FREE FROM HARM THIS IS AN OUTSOURCING FACILITY REGISTERD WITH THE FDA.

CONFIDENTIAL TO:
Jeffrey S Goldrich, RPh
7427 Shellridge Ter
Lake Worth, FL 33467

December 29, 2017

Case Number: 2017-23346

Dear Jeffrey S. Goldrich, RPh:

We are currently investigating the enclosed document received by the Department of Health. This investigation was initiated after it was determined that you may have violated the Florida Board of Pharmacy Practice Act.

Within **20 days** of receiving this letter, you may:

- submit a **written response** to the address below; **or**
- call our office to schedule an **interview**.

Please provide a copy of your **curriculum vitae** and identify your **specialty** even if you choose not to submit a response. Include the above-referenced case number in any correspondence that you send.

Florida law requires that this case and all investigative information remain confidential until 10 days after the Probable Cause Panel has determined that a violation occurred or you give up the right to confidentiality. Therefore, the contents of the investigation cannot be disclosed to you or the general public. You may make a written request for a copy of the investigative file and it will be sent to you when the investigation is complete.

You are not required to answer any questions or give any statement, and you have the right to be represented by an attorney. It is not possible to estimate how long it will take to complete this investigation because the circumstances of each investigation differ.

The mission of the Department of Health is to protect, promote & improve the health of all people in Florida through intregrated state, county and community efforts. If you have any questions please call us at 954-202-3256.

Sincerely,

M. Boatwright

Marsha Boatwright
Investigation Specialist II

/MB
Enclosure: Case Summary & Attachments

STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES
INV797-Sterile Compounding

File # 21375
Insp # 138417

NAME	PERMIT NUMBER	DATE OF INSPECTION
HYBRID PHARMA, LLC		05/27/2015
DOING BUSINESS AS		
STREET ADDRESS 1015 W NEWPORT CTR DR #106-A	**TELEPHONE #**	**EXT**
CITY DEERFIELD BEACH	**COUNTY** BROWARD	**STATE/ZIP** FL/33442

Additional Information

Business Operation Hours

Registered Pharmacist / Intern / Tech

License # PS27855	Licensee Name Jeff Goldrich
License Type Registered Pharmacists	
License # PS23256	Licensee Name Nicholas Pick
License Type Registered Pharmacists	
License # RPT45465	Licensee Name Umarani Rajalingham
License Type Pharmacy Tech	

ACS Manager

Optional Information

Basic License Data - PSD

DEA Reg # FH4258706	

INV797 - Sterile Compounding

LOW RISK

1. Low risk CSP's are properly identified: Aseptic manipulations within an ISO Class 5 environment using three or fewer sterile products and no more than two entries into any container. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Low-Risk Level CSPs]	
2. Low Risk CSP's, in absence of passing sterility test, stored not more than 48 hours at controlled room temperature, 14 days at cold temperature, or 45 days in solid frozen state at -25° to -10° or colder. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Low-Risk Level CSPs]	
3. Low Risk media-fill tests are completed at least annually by compounding personnel. Media-filled vials are appropriately incubated for 14 days. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Low-Risk Level CSPs]	
4. Low Risk CSP's with 12 hour BUD are properly identified and comply with all four specific criteria. 1. PEC in Segregated Compounding area 2. Away from windows, doors , high traffic areas 3. Hygiene & garbing required, sinks not adjacent to PEC. 4. Cleaning & Disinfecting, Personnel training, Competency evaluation, Garbing, Aseptic work practices, Viable and non-viable environmental sampling apply. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Low-Risk Level CSPs]	

MEDIUM RISK

5. Medium Risk CSP's are properly identified: Aseptic manipulations within an ISO Class 5 environment using prolonged and complex mixing and transfer, more than three sterile products and entries into any container, and pooling ingredients from multiple sterile products to prepare multiple CSPs. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Medium-Risk Level CSPs]	
6. Medium Risk CSP's, In absence of passing sterility test, stored not more than 30 hours at controlled room temperature, 9 days at cold temperature, or 45 days in solid frozen state at -25° to -10° or colder. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Medium-Risk Level CSPs]	
7. Medium Risk media-fill tests are completed at least annually by compounding personnel. Media-filled vials are appropriately incubated for 14 days. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Medium-Risk Level CSPs]	

HIGH RISK

8. High Risk CSP's are properly identified: Confirmed presence of nonsterile ingredients and devices, or confirmed or suspected exposure of sterile ingredients for more than one hour to air quality inferior to ISO Class 5 before final sterilization. [CSP MICROBIAL CONTAMINATION RISK LEVELS : High-Risk Level CSPs] *You need a policy that describes how you identify high risk*	No

Exhibit #3

000020

9. High Risk CSP's, in absence of passing sterility test are not stored more than 24 hours at controlled room temperature, 3 days at cold temperature, or 45 days in solid frozen state at -25° to -10° or colder. [CSP MICROBIAL CONTAMINATION RISK LEVELS : High-Risk Level CSPs] *Not currently compounding*	N/A
10. High Risk Media-fill tests have been completed at least semiannually by compounding personnel. Media-filled vials are appropriately incubated for 14 days. [CSP MICROBIAL CONTAMINATION RISK LEVELS : High-Risk Level CSPs] *Media fills were conducted with a commercial kit. This does not closely simulate the most stressful and challenging compounding that the pharmacy has done in the past and plans to do in the future. The pharmacy sterilizes its own vials and the kit comes with sterile vials. There are only 8 vials in the kit and the pharmacy has shown in past compounding that batches are much larger. The pharmacy has a lyophilizer in the buffer room and the media fill conducted does not validate or simulate this process.*	No
11. A 0.2-µm certified sterilizing membrane filter is used that is chemically and physically compatible with the CSP. Filtration is completed rapidly without filter replacement. Sterilization method is verified to achieve sterility for the quantity and type of containers. [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Sterilization of High-Risk Level CSPs by Filtration] *The pharmacy has purchased a stanless steel re usuable filter housing. The disc filter insert states that it is manufactured for the microbiological analysis of potable, waste, process and natural water for Psuedomonas sp isolation and enumeration. This is not an approved filter for the sterilization of pharmaceutical fluids for human use.*	No
12. Outsourced endotoxin testing results indicate that it is compliant with USP<85>. [BACTERIAL ENDOTOXINS TEST USP<85>]	N/A
13. Is a USP<85> Endotoxin testing done on site? [BACTERIAL ENDOTOXINS TEST USP<85>]	N/A
14. Endotoxin testing method is compliant? Indicate: Gel clot, chromogenic or turbidimetric? [BACTERIAL ENDOTOXINS TEST USP<85>]	N/A
15. High Risk CSP's are within allowable limits for bacterial endotoxins. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Bacterial Endotoxin (Pyrogen) Testing]	N/A
16. Sterilization method used has documentation that acceptable strength and purity of ingredients and integrity of containers is maintained. [CSP MICROBIAL CONTAMINATION RISK LEVELS : High-Risk Level CSPs] *Sterilization method chosen is not appropriate for sterilizing pharmaceutical fluids*	No
17. The manufacturer recommended filter integrity (e.g., bubble point) test is performed and documented for all sterilizing filters after filtering CSPs. [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Sterilization of High-Risk Level CSPs by Filtration]	N/A
18. Autoclave cycle has been verified using appropriate biological indicators. Solutions are passed through a 1.2-µm or smaller filter into final containers to remove particulates before sterilization. [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Sterilization of High-Risk Level CSPs by Steam] *The autoclave cycle has not been validated.*	No
19. Dry heat ovens used for sterilization have filtered forced air. Only those items that will be damaged by steam are sterilized by dry heat. [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Sterilization of High-Risk Level CSPs by Dry Heat]	N/A
20. The description of dry heat sterilization conditions and duration for specific CSPs is included in written documentation in the compounding facility. The effectiveness of dry heat sterilization is verified using appropriate biological indicators and other confirmation. [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Sterilization of High-Risk Level CSPs by Dry Heat]	N/A
21. Dry heat depyrogenation is used to render glassware or containers, such as vials free from pyrogens as well as viable microbes. The description of the dry heat depyrogenation cycle and duration for specific load items is included in written documentation in the compounding facility. The effectiveness of the dry heat depyrogenation cycle is verified using endotoxin challenge vials (ECVs). [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Depyrogenation by Dry Heat] *There is no dry heat oven. There is no description of the dry heat depyrogenation cycle. The pharmacy sterilizes it own vials and glassware.*	No
22. Presterilization procedures for high-risk level CSPs, such as weighing and mixing, are completed in no worse than an ISO Class 8 environment. [ENVIRONMENTAL QUALITY AND CONTROL : Placement of Primary Engineering Controls Within ISO Class 7 Buffer Areas] *The room where API is weighed is not classified*	No
23. Sterility testing is completed for all High-risk level CSPs prepared in batches of more than 25 identical containers, or exposed longer than 12 hours at 2° to 8°, and 6 hours at warmer than 8° before being sterilized. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Sterility Testing]	N/A
24. Endotoxin testing is conducted for High-risk level CSP's that are prepared in batches of more than 25 identical containers, or exposed longer than 12 hours at 2° to 8°, and 6 hours at warmer than 8°, before being sterilized or in multidose containers for administration to multiple patients. (excluding those for inhalation and ophthalmic administration) [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Bacterial Endotoxin (Pyrogen) Testing]	N/A

IMMEDIATE USE COMPOUNDING

25. Immediate-use compounding complies with all six specified criteria. 1. Low-risk sterile nonhazardous products or diagnostic radiopharmaceutical products from the manufacturers' original containers. Anti-neoplastics shall not be prepared as immediate-use CSPs because they are hazardous drugs. 2. Unless required for the preparation, the compounding procedure is a continuous process not to exceed 1 hour. 3. During preparation, aseptic technique is followed and, if not immediately administered, the finished CSP is under continuous supervision to minimize the potential for contact with nonsterile surfaces, introduction of particulate matter or biological fluids, mix-ups with other CSPs, and direct contact of outside surfaces. 4. Administration begins not later than 1 hour following the start of the preparation of the CSP. 5. Unless immediately and completely administered by the person who prepared it or immediate and complete administration is witnessed by the preparer, the CSP shall bear a label listing patient identification information, the names and amounts of all ingredients, the name or initials of the person who prepared the CSP, and the exact 1-hour BUD and time. 6. If administration has not begun within 1 hour following the start of preparing the CSP, the CSP shall be promptly, properly, and safely discarded. [IMMEDIATE-USE CSPs]	N/A

SINGLE/MULTIPLE DOSE CONTAINER BUD

26. Beyond-use date does not exceed 28 days for multiple-dose containers after initial opening or entry, unless specified otherwise by the manufacturer. [SINGLE-DOSE AND MULTIPLE-DOSE CONTAINERS] *You need this in your policy*	No
27. Beyond-use time does not exceed 6 hours for closure sealed single-dose containers in ISO Class 5 or cleaner air after initial opening or entry, unless specified otherwise by the manufacturer. [SINGLE-DOSE AND MULTIPLE-DOSE CONTAINERS] *Must add to your policy*	No
28. Beyond-use time does not exceed 1 hour for closure sealed single-dose containers after being opened or entered in worse than ISO Class 5 air. [SINGLE-DOSE AND MULTIPLE-DOSE CONTAINERS]	No
29. Single-dose ampules are discarded immediately after use. [SINGLE-DOSE AND MULTIPLE-DOSE CONTAINERS] *need policy*	No

HAZARDOUS DRUGS

30. Hazardous drug buffer room is at least 0.01 inch water column negative pressure with 30 ACPH of HEPA filtered air. [HAZARDOUS DRUGS AS CSPs] *The pharmacy has compounded Testosterone in the past and may compound in future. This is a hazardous drug and requires negative containment engineering controls. Advise that a negative pressure buffer room with a c-PEC is required for compounding hazardous drugs*	No
31. Personnel compounding hazardous drugs wear appropriate personal protective equipment. [HAZARDOUS DRUGS AS CSPs]	N/A
32. Appropriate primary engineering controls (BSCs and CACIs) are used for concurrent personnel protection and exposure of critical sites. [HAZARDOUS DRUGS AS CSPs]	No
33. Hazardous drugs are stored separately from other inventory in a manner to prevent contamination and personnel exposure. [HAZARDOUS DRUGS AS CSPs]	No
34 .At least 0.01 inch water column negative pressure and 12 air changes per hour in non-cleanrooms in which CACIs are located. FAC: USP Chapter 797 requires that: "When closed-system vial-transfer devices (CSTDs) (i.e., vial-transfer systems that allow no venting or exposure of hazardous substance to the environment) are used, they shall be used within an ISO Class 5 environment of a BSC or CACI. The use of the CSTD is preferred because of their inherent closed system process. In facilities that prepare a low volume of hazardous drugs, the use of two tiers of containment (e.g., CSTD within a BSC or CACI that is located in a non-negative pressure room) is acceptable." For purpose of said provision, a "low volume of hazardous drugs" is defined as less than 40 doses per month. [HAZARDOUS DRUGS AS CSPs]	No
35. Hazardous drugs are handled with caution at all times using appropriate chemotherapy gloves during receiving, distribution, stocking, inventorying, preparing for administration, and disposal. Spill kits are available. [HAZARDOUS DRUGS AS CSPs]	No
36. Hazardous drugs are prepared in an ISO Class 5 environment with protective engineering controls in place, following aseptic practices specified for the appropriate contamination risk levels. [HAZARDOUS DRUGS AS CSPs]	N/A
37. Access to hazardous drug preparation areas is limited to authorized compounding personnel. [HAZARDOUS DRUGS AS CSPs]	N/A
38. A pressure indicator is installed and differential pressures are monitored and documented daily for hazardous buffer room. [HAZARDOUS DRUGS AS CSPs]	No
39. Annual documentation of hazardous drug training of personnel regarding storage, handling, containment techniques and disposal of hazardous drugs is available. [HAZARDOUS DRUGS AS CSPs]	No
40. Compounding personnel of reproductive capability have confirmed in writing that they understand the risks of handling hazardous drugs. [HAZARDOUS DRUGS AS CSPs]	No
41. Facility maintains appropriate disposal containers for all hazardous waste. [HAZARDOUS DRUGS AS CSPs]	No

RADIOPHARMACEUTICALS

42. Facility has appropriate primary engineering controls and radioactivity containment and shielding. Location of primary engineering controls permitted in ISO Class 8 controlled environment. [RADIOPHARMACEUTICALS AS CSPs]	
43. Radiopharmaceuticals prepared as low-risk level CSPs with 12-hour or less BUD are prepared in a segregated compounding area. Segregated compounding area is designated with a line of demarcation. [RADIOPHARMACEUTICALS AS CSPs]	
44. Technetium-99m/Molybdenum-99 generators are eluted in ISO Class 8 conditions. [RADIOPHARMACEUTICALS AS CSPs]	
45. When compounding activities require the manipulation of a patient's blood-derived or other biological material (e.g., radiolabeling a patient's or a donor's white blood cells), the manipulations are clearly separated from routine material-handling procedures and equipment used in CSP preparation activities, and they are controlled by specific standard operating procedures in order to avoid any cross-contamination. [ENVIRONMENTAL QUALITY AND CONTROL : Placement of Primary Engineering Controls Within ISO Class 7 Buffer Areas]	

FACILITY DESIGN AND CERTIFICATION

46. Certification and testing of primary (LAFWs, BSCs, CAIs and CACIs) and secondary engineering controls (buffer and ante areas) have been performed by a qualified individual no less than every six months and whenever the device or room is relocated, altered, or major service to the facility is performed. Corrective action for deficiencies are documented. Certification procedures such as those outlined in the CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2006) are conducted under dynamic conditions. [ENVIRONMENTAL QUALITY AND CONTROL : Environmental Nonviable Particle Testing Program] *Facility certified Jan 2014, was not certified again until April 2015. Certification not conducted to CETA guidelines. Not tested under dynamic conditions,certification documented as at rest. Lyophilizer was not run during certification*	No
47. Facility has pressure gauges or velocity meters to monitor the pressure differential or airflow between the buffer area and ante-area, and the ante-area and the general environment outside the compounding area. The results are reviewed and documented on a log at least daily or by a continuous recording device. The pressures differentials meet or exceed 5 Pa (0.02 inch water column (w.c.)). Alternatively, in facilities where low- and medium-risk level CSPs are prepared, differential airflow is maintained at a minimum velocity of 0.2 meter/second (40 fpm) across a line of demarcation between buffer area and ante-area. [ENVIRONMENTAL QUALITY AND CONTROL : Pressure Differential Monitoring] *Pressure gauge in the buffer room is installed but does not measure the pressure from the plastic sheeting to area behind it.*	No
48. Primary engineering controls provide unidirectional (i.e., laminar) HEPA air at a velocity sufficient to prevent airborne particles from contacting critical sites. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls] *Not documented in the certification*	No
49. Air pattern analysis via smoke studies are conducted at the critical site to demonstrate unidirectional airflow and sweeping action over and away from the product under dynamic conditions. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls] *Not documented on the certification report*	No
50. Clean rooms for nonhazardous and nonradioactive CSPs are supplied with HEPA filtered air that enters from ceilings with return vents low on walls, and that provides not less than 30 air changes per hour. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls] *Not on the certification report*	No
51. The primary engineering controls are placed within a buffer area in such a manner as to avoid conditions that could adversely affect their operation. The PEC is placed out of the traffic flow and in a manner to avoid disruption from the HVAC system and room cross drafts. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls] *This needs to be validated with the lyophilizer running*	Yes
52. Primary engineering controls for nonhazardous and nonradioactive CSPs are located in buffer areas, except for CAIs that are proven to maintain ISO Class 5 air when particle counts are sampled 6 to 12 inches upstream of critical site exposure areas during performance of normal inward and outward transfer of materials, and compounding manipulations when such CAIs are located in air quality worse than ISO Class 7. [ENVIRONMENTAL QUALITY AND CONTROL : Placement of Primary Engineering Controls Within ISO Class 7 Buffer Areas]	Yes
53. Adequate recovery time for isolators to achieve ISO Class 5 air quality is allowed after material transfer before and during compounding operations. [ENVIRONMENTAL QUALITY AND CONTROL : Placement of Primary Engineering Controls Within ISO Class 7 Buffer Areas]	N/A
54. All HEPA filters are leak tested after installation and every six months thereafter. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls] *The facility was certified January 9, 2014 and was not certified again until April 3, 2015.*	No

55. Activities and tasks carried out within the buffer area are limited to only those necessary when working within a controlled environment. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	N/A
56. Only the furniture, equipment, supplies, and other material required for the compounding activities to be performed are brought into the buffer room. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	N/A
57. Surfaces and essential furniture in buffer rooms or zones and clean rooms are nonporous, smooth, non-shedding, impermeable, cleanable, and resistant to disinfectants. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	No
58. The surfaces of ceilings, walls, floors, fixtures, shelving, counters, and cabinets in the buffer area are smooth, impervious, free from cracks and crevices, and non-shedding, thereby promoting cleanability, and minimizing spaces in which microorganisms and other contaminants may accumulate. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls] *The walls of the buffer room are hung with plastic sheets. The plastic sheets are stuck together with scotch tape, push pins and screws. The use of heavy gauge polymer is allowed if the sheets are in panels that lock together. The sheets are not in panels and are not locked together.Screws are in the walls and have pulled through the plastic sheeting leaving holes. There is dried paint on the plastic. Baseboards are exposed and not smooth for easy cleaning. The paint comes off the baseboards when wiped with alcohol swab and cannot be cleaned appropriately with disinfectant agents. The lyophilizer is installed in the wall of the buffer room and sealed to the wall with aluminum tape. In places with large gaps, the tape is the only barrier between the gown room and the buffer room. It is very fragile and will break when pressure is applied(such as during cleaning). The floors have seams with cracks and are not fixed to the walls (plastic sheets).*	No
59. Ceiling tiles are caulked around each perimeter and to walls to seal them to the support frame. The exterior lens surface of ceiling lighting fixtures is smooth, mounted flush, and sealed. All other penetrations through the ceiling or walls are sealed. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls] *Ceiling tiles are not caulked. Fixtures are not sealed and have the rough side showing.*	No
60. The buffer area does not contain sources of water (sinks) or floor drains. Work surfaces are constructed of smooth, impervious materials, such as stainless steel or molded plastic, so that they are easily cleaned and disinfected. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
61. Carts are made of stainless steel wire, or nonporous plastic, or sheet metal construction with good quality, cleanable casters. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
62. Storage shelving, counters, and cabinets in the buffer area are smooth, impervious, free from cracks and crevices, non-shedding, cleanable, and disinfectable. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
63. When devices (e.g., computers and printers) and objects (e.g., carts and cabinets) are placed in buffer areas, air quality is verified by particle counts on certification. [ENVIRONMENTAL QUALITY AND CONTROL : ISO Class 5 Air Sources, Buffer Areas, and Ante-Areas] *Certification does not indicated that it was conducted with the lyophylizer running.*	No

QUALITY AND CONTROL

64. An appropriate environmental sampling plan has been developed for airborne viable particles based on a risk assessment of compounding activities performed. Volumetric air sampling is conducted every six months and sites include locations within each ISO Class 5 environment and in the ISO Class 7 and 8 areas, and the areas at greatest risk of contamination (e.g., work areas near the ISO Class 5 environment, counters near doors, pass-through boxes). The plan includes sample locations, method of collection, frequency of sampling, volume of air sampled, and time of day as related to activity in the compounding area and action levels. [ENVIRONMENTAL QUALITY AND CONTROL : Environmental Viable Airborne Particle Testing Program—Sampling Plan] *Your sampling plan restates the requirement in USP<797>. You need to put into your policy locations, volume of air sampled, time of day related to compounding, frequency of sampling and action levels*	No
65. Surface sampling is accomplished in all ISO classified areas on a periodic basis using TSA contact plates with lecithin and polysorbate 80 and/or swabs and is done at the conclusion of compounding. [ENVIRONMENTAL QUALITY AND CONTROL : Surface Cleaning and Disinfection Sampling and Assessment] *Swabs are used but policy does not call for the use of neutralizing agents*	No
66. Evaluation of airborne microorganisms using volumetric collection methods in the controlled air environments is performed by properly trained individuals for all compounding risk levels. [ENVIRONMENTAL QUALITY AND CONTROL : Viable Air Sampling] *Staff are performing thier own viable air sampling. There is no documented training for staff on this device*	No
67. Volumetric air sampling using malt extract agar (MEA) or some other media that supports the growth of fungi is used in high-risk level compounding environments. [ENVIRONMENTAL QUALITY AND CONTROL : Growth Media]	Yes
68. For low-risk level CSPs with 12-hour or less BUD, air sampling is performed at locations inside the ISO Class 5 environment and other areas that are in close proximity to the ISO class 5 environment. [ENVIRONMENTAL QUALITY AND CONTROL : Viable Air Sampling]	N/A
69. The number of discrete colonies of microorganisms is counted and reported as colony-forming units (cfu) and documented on an environmental monitoring form. Counts from air monitoring are transformed into cfu/cubic meter of air and evaluated for adverse trends. [ENVIRONMENTAL QUALITY AND CONTROL : Incubation Period] *The air sampling results must be converted to cfu per 1000liters of air. You need a description in your policy*	No
70. Sampling data is collected and reviewed on a periodic basis as a means of evaluating the overall state of control of the compounding environment. [ENVIRONMENTAL QUALITY AND CONTROL : Action Levels, Documentation and Data Evaluation]	Yes
71. Competent microbiology personnel are consulted if an environmental sampling consistently shows elevated levels of microbial growth. If any mold, yeast, coagulase positive staphylococcus, or gram negative rods are detected immediate remediation and investigation into the cause and source was conducted. [ENVIRONMENTAL QUALITY AND CONTROL : Action Levels, Documentation and Data Evaluation]	N/A
72. Written procedures detail cleaning and disinfecting the sterile compounding areas including cleansers, disinfectants, and non-shedding wipe and mop materials. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas] *Cleaning procedures do not describe the cleaning procedures, materials or disinfectants. Policy states that a cleanroom mop with bucket and wringer is used. No procedures for or schedule for cleaning.*	No
73. Surfaces in the LAFWs, BSCs, CAIs, and CACIs are cleaned and disinfected frequently, including at the beginning of each work shift, before each batch preparation is started, every 30 minutes during continuous compounding periods of individual CSPs, when there are spills, and when surface contamination is known or suspected from procedural breaches. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas] *Documentation needs to identify specific areas cleaned*	Yes
74. A written procedure is in place for cleaning and disinfecting the Direct Compounding Areas. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas] *Written procedure is inadequate. Does not call for use of Sterile 70% IPA. No procedure that adequately describes cleaning procedure*	No
75. Cleaning and disinfecting occurs before compounding is performed. Items are removed from all areas to be cleaned, and surfaces are cleaned by removing loose material and residue from spills, e.g., water-soluble solid residues are removed with Sterile Water and low-shedding wipes. This shall be followed by wiping with a residue-free disinfecting agent, such as sterile 70% IPA, which is allowed to dry before compounding begins. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes

76. Work surfaces in ISO Class 7 and 8 areas and segregated compounding areas are cleaned at least daily. IPA (70% isopropyl alcohol) remains on surfaces to be disinfected for at least 30 seconds before such surfaces are used to prepare CSPs. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
77. Floors in ISO Class 7 and 8 areas are mopped daily by trained personnel at a time when no aseptic operations are in progress using approved agents and procedures described in written SOP's. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
78. Shelving, walls, and ceilings in ante-areas are cleaned and disinfected at least monthly. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas] *No procedure in policy for cleaning the plastic sheets. No evidence or documentation that all surfaces have been cleaned. The walls cannot be cleaned with the plastic in place. Paint on buffer walls comes off with alcohol and will not withstand harsh cleansers*	No
79. Cleaning and disinfecting agents and methods of application are in accordance with written SOPs and followed by custodial and/or compounding personnel. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas] *No protocols*	No
80. Cleaning materials, such as wipes, sponges, and mops, are non-shedding, preferably composed of synthetic micro fibers, and dedicated to use in the buffer area, ante-area, and segregated compounding areas and are not removed from these areas except for disposal. If cleaning materials are reused (e.g., mops), there are procedures based on manufacturer recommendations that ensure that the effectiveness of the cleaning device is maintained and repeated use does not add to the bioburden of the area being cleaned. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas] *Your policy states that you use a mop and bucket and wringer, which is not consistent with current practices.*	Yes
81. Supplies and equipment removed from shipping cartons are wiped with a suitable disinfecting agent (e.g., sterile 70% IPA). [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
82. Disinfectant sprayed or wiped on a surface to be disinfected is allowed to dry, and during this time the item is not be used for compounding purposes. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas] *You need this in your policy*	N/A
83. Sterile 70% IPA pads are used to disinfect the sterile entry points of packages and devices. Wetted gauze pads or other particle-generating material are not appropriate. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes

PERSONNEL CLEANSING, GARBING & COMPETENCY EVALUATION

84. Personnel preparing CSP's are free from rashes, sunburn, weeping sores, conjunctivitis, and active respiratory infections. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	Yes
85. Compounding personnel remove personal outer garments; cosmetics; artificial nails; hand, wrist, and body jewelry that can interfere with the fit of gowns and gloves; and visible body piercing above the neck. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	Yes
86. Facility has adequate supplies to meet PPE requirements of USP<797>. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	Yes
87. Garbing and hand hygiene are accomplished in the ante-area in order of dirtiest to cleanest: shoes or shoe covers, head and facial hair covers, face mask, fingernail cleansing, hand and forearm washing and drying; non-shedding gown. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing] *Hand hygeine does not include nail cleaning, there are no nail picks avalable*	No
88. Sterile gloves are donned in the buffer room after hand cleansing with an alcohol-based product with persistent activity and hands are allowed to dry. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing] *There is no alcohol based hand cleanser with persistent activity*	No
89. Gloves are routinely disinfected with sterile 70% IPA after contacting nonsterile objects. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing] *This needs to be in your policy*	No
90. Personnel repeat garbing and hand hygiene after they are exposed to direct contact contamination or worse than ISO Class 8 air. Gowns may be hung in the anteroom and reused during the same workshift. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing] *Policy call for gowns bouffant caps, masks boots and arm sleeves to be changed weekly.*	No
91. Personnel garbing requirements are followed for CAIs unless manufacturer provides written documentation based on validated testing that any components of PPE are not required to maintain sterility of CSPs. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	N/A
92. Documentation indicates compounding personnel have successfully completed didactic training, passed written competency assessments, undergone skill assessment using observational audit tools, and media-fill testing before any compounding personnel begin to prepare CSPs. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures]	Yes
93. Compounding personnel who fail written tests, observational audits, or whose media-fill test vials have one or more units showing visible microbial contamination, are reinstructed and re-evaluated by expert compounding personnel to ensure correction of all aseptic work practice deficiencies. Compounding personnel pass all evaluations prior to resuming compounding of sterile preparations. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures]	N/A
94. Corrective action is documented for compounding personnel who fail written tests or media-fill test. [PERSONNEL TRAINING AND EVALUATION IN ASEPTIC MANIPULATIONS SKILLS]	N/A
95. Other cleaning personnel performing cleaning and disinfecting procedures (e.g. environmental) are thoroughly trained in proper hand hygiene, and garbing, cleaning, and disinfection procedures by a qualified aseptic compounding expert. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures]	N/A
96. Compounding personnel and other personnel responsible for cleaning routinely undergo performance evaluation of proper hand hygiene, garbing, and all applicable cleaning and disinfecting procedures conducted by a qualified aseptic compounding expert. Visual observation of hand hygiene, garbing and cleaning is documented and maintained to provide a permanent record and long-term assessment of personnel competency. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures] *N. Pick needs to do this*	No
97. Compounding personnel are visually observed annually or semiannually (high risk) during the process of performing hand hygiene, garbing procedures and aseptic technique. The visual observation is documented on a form for Assessing Hand Hygiene, Garbing and Aseptic Technique and maintained to provide a permanent record. [ENVIRONMENTAL QUALITY AND CONTROL : Garbing and Gloving Competency Evaluation]	Yes
98. Immediately after the compounder completes the hand hygiene and garbing procedure, the evaluator collects a gloved fingertip and thumb sample from both hands of the compounder onto appropriate agar plates. The plates are incubated at 30-35° for 2–3 days. All compounding personnel have successfully completed an initial competency evaluation and gloved fingertip/thumb sampling procedure (0 cfu) no less than three times before initially being allowed to compound CSPs for human use. [ENVIRONMENTAL QUALITY AND CONTROL : Gloved Fingertip Sampling] *3 GFT test not done for all personnel. Failed GFT for JG, not 3 passed*	No

99. Re-evaluation of glove fingertip testing onto appropriate agar plates (Trypticase soy agar (TSA) with lecithin and polysorbate 80) for all compounding personnel occurs at least annually for low- and medium-risk level CSPs and semiannually for high-risk level CSPs before being allowed to continue compounding CSPs. Gloves shall not be disinfected with sterile 70% IPA prior to testing. The cfu action level is based on the total number of cfu on both gloves and not per hand. [ENVIRONMENTAL QUALITY AND CONTROL : Gloved Fingertip Sampling]	N/A

VERIFICATION

100. Facility has written procedures to verify correct identity, quality, amounts, and purities of ingredients used in CSPs. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Identity and Strength Verification of Ingredients]	Yes
101. Labels of CSPs contain name and address of pharmacy, correct names and amounts or concentrations of ingredients, total volumes, beyond-use dates, storage conditions, and route(s) of administration. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Identity and Strength Verification of Ingredients]	N/A
102. Facility has documentation that procedures have been followed to ensure sterility, purity, correct identities and amounts of ingredients, and stability. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Inspection of Solution Dosage Forms and Review of Compounding Procedures]	N/A
103. CSP's are visually inspected for abnormal particulate matter and color, and intact containers and seals. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Inspection of Solution Dosage Forms and Review of Compounding Procedures] *Its in the policy*	N/A
104. Beyond Use Dates are assigned using direct stability-indicating assays or authoritative literature that supports the assigned BUD. [STORAGE AND BEYOND-USE DATING : Determining Beyond-Use Dates]	N/A
105. Storage time of assembled bag and vial systems are according to the manufacturer recommendations. (eg Minibag plus, Addvantage, Add-ease) [STORAGE AND BEYOND-USE DATING : Proprietary Bag and Vial Systems]	N/A
106. Facility has written procedures for proper packaging, storage, and transportation conditions to maintain sterility, quality, purity, and strength of CSPs. [MAINTAINING STERILITY, PURITY, AND STABILITY OF DISPENSED AND DISTRIBUTED CSPs :]	Yes
107. Policies address packaging to maintain physical integrity, sterility, stability, and purity of CSPs. [MAINTAINING STERILITY, PURITY, AND STABILITY OF DISPENSED AND DISTRIBUTED CSPs : Packaging and Transporting CSPs]	Yes

DISPENSING/DISTRIBUTION

108. Modes of transport are used that maintain appropriate temperatures and prevent damage to CSPs. [MAINTAINING STERILITY, PURITY, AND STABILITY OF DISPENSED AND DISTRIBUTED CSPs : Packaging and Transporting CSPs]	N/A
109. Facility provides a multiple component formal training program to ensure patients and caregivers understand the proper storage, handling, use, and disposal of CSPs. [PATIENT OR CAREGIVER TRAINING]	No
110. Written standard procedures describe means for patients to ask questions and report concerns and adverse events with CSPs, and for compounding pharmacists to correct and prevent future problems. [PATIENT MONITORING AND ADVERSE EVENTS REPORTING]	No

USP <71> STERILITY TESTING

111. Outsourced sterility testing results indicate that it is compliant with USP<71>. A method not described in the USP may be used if validation demonstrates that the alternative is at least as effective and reliable. [STERILITY TEST USP<71>]	N/A
112. Outsourced: The number of articles tested are appropriate according to USP<71>. [STERILITY TEST USP<71> : Number of Articles to Be Tested]	N/A
113. Outsourced: The volume/quantity tested is according to USP<71>. [STERILITY TEST USP<71> : Number of Articles to Be Tested]	N/A
114. On site: Membrane filtration is used whenever the nature of the product permits. Filters are rinsed according to USP<71>. Sterility testing results indicate that it is compliant with USP<71>. A method not described in the USP may be used if validation demonstrates that the alternative is at least as effective and reliable. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Sterility Testing] *Pharmacist states they will be conducting thier own sterility testing. Policy for this is not complaint with USP<71>.*	No
115. On site: Direct inoculation is done only when membrane filtration cannot be carried out. Volume to be inoculated does not exceed 10% of the culture media volume. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Sterility Testing] *Policy states that all products will be tested by direct inoculation. These products will be sterilized by filtration and can be tested by membrane filtration*	No
116. On site: The number of articles tested are appropriate according to USP<71>. [STERILITY TEST USP<71> : Number of Articles to Be Tested] *Policy does not call for appropriate number of samples*	No
117. On site: The volume/quantity tested is according to USP<71>. [STERILITY TEST USP<71> : Number of Articles to Be Tested] *Policy calls for testing 1ml, not quantity required in USP <71>*	No
118. On site: A growth promotion test has been done on the media with the 5 specified organisms (not more than 100 CFU) according to USP<71>. [STERILITY TEST USP<71> : Growth Promotion Test of Aerobes, Anaerobes, and Fungi] *Not in policy*	No
119. On site: A USP<71> method suitability test has been done with appropriate inoculum, additives and rinses. [STERILITY TEST USP<71> : Method Suitability Test] *Not in policy*	No
120. On site: TSB or SCD is incubated at 20-25 C for 14 days (2 incubators present). [STERILITY TEST USP<71> : Culture Media and Incubation Temperatures]	Yes
121. On site: FTM is incubated at 30-35 C for 14 days (2 incubators present). [STERILITY TEST USP<71> : Culture Media and Incubation Temperatures] *Policy does not call for use of FTM*	No
122. On site: Sterility testing is documented including lot numbers and expiration dates of media. [FINISHED PREPARATION RELEASE CHECKS AND TESTS] *No policy*	No
123. Sterility testing reports are reviewed and appropriate actions taken and documented. [FINISHED PREPARATION RELEASE CHECKS AND TESTS]	N/A

MISCELLANEOUS

124. Facility engaged in office use sterile compounding for human use is registered with FDA as an outsourcing facility. [FAC 64B16-27.700 (3)(g]	Yes
125. Compounding records are properly maintained. [FAC 64B16-28.140(4)]	N/A

Remarks:

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge. I have received a copy of the Licensee Bill of Rights.

Investigator/Sr. Pharmacist Signature:

CRANE, MARY

Date:5/27/2015

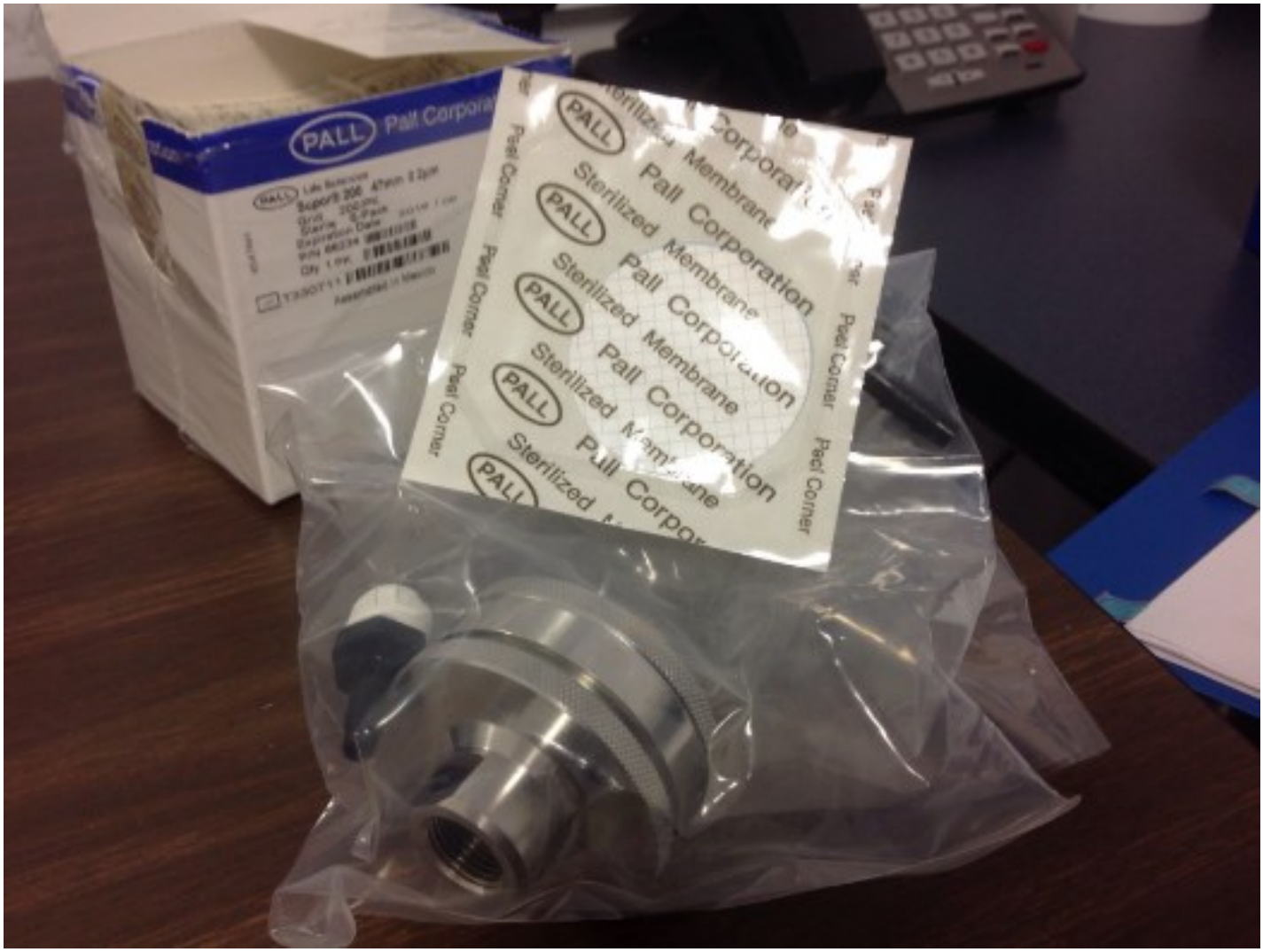
Representative:

Nicholas Pick

Date:5/27/2015

CLEANROOM
Keep Door Closed
at ALL TIMES
FDA
REGISTERED
FACILITY

Corporation
Sterilized Membrane
PALL
Pall Corporation
Sterilized Membrane
PALL
Pall Corporation
Sterilized Membrane
PALL
Pall Corporation
Sterilized Membrane
PALL
Pall
Peel Corner
Peel Corner
Peel Corner
Peel Corner


PALL
Pall Corporation
Sterilized Membrane
Pall Corporation
Peel Corner
Peel Corner

5.1 Procedure For Surface testing by Sterile Swab sticks

5.1.1 Swab should only be used when it is not possible to use RODAC for the swab test. A cotton stick (swab) should be preferred. The swab should be moistened in sterile saline or sterile water & rubbed on the sampling site and then rubbed in a SCD agar plate. All operations made in the sampling area.

5.1.2 After sampling incubate the plates at 30°C - 35°C for 72 Hrs and then record the results in terms of CFU / plate in Annexure - I.

Limit : Results CFU per sample.

Class	Location	Alert Level	Action Level
100	* Critical sites (Filling line)	* 1	* > 1
	Other sites	1 – 3	> 3
10,000	Above Floor level	3 – 5	> 5
	At floor level	7 – 10	> 10
100,000 Pre & Wash	Above Floor level	15 - 25	> 25
	At floor level	25 - 50	> 50
100,000 Other area	Above Floor level	25 – 50	> 50
	At floor level	50 – 100	> 100

Colony should be within Limit or Fungi should be

STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES
INV797-Sterile Compounding

File # 21375
Insp # 138768

NAME	PERMIT NUMBER	DATE OF INSPECTION
HYBRID PHARMA, LLC		09/04/2015
DOING BUSINESS AS		
STREET ADDRESS 1015 W NEWPORT CTR DR #106-A	**TELEPHONE #**	**EXT**
CITY DEERFIELD BEACH	**COUNTY** BROWARD	**STATE/ZIP** FL/33442

Additional Information

Business Operation Hours

Registered Pharmacist / Intern / Tech

License # PS27855	Licensee Name Jeff Goldrich
License Type Registered Pharmacists	
License # PS23256	Licensee Name Nicholas Pick
License Type Registered Pharmacists	
License # RPT45465	Licensee Name Umarani Rajalingham
License Type Pharmacy Tech	

ACS Manager

Optional Information

Basic License Data - PSD

DEA Reg # FH4258706	

INV797 - Sterile Compounding

LOW RISK

1. Low risk CSP's are properly identified: Aseptic manipulations within an ISO Class 5 environment using three or fewer sterile products and no more than two entries into any container. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Low-Risk Level CSPs]	
2. Low Risk CSP's, in absence of passing sterility test, stored not more than 48 hours at controlled room temperature, 14 days at cold temperature, or 45 days in solid frozen state at -25° to -10° or colder. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Low-Risk Level CSPs]	
3. Low Risk media-fill tests are completed at least annually by compounding personnel. Media-filled vials are appropriately incubated for 14 days. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Low-Risk Level CSPs]	
4. Low Risk CSP's with 12 hour BUD are properly identified and comply with all four specific criteria. 1. PEC in Segregated Compounding area 2. Away from windows, doors , high traffic areas 3. Hygiene & garbing required, sinks not adjacent to PEC. 4. Cleaning & Disinfecting, Personnel training, Competency evaluation, Garbing, Aseptic work practices, Viable and non-viable environmental sampling apply. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Low-Risk Level CSPs]	

MEDIUM RISK

5. Medium Risk CSP's are properly identified: Aseptic manipulations within an ISO Class 5 environment using prolonged and complex mixing and transfer, more than three sterile products and entries into any container, and pooling ingredients from multiple sterile products to prepare multiple CSPs. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Medium-Risk Level CSPs]	
6. Medium Risk CSP's, In absence of passing sterility test, stored not more than 30 hours at controlled room temperature, 9 days at cold temperature, or 45 days in solid frozen state at -25° to -10° or colder. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Medium-Risk Level CSPs]	
7. Medium Risk media-fill tests are completed at least annually by compounding personnel. Media-filled vials are appropriately incubated for 14 days. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Medium-Risk Level CSPs]	

HIGH RISK

8. High Risk CSP's are properly identified: Confirmed presence of nonsterile ingredients and devices, or confirmed or suspected exposure of sterile ingredients for more than one hour to air quality inferior to ISO Class 5 before final sterilization. [CSP MICROBIAL CONTAMINATION RISK LEVELS : High-Risk Level CSPs] *High Risk levels are properly identified in SOP*	Yes

9. High Risk CSP's, in absence of passing sterility test are not stored more than 24 hours at controlled room temperature, 3 days at cold temperature, or 45 days in solid frozen state at -25° to -10° or colder. [CSP MICROBIAL CONTAMINATION RISK LEVELS : High-Risk Level CSPs]	N/A
10. High Risk Media-fill tests have been completed at least semiannually by compounding personnel. Media-filled vials are appropriately incubated for 14 days. [CSP MICROBIAL CONTAMINATION RISK LEVELS : High-Risk Level CSPs]	Yes
11. A 0.2-µm certified sterilizing membrane filter is used that is chemically and physically compatible with the CSP. Filtration is completed rapidly without filter replacement. Sterilization method is verified to achieve sterility for the quantity and type of containers. [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Sterilization of High-Risk Level CSPs by Filtration] *Current filters provided during inspection do not have documentation that filters are FDA approved sterilizing grade filters for human use. Facility will provided documentation and proof of purchase that the correct filters have been obtained prior to issuance of a permit*	No
12. Outsourced endotoxin testing results indicate that it is compliant with USP<85>. [BACTERIAL ENDOTOXINS TEST USP<85>]	N/A
13. Is a USP<85> Endotoxin testing done on site? [BACTERIAL ENDOTOXINS TEST USP<85>]	N/A
14. Endotoxin testing method is compliant? Indicate: Gel clot, chromogenic or turbidimetric? [BACTERIAL ENDOTOXINS TEST USP<85>]	N/A
15. High Risk CSP's are within allowable limits for bacterial endotoxins. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Bacterial Endotoxin (Pyrogen) Testing]	N/A
16. Sterilization method used has documentation that acceptable strength and purity of ingredients and integrity of containers is maintained. [CSP MICROBIAL CONTAMINATION RISK LEVELS : High-Risk Level CSPs] *SOP's describe various methods of sterization methods*	Yes
17. The manufacturer recommended filter integrity (e.g., bubble point) test is performed and documented for all sterilizing filters after filtering CSPs. [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Sterilization of High-Risk Level CSPs by Filtration]	N/A
18. Autoclave cycle has been verified using appropriate biological indicators. Solutions are passed through a 1.2-µm or smaller filter into final containers to remove particulates before sterilization. [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Sterilization of High-Risk Level CSPs by Steam] *Documentation shows Biolaogical Indicatos were used to valdiate.*	Yes
19. Dry heat ovens used for sterilization have filtered forced air. Only those items that will be damaged by steam are sterilized by dry heat. [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Sterilization of High-Risk Level CSPs by Dry Heat]	N/A
20. The description of dry heat sterilization conditions and duration for specific CSPs is included in written documentation in the compounding facility. The effectiveness of dry heat sterilization is verified using appropriate biological indicators and other confirmation. [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Sterilization of High-Risk Level CSPs by Dry Heat]	N/A
21. Dry heat depyrogenation is used to render glassware or containers, such as vials free from pyrogens as well as viable microbes. The description of the dry heat depyrogenation cycle and duration for specific load items is included in written documentation in the compounding facility. The effectiveness of the dry heat depyrogenation cycle is verified using endotoxin challenge vials (ECVs). [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Depyrogenation by Dry Heat] *A dry heat oven is in place and has been validated using ECV's and temperature mapping*	Yes
22. Presterilization procedures for high-risk level CSPs, such as weighing and mixing, are completed in no worse than an ISO Class 8 environment. [ENVIRONMENTAL QUALITY AND CONTROL : Placement of Primary Engineering Controls Within ISO Class 7 Buffer Areas] *A scale is in place in the ISO 7 buffer room*	Yes
23. Sterility testing is completed for all High-risk level CSPs prepared in batches of more than 25 identical containers, or exposed longer than 12 hours at 2° to 8°, and 6 hours at warmer than 8° before being sterilized. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Sterility Testing]	N/A
24. Endotoxin testing is conducted for High-risk level CSP's that are prepared in batches of more than 25 identical containers, or exposed longer than 12 hours at 2° to 8°, and 6 hours at warmer than 8°, before being sterilized or in multidose containers for administration to multiple patients. (excluding those for inhalation and ophthalmic administration) [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Bacterial Endotoxin (Pyrogen) Testing]	N/A

IMMEDIATE USE COMPOUNDING

25. Immediate-use compounding complies with all six specified criteria. 1. Low-risk sterile nonhazardous products or diagnostic radiopharmaceutical products from the manufacturers' original containers. Anti-neoplastics shall not be prepared as immediate-use CSPs because they are hazardous drugs. 2. Unless required for the preparation, the compounding procedure is a continuous process not to exceed 1 hour. 3. During preparation, aseptic technique is followed and, if not immediately administered, the finished CSP is under continuous supervision to minimize the potential for contact with nonsterile surfaces, introduction of particulate matter or biological fluids, mix-ups with other CSPs, and direct contact of outside surfaces. 4. Administration begins not later than 1 hour following the start of the preparation of the CSP. 5. Unless immediately and completely administered by the person who prepared it or immediate and complete administration is witnessed by the preparer, the CSP shall bear a label listing patient identification information, the names and amounts of all ingredients, the name or initials of the person who prepared the CSP, and the exact 1-hour BUD and time. 6. If administration has not begun within 1 hour following the start of preparing the CSP, the CSP shall be promptly, properly, and safely discarded. [IMMEDIATE-USE CSPs]	N/A

SINGLE/MULTIPLE DOSE CONTAINER BUD

26. Beyond-use date does not exceed 28 days for multiple-dose containers after initial opening or entry, unless specified otherwise by the manufacturer. [SINGLE-DOSE AND MULTIPLE-DOSE CONTAINERS]	Yes
27. Beyond-use time does not exceed 6 hours for closure sealed single-dose containers in ISO Class 5 or cleaner air after initial opening or entry, unless specified otherwise by the manufacturer. [SINGLE-DOSE AND MULTIPLE-DOSE CONTAINERS]	Yes
28. Beyond-use time does not exceed 1 hour for closure sealed single-dose containers after being opened or entered in worse than ISO Class 5 air. [SINGLE-DOSE AND MULTIPLE-DOSE CONTAINERS]	Yes
29. Single-dose ampules are discarded immediately after use. [SINGLE-DOSE AND MULTIPLE-DOSE CONTAINERS]	Yes

HAZARDOUS DRUGS

30. Hazardous drug buffer room is at least 0.01 inch water column negative pressure with 30 ACPH of HEPA filtered air. [HAZARDOUS DRUGS AS CSPs]	
31. Personnel compounding hazardous drugs wear appropriate personal protective equipment. [HAZARDOUS DRUGS AS CSPs]	
32. Appropriate primary engineering controls (BSCs and CACIs) are used for concurrent personnel protection and exposure of critical sites. [HAZARDOUS DRUGS AS CSPs]	
33. Hazardous drugs are stored separately from other inventory in a manner to prevent contamination and personnel exposure. [HAZARDOUS DRUGS AS CSPs]	

34 .At least 0.01 inch water column negative pressure and 12 air changes per hour in non-cleanrooms in which CACIs are located. FAC: USP Chapter 797 requires that: "When closed-system vial-transfer devices (CSTDs) (i.e., vial-transfer systems that allow no venting or exposure of hazardous substance to the environment) are used, they shall be used within an ISO Class 5 environment of a BSC or CACI. The use of the CSTD is preferred because of their inherent closed system process. In facilities that prepare a low volume of hazardous drugs, the use of two tiers of containment (e.g., CSTD within a BSC or CACI that is located in a non-negative pressure room) is acceptable." For purpose of said provision, a "low volume of hazardous drugs" is defined as less than 40 doses per month. [HAZARDOUS DRUGS AS CSPs]	
35. Hazardous drugs are handled with caution at all times using appropriate chemotherapy gloves during receiving, distribution, stocking, inventorying, preparing for administration, and disposal. Spill kits are available. [HAZARDOUS DRUGS AS CSPs]	
36. Hazardous drugs are prepared in an ISO Class 5 environment with protective engineering controls in place, following aseptic practices specified for the appropriate contamination risk levels. [HAZARDOUS DRUGS AS CSPs]	
37. Access to hazardous drug preparation areas is limited to authorized compounding personnel. [HAZARDOUS DRUGS AS CSPs]	
38. A pressure indicator is installed and differential pressures are monitored and documented daily for hazardous buffer room. [HAZARDOUS DRUGS AS CSPs]	
39. Annual documentation of hazardous drug training of personnel regarding storage, handling, containment techniques and disposal of hazardous drugs is available. [HAZARDOUS DRUGS AS CSPs]	
40. Compounding personnel of reproductive capability have confirmed in writing that they understand the risks of handling hazardous drugs. [HAZARDOUS DRUGS AS CSPs]	
41. Facility maintains appropriate disposal containers for all hazardous waste. [HAZARDOUS DRUGS AS CSPs]	

RADIOPHARMACEUTICALS

42. Facility has appropriate primary engineering controls and radioactivity containment and shielding. Location of primary engineering controls permitted in ISO Class 8 controlled environment. [RADIOPHARMACEUTICALS AS CSPs]	
43. Radiopharmaceuticals prepared as low-risk level CSPs with 12-hour or less BUD are prepared in a segregated compounding area. Segregated compounding area is designated with a line of demarcation. [RADIOPHARMACEUTICALS AS CSPs]	
44. Technetium-99m/Molybdenum-99 generators are eluted in ISO Class 8 conditions. [RADIOPHARMACEUTICALS AS CSPs]	
45. When compounding activities require the manipulation of a patient's blood-derived or other biological material (e.g., radiolabeling a patient's or a donor's white blood cells), the manipulations are clearly separated from routine material-handling procedures and equipment used in CSP preparation activities, and they are controlled by specific standard operating procedures in order to avoid any cross-contamination. [ENVIRONMENTAL QUALITY AND CONTROL : Placement of Primary Engineering Controls Within ISO Class 7 Buffer Areas]	

FACILITY DESIGN AND CERTIFICATION

46. Certification and testing of primary (LAFWs, BSCs, CAIs and CACIs) and secondary engineering controls (buffer and ante areas) have been performed by a qualified individual no less than every six months and whenever the device or room is relocated, altered, or major service to the facility is performed. Corrective action for deficiencies are documented. Certification procedures such as those outlined in the CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2006) are conducted under dynamic conditions. [ENVIRONMENTAL QUALITY AND CONTROL : Environmental Nonviable Particle Testing Program] *Certification testing has been completed by TMI of Cooper City, FL on June 22,2015* *Results of testing indicate that testing was performed under dynamic conditions with Lyophyllizer running*	Yes
47. Facility has pressure gauges or velocity meters to monitor the pressure differential or airflow between the buffer area and ante-area, and the ante-area and the general environment outside the compounding area. The results are reviewed and documented on a log at least daily or by a continuous recording device. The pressures differentials meet or exceed 5 Pa (0.02 inch water column (w.c.)). Alternatively, in facilities where low- and medium-risk level CSPs are prepared, differential airflow is maintained at a minimum velocity of 0.2 meter/second (40 fpm) across a line of demarcation between buffer area and ante-area. [ENVIRONMENTAL QUALITY AND CONTROL : Pressure Differential Monitoring]	Yes
48. Primary engineering controls provide unidirectional (i.e., laminar) HEPA air at a velocity sufficient to prevent airborne particles from contacting critical sites. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
49. Air pattern analysis via smoke studies are conducted at the critical site to demonstrate unidirectional airflow and sweeping action over and away from the product under dynamic conditions. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
50. Clean rooms for nonhazardous and nonradioactive CSPs are supplied with HEPA filtered air that enters from ceilings with return vents low on walls, and that provides not less than 30 air changes per hour. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
51. The primary engineering controls are placed within a buffer area in such a manner as to avoid conditions that could adversely affect their operation. The PEC is placed out of the traffic flow and in a manner to avoid disruption from the HVAC system and room cross drafts. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
52. Primary engineering controls for nonhazardous and nonradioactive CSPs are located in buffer areas, except for CAIs that are proven to maintain ISO Class 5 air when particle counts are sampled 6 to 12 inches upstream of critical site exposure areas during performance of normal inward and outward transfer of materials, and compounding manipulations when such CAIs are located in air quality worse than ISO Class 7. [ENVIRONMENTAL QUALITY AND CONTROL : Placement of Primary Engineering Controls Within ISO Class 7 Buffer Areas]	Yes
53. Adequate recovery time for isolators to achieve ISO Class 5 air quality is allowed after material transfer before and during compounding operations. [ENVIRONMENTAL QUALITY AND CONTROL : Placement of Primary Engineering Controls Within ISO Class 7 Buffer Areas]	N/A
54. All HEPA filters are leak tested after installation and every six months thereafter. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls] *Hepa filter were leak tested on 6/22/15*	Yes
55. Activities and tasks carried out within the buffer area are limited to only those necessary when working within a controlled environment. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	N/A
56. Only the furniture, equipment, supplies, and other material required for the compounding activities to be performed are brought into the buffer room. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
57. Surfaces and essential furniture in buffer rooms or zones and clean rooms are nonporous, smooth, non-shedding, impermeable, cleanable, and resistant to disinfectants. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
58. The surfaces of ceilings, walls, floors, fixtures, shelving, counters, and cabinets in the buffer area are smooth, impervious, free from cracks and crevices, and non-shedding, thereby promoting cleanability, and minimizing spaces in which microorganisms and other contaminants may accumulate. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls] *Plastic sheeting on walls have been removed, however wall are not smooth.*	No

59. Ceiling tiles are caulked around each perimeter and to walls to seal them to the support frame. The exterior lens surface of ceiling lighting fixtures is smooth, mounted flush, and sealed. All other penetrations through the ceiling or walls are sealed. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls] *Ceiling tiles are now caulked*	Yes
60. The buffer area does not contain sources of water (sinks) or floor drains. Work surfaces are constructed of smooth, impervious materials, such as stainless steel or molded plastic, so that they are easily cleaned and disinfected. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
61. Carts are made of stainless steel wire, or nonporous plastic, or sheet metal construction with good quality, cleanable casters. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
62. Storage shelving, counters, and cabinets in the buffer area are smooth, impervious, free from cracks and crevices, non-shedding, cleanable, and disinfectable. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
63. When devices (e.g., computers and printers) and objects (e.g., carts and cabinets) are placed in buffer areas, air quality is verified by particle counts on certification. [ENVIRONMENTAL QUALITY AND CONTROL : ISO Class 5 Air Sources, Buffer Areas, and Ante-Areas] *Particle counts were taken with lyophllizer running*	Yes

QUALITY AND CONTROL

64. An appropriate environmental sampling plan has been developed for airborne viable particles based on a risk assessment of compounding activities performed. Volumetric air sampling is conducted every six months and sites include locations within each ISO Class 5 environment and in the ISO Class 7 and 8 areas, and the areas at greatest risk of contamination (e.g., work areas near the ISO Class 5 environment, counters near doors, pass-through boxes). The plan includes sample locations, method of collection, frequency of sampling, volume of air sampled, and time of day as related to activity in the compounding area and action levels. [ENVIRONMENTAL QUALITY AND CONTROL : Environmental Viable Airborne Particle Testing Program—Sampling Plan]	Yes
65. Surface sampling is accomplished in all ISO classified areas on a periodic basis using TSA contact plates with lecithin and polysorbate 80 and/or swabs and is done at the conclusion of compounding. [ENVIRONMENTAL QUALITY AND CONTROL : Surface Cleaning and Disinfection Sampling and Assessment]	Yes
66. Evaluation of airborne microorganisms using volumetric collection methods in the controlled air environments is performed by properly trained individuals for all compounding risk levels. [ENVIRONMENTAL QUALITY AND CONTROL : Viable Air Sampling] *Adequate documentation of personnel performing volumetric air sampling being properly training was not available at the time of inspection. Facility will provide prior to issuance of a permit*	No
67. Volumetric air sampling using malt extract agar (MEA) or some other media that supports the growth of fungi is used in high-risk level compounding environments. [ENVIRONMENTAL QUALITY AND CONTROL : Growth Media]	Yes
68. For low-risk level CSPs with 12-hour or less BUD, air sampling is performed at locations inside the ISO Class 5 environment and other areas that are in close proximity to the ISO class 5 environment. [ENVIRONMENTAL QUALITY AND CONTROL : Viable Air Sampling]	N/A
69. The number of discrete colonies of microorganisms is counted and reported as colony-forming units (cfu) and documented on an environmental monitoring form. Counts from air monitoring are transformed into cfu/cubic meter of air and evaluated for adverse trends. [ENVIRONMENTAL QUALITY AND CONTROL : Incubation Period]	Yes
70. Sampling data is collected and reviewed on a periodic basis as a means of evaluating the overall state of control of the compounding environment. [ENVIRONMENTAL QUALITY AND CONTROL : Action Levels, Documentation and Data Evaluation]	Yes
71. Competent microbiology personnel are consulted if an environmental sampling consistently shows elevated levels of microbial growth. If any mold, yeast, coagulase positive staphylococcus, or gram negative rods are detected immediate remediation and investigation into the cause and source was conducted. [ENVIRONMENTAL QUALITY AND CONTROL : Action Levels, Documentation and Data Evaluation]	N/A
72. Written procedures detail cleaning and disinfecting the sterile compounding areas including cleansers, disinfectants, and non-shedding wipe and mop materials. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
73. Surfaces in the LAFWs, BSCs, CAIs, and CACIs are cleaned and disinfected frequently, including at the beginning of each work shift, before each batch preparation is started, every 30 minutes during continuous compounding periods of individual CSPs, when there are spills, and when surface contamination is known or suspected from procedural breaches. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
74. A written procedure is in place for cleaning and disinfecting the Direct Compounding Areas. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
75. Cleaning and disinfecting occurs before compounding is performed. Items are removed from all areas to be cleaned, and surfaces are cleaned by removing loose material and residue from spills, e.g., water-soluble solid residues are removed with Sterile Water and low-shedding wipes. This shall be followed by wiping with a residue-free disinfecting agent, such as sterile 70% IPA, which is allowed to dry before compounding begins. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
76. Work surfaces in ISO Class 7 and 8 areas and segregated compounding areas are cleaned at least daily. IPA (70% isopropyl alcohol) remains on surfaces to be disinfected for at least 30 seconds before such surfaces are used to prepare CSPs. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
77. Floors in ISO Class 7 and 8 areas are mopped daily by trained personnel at a time when no aseptic operations are in progress using approved agents and procedures described in written SOP's. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
78. Shelving, walls, and ceilings in ante-areas are cleaned and disinfected at least monthly. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
79. Cleaning and disinfecting agents and methods of application are in accordance with written SOPs and followed by custodial and/or compounding personnel. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
80. Cleaning materials, such as wipes, sponges, and mops, are non-shedding, preferably composed of synthetic micro fibers, and dedicated to use in the buffer area, ante-area, and segregated compounding areas and are not removed from these areas except for disposal. If cleaning materials are reused (e.g., mops), there are procedures based on manufacturer recommendations that ensure that the effectiveness of the cleaning device is maintained and repeated use does not add to the bioburden of the area being cleaned. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
81. Supplies and equipment removed from shipping cartons are wiped with a suitable disinfecting agent (e.g., sterile 70% IPA). [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
82. Disinfectant sprayed or wiped on a surface to be disinfected is allowed to dry, and during this time the item is not be used for compounding purposes. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	N/A
83. Sterile 70% IPA pads are used to disinfect the sterile entry points of packages and devices. Wetted gauze pads or other particle-generating material are not appropriate. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes

PERSONNEL CLEANSING, GARBING & COMPETENCY EVALUATION

84. Personnel preparing CSP's are free from rashes, sunburn, weeping sores, conjunctivitis, and active respiratory infections. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	Yes
85. Compounding personnel remove personal outer garments; cosmetics; artificial nails; hand, wrist, and body jewelry that can interfere with the fit of gowns and gloves; and visible body piercing above the neck. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	Yes
86. Facility has adequate supplies to meet PPE requirements of USP<797>. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	Yes
87. Garbing and hand hygiene are accomplished in the ante-area in order of dirtiest to cleanest: shoes or shoe covers, head and facial hair covers, face mask, fingernail cleansing, hand and forearm washing and drying; non-shedding gown. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing] *Nail pics are present and described in SOP*	Yes
88. Sterile gloves are donned in the buffer room after hand cleansing with an alcohol-based product with persistent activity and hands are allowed to dry. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing] *Triseptin is used and documentation indicated persistent activity*	Yes
89. Gloves are routinely disinfected with sterile 70% IPA after contacting nonsterile objects. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing] *SOP describes this practice*	Yes
90. Personnel repeat garbing and hand hygiene after they are exposed to direct contact contamination or worse than ISO Class 8 air. Gowns may be hung in the anteroom and reused during the same workshift. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	Yes
91. Personnel garbing requirements are followed for CAIs unless manufacturer provides written documentation based on validated testing that any components of PPE are not required to maintain sterility of CSPs. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	N/A
92. Documentation indicates compounding personnel have successfully completed didactic training, passed written competency assessments, undergone skill assessment using observational audit tools, and media-fill testing before any compounding personnel begin to prepare CSPs. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures]	Yes
93. Compounding personnel who fail written tests, observational audits, or whose media-fill test vials have one or more units showing visible microbial contamination, are reinstructed and re-evaluated by expert compounding personnel to ensure correction of all aseptic work practice deficiencies. Compounding personnel pass all evaluations prior to resuming compounding of sterile preparations. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures]	N/A
94. Corrective action is documented for compounding personnel who fail written tests or media-fill test. [PERSONNEL TRAINING AND EVALUATION IN ASEPTIC MANIPULATIONS SKILLS]	N/A
95. Other cleaning personnel performing cleaning and disinfecting procedures (e.g. environmental) are thoroughly trained in proper hand hygiene, and garbing, cleaning, and disinfection procedures by a qualified aseptic compounding expert. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures]	N/A
96. Compounding personnel and other personnel responsible for cleaning routinely undergo performance evaluation of proper hand hygiene, garbing, and all applicable cleaning and disinfecting procedures conducted by a qualified aseptic compounding expert. Visual observation of hand hygiene, garbing and cleaning is documented and maintained to provide a permanent record and long-term assessment of personnel competency. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures]	Yes
97. Compounding personnel are visually observed annually or semiannually (high risk) during the process of performing hand hygiene, garbing procedures and aseptic technique. The visual observation is documented on a form for Assessing Hand Hygiene, Garbing and Aseptic Technique and maintained to provide a permanent record. [ENVIRONMENTAL QUALITY AND CONTROL : Garbing and Gloving Competency Evaluation]	Yes
98. Immediately after the compounder completes the hand hygiene and garbing procedure, the evaluator collects a gloved fingertip and thumb sample from both hands of the compounder onto appropriate agar plates. The plates are incubated at 30-35° for 2–3 days. All compounding personnel have successfully completed an initial competency evaluation and gloved fingertip/thumb sampling procedure (0 cfu) no less than three times before initially being allowed to compound CSPs for human use. [ENVIRONMENTAL QUALITY AND CONTROL : Gloved Fingertip Sampling]	Yes
99. Re-evaluation of glove fingertip testing onto appropriate agar plates (Trypticase soy agar (TSA) with lecithin and polysorbate 80) for all compounding personnel occurs at least annually for low- and medium-risk level CSPs and semiannually for high-risk level CSPs before being allowed to continue compounding CSPs. Gloves shall not be disinfected with sterile 70% IPA prior to testing. The cfu action level is based on the total number of cfu on both gloves and not per hand. [ENVIRONMENTAL QUALITY AND CONTROL : Gloved Fingertip Sampling]	N/A

VERIFICATION

100. Facility has written procedures to verify correct identity, quality, amounts, and purities of ingredients used in CSPs. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Identity and Strength Verification of Ingredients]	Yes
101. Labels of CSPs contain name and address of pharmacy, correct names and amounts or concentrations of ingredients, total volumes, beyond-use dates, storage conditions, and route(s) of administration. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Identity and Strength Verification of Ingredients]	N/A
102. Facility has documentation that procedures have been followed to ensure sterility, purity, correct identities and amounts of ingredients, and stability. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Inspection of Solution Dosage Forms and Review of Compounding Procedures]	N/A
103. CSP's are visually inspected for abnormal particulate matter and color, and intact containers and seals. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Inspection of Solution Dosage Forms and Review of Compounding Procedures]	N/A
104. Beyond Use Dates are assigned using direct stability-indicating assays or authoritative literature that supports the assigned BUD. [STORAGE AND BEYOND-USE DATING : Determining Beyond-Use Dates]	N/A
105. Storage time of assembled bag and vial systems are according to the manufacturer recommendations. (eg Minibag plus, Addvantage, Add-ease) [STORAGE AND BEYOND-USE DATING : Proprietary Bag and Vial Systems]	N/A
106. Facility has written procedures for proper packaging, storage, and transportation conditions to maintain sterility, quality, purity, and strength of CSPs. [MAINTAINING STERILITY, PURITY, AND STABILITY OF DISPENSED AND DISTRIBUTED CSPs :]	Yes
107. Policies address packaging to maintain physical integrity, sterility, stability, and purity of CSPs. [MAINTAINING STERILITY, PURITY, AND STABILITY OF DISPENSED AND DISTRIBUTED CSPs : Packaging and Transporting CSPs]	Yes

DISPENSING/DISTRIBUTION

108. Modes of transport are used that maintain appropriate temperatures and prevent damage to CSPs. [MAINTAINING STERILITY, PURITY, AND STABILITY OF DISPENSED AND DISTRIBUTED CSPs : Packaging and Transporting CSPs]	N/A
109. Facility provides a multiple component formal training program to ensure patients and caregivers understand the proper storage, handling, use, and disposal of CSPs. [PATIENT OR CAREGIVER TRAINING]	Yes

110. Written standard procedures describe means for patients to ask questions and report concerns and adverse events with CSPs, and for compounding pharmacists to correct and prevent future problems. [PATIENT MONITORING AND ADVERSE EVENTS REPORTING]	Yes

USP <71> STERILITY TESTING

111. Outsourced sterility testing results indicate that it is compliant with USP<71>. A method not described in the USP may be used if validation demonstrates that the alternative is at least as effective and reliable. [STERILITY TEST USP<71>]	N/A
112. Outsourced: The number of articles tested are appropriate according to USP<71>. [STERILITY TEST USP<71> : Number of Articles to Be Tested]	N/A
113. Outsourced: The volume/quantity tested is according to USP<71>. [STERILITY TEST USP<71> : Number of Articles to Be Tested]	N/A
114. On site: Membrane filtration is used whenever the nature of the product permits. Filters are rinsed according to USP<71>. Sterility testing results indicate that it is compliant with USP<71>. A method not described in the USP may be used if validation demonstrates that the alternative is at least as effective and reliable. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Sterility Testing] *Current policy states that sterility testing will be conducted in accordance with USP 71 standards*	Yes
115. On site: Direct inoculation is done only when membrane filtration cannot be carried out. Volume to be inoculated does not exceed 10% of the culture media volume. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Sterility Testing] *Current policy states that direct inoculation will only be carried out in the event that membrane filtration cannot be conducted*	Yes
116. On site: The number of articles tested are appropriate according to USP<71>. [STERILITY TEST USP<71> : Number of Articles to Be Tested]	Yes
117. On site: The volume/quantity tested is according to USP<71>. [STERILITY TEST USP<71> : Number of Articles to Be Tested]	Yes
118. On site: A growth promotion test has been done on the media with the 5 specified organisms (not more than 100 CFU) according to USP<71>. [STERILITY TEST USP<71> : Growth Promotion Test of Aerobes, Anaerobes, and Fungi]	Yes
119. On site: A USP<71> method suitability test has been done with appropriate inoculum, additives and rinses. [STERILITY TEST USP<71> : Method Suitability Test]	Yes
120. On site: TSB or SCD is incubated at 20-25 C for 14 days (2 incubators present). [STERILITY TEST USP<71> : Culture Media and Incubation Temperatures]	Yes
121. On site: FTM is incubated at 30-35 C for 14 days (2 incubators present). [STERILITY TEST USP<71> : Culture Media and Incubation Temperatures] *New SOP calls for the use of FTM*	Yes
122. On site: Sterility testing is documented including lot numbers and expiration dates of media. [FINISHED PREPARATION RELEASE CHECKS AND TESTS]	Yes
123. Sterility testing reports are reviewed and appropriate actions taken and documented. [FINISHED PREPARATION RELEASE CHECKS AND TESTS]	N/A

MISCELLANEOUS

124. Facility engaged in office use sterile compounding for human use is registered with FDA as an outsourcing facility. [FAC 64B16-27.700 (3)(g]	Yes
125. Compounding records are properly maintained. [FAC 64B16-28.140(4)]	N/A

Remarks:

A board of pharmacy requested inspection to determine corrections of deficiencies from the previous 5/27/15 inspection was conducted in the presence of RPH Jeff Goldrich and RPT Umarani Rajalingham.
It should be noted that passing of this inspection does not set precedent for passing future inspections as NO sterile compounding has been conducted at this time. Subsequent inspections will focus on actual sterile compounding and documentation provided.

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge. I have received a copy of the Licensee Bill of Rights.

Investigator/Sr. Pharmacist Signature:

DIFIORE, ROBERT

Date:9/4/2015

Representative:

Jeffrey Goldrich RPh

Date:9/4/2015

STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES
INV797-Sterile Compounding

File # 21375
Insp # 140825

NAME	PERMIT NUMBER	DATE OF INSPECTION
HYBRID PHARMA, LLC	29374	06/14/2017
DOING BUSINESS AS		
STREET ADDRESS 1015 W NEWPORT CTR DR #106-A	**TELEPHONE #**	**EXT**
CITY DEERFIELD BEACH	**COUNTY** BROWARD	**STATE/ZIP** FL/33442

Additional Information

Business Operation Hours

M-T-W-TH-F Y	Weekly Hours 10am-6pm
Monday Y	Monday Hours
Tuesday N	Tuesday Hours
Wednesday N	Wednesday Hours
Thursday N	Thursday Hours
Friday N	Friday Hours
Saturday N	Saturday Hours
Sunday N	Sunday Hours

Registered Pharmacist / Intern / Tech

License # PS27855	Licensee Name Jeff Goldrich
License Type Registered Pharmacists	
License # RPT45465	Licensee Name Umarani Rajalingham
License Type Pharmacy Tech	

ACS Manager

Optional Information

Basic License Data - PSD

DEA Reg # FH4258706	

INV797 - Sterile Compounding

LOW RISK

1. Low risk CSP's are properly identified: Aseptic manipulations within an ISO Class 5 environment using three or fewer sterile products and no more than two entries into any container. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Low-Risk Level CSPs]	
2. Low Risk CSP's, in absence of passing sterility test, stored not more than 48 hours at controlled room temperature, 14 days at cold temperature, or 45 days in solid frozen state at -25° to -10° or colder. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Low-Risk Level CSPs]	
3. Low Risk CSP's with 12 hour BUD are properly identified and comply with all four specific criteria. 1. PEC in Segregated Compounding area 2. Away from windows, doors , high traffic areas 3. Hygiene & garbing required, sinks not adjacent to PEC. 4. Cleaning & Disinfecting, Personnel training, Competency evaluation, Garbing, Aseptic work practices, Viable and non-viable environmental sampling apply. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Low-Risk Level CSPs]	

MEDIUM RISK

4. Medium Risk CSP's are properly identified: Aseptic manipulations within an ISO Class 5 environment using prolonged and complex mixing and transfer, more than three sterile products and entries into any container, and pooling ingredients from multiple sterile products to prepare multiple CSPs. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Medium-Risk Level CSPs]	
5. Medium Risk CSP's, In absence of passing sterility test, stored not more than 30 hours at controlled room temperature, 9 days at cold temperature, or 45 days in solid frozen state at -25° to -10° or colder. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Medium-Risk Level CSPs]	

HIGH RISK

6. Presterilization procedures for high-risk level CSPs, such as weighing and mixing, are completed in no worse than an ISO Class 8 environment. [ENVIRONMENTAL QUALITY AND CONTROL : Placement of Primary Engineering Controls Within ISO Class 7 Buffer Areas]	N/A
7. High Risk CSP's are properly identified: Confirmed presence of nonsterile ingredients and devices, or confirmed or suspected exposure of sterile ingredients for more than one hour to air quality inferior to ISO Class 5 before final sterilization. [CSP MICROBIAL CONTAMINATION RISK LEVELS : High-Risk Level CSPs]	N/A
8. High Risk CSP's, in absence of passing sterility test are not stored more than 24 hours at controlled room temperature, 3 days at cold temperature, or 45 days in solid frozen state at -25° to -10° or colder. [CSP MICROBIAL CONTAMINATION RISK LEVELS : High-Risk Level CSPs]	Yes
9. A 0.2-µm certified sterilizing membrane filter is used that is chemically and physically compatible with the CSP. Filtration is completed rapidly without filter replacement. Sterilization method is verified to achieve sterility for the quantity and type of containers. [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Sterilization of High-Risk Level CSPs by Filtration]	N/A
10. Sterilization method used has documentation that acceptable strength and purity of ingredients and integrity of containers is maintained. [CSP MICROBIAL CONTAMINATION RISK LEVELS : High-Risk Level CSPs] *There was no documentation that the sterilizing filter your using is pharmaceutical grade ; THIS IS YOUR SECOND ADVISORY.*	No
11. The manufacturer recommended filter integrity (e.g., bubble point) test is performed and documented for all sterilizing filters after filtering CSPs. [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Sterilization of High-Risk Level CSPs by Filtration] *FIRM IS NOT DOCUMENTING THE ACTUAL BUBBLE POINT ; COMPOUNDING RECORDS SIMPLY STATE "PASS >50PSI . The PDM demonstrated a filter integrity test on 6/14/2017 on a filter that was used to compound Ascorbic acid lot 170512A. The filter was not rinsed. The filter was hooked up to a source of nitrogen and the pressure increased until a small amount of foam came out of the filter port outlet. Tubing was not attached to the outlet therefore a steady stream of bubbles could not be observed coming out of the filter. The PDM indicated that this filter passed the filter integrity test and documented such on the compounding record.*	No
12. Autoclave cycle has been verified using appropriate biological indicators. Solutions are passed through a 1.2-µm or smaller filter into final containers to remove particulates before sterilization. [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Sterilization of High-Risk Level CSPs by Steam] *Auto clave documents show SCP's methylcobalamin and MIC are being autoclaved for 15 to 25 minutes.*	No
13. Dry heat ovens used for sterilization have filtered forced air. Only those items that will be damaged by steam are sterilized by dry heat. [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Sterilization of High-Risk Level CSPs by Dry Heat]	Yes
14. The description of dry heat sterilization conditions and duration for specific CSPs is included in written documentation in the compounding facility. The effectiveness of dry heat sterilization is verified using appropriate biological indicators and other confirmation. [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Sterilization of High-Risk Level CSPs by Dry Heat]	N/A
15. Dry heat depyrogenation is used to render glassware or containers, such as vials free from pyrogens as well as viable microbes. The description of the dry heat depyrogenation cycle and duration for specific load items is included in written documentation in the compounding facility. The effectiveness of the dry heat depyrogenation cycle is verified using endotoxin challenge vials (ECVs). [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Depyrogenation by Dry Heat] *non sterile glassware is not being wrapped properly with foil SOME GLASSWARE HAVE EXPOSED SURFACE AFTER DEPYROGENATION; , they are rinsing they're glassware with sterile water; there is no sterile water where they are rinsing ; two gallons of distilled water are where the sink is located and glassware get rinsed.*	No
16. Sterility testing is completed for all High-risk level CSPs prepared in batches of more than 25 identical containers, or exposed longer than 12 hours at 2° to 8°, and 6 hours at warmer than 8° before being sterilized. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Sterility Testing]	Yes

USP <71> STERILITY TESTING (Outsourced)

17. Outsourced sterility testing results indicate that it is compliant with USP<71>. A method not described in the USP may be used if validation demonstrates that the alternative is at least as effective and reliable. [STERILITY TEST USP<71>]	
18. Outsourced: The number of articles tested are appropriate according to USP<71>. [STERILITY TEST USP<71> : Number of Articles to Be Tested]	
19. Outsourced: The volume/quantity tested is according to USP<71>. [STERILITY TEST USP<71> : Number of Articles to Be Tested]	
20. Outsourced: A USP<71> method suitability test has been done with appropriate inoculum, additives and rinses. [STERILITY TEST USP<71> : Method Suitability Test]	
21. Outsourced: Sterility testing reports are reviewed and appropriate actions taken and documented. [FINISHED PREPARATION RELEASE CHECKS AND TESTS]	

USP <71> STERILITY TESTING

22. On site: Membrane filtration is used if appropriate. (The technique of membrane filtration is used whenever the nature of the product permits; that is, for filterable aqueous preparations, for alcoholic or oily preparations, and for preparations miscible with, or soluble in, aqueous or oily solvents, provided these solvents do not have an antimicrobial effect in the conditions of the test.) Filters are rinsed according to USP<71>. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Sterility Testing]	No
23. On site: Direct inoculation is done only when membrane filtration cannot be carried out. Volume to be inoculated does not exceed 10% of the culture media volume. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Sterility Testing] *All sterility testing is done through membrane filtration.*	N/A
24. On site: The number of articles tested are appropriate according to USP<71>. [STERILITY TEST USP<71> : Number of Articles to Be Tested] *Batch of HCG lot#170421F with a BUD of 6 months batch size 150 vials , a total of 8 vials were inhouse tested for sterility A batch of Ascorbic acid 3000 ml was compounded and filled into 50 ml vials. The theoretical batch yield would have been 60 vials. 60 vials remain in the refrigerator 3 vials are documented as being sterility tested, 2 vials with TSB and 1 vial with FTM. A minimum of 4 vials are required for a USP 71 sterility test. YOU ARE NOT FOLLOWING USP <71> MINIMUM # OF ITEMS REQUIREMENT.*	No
25. On site: The volume/quantity tested is according to USP<71>. [STERILITY TEST USP<71> : Number of Articles to Be Tested] *Volume tested is not indicated on the sterility test reports.*	No
26. On site: A growth promotion test has been done on the media with the 5 specified organisms (not more than 100 CFU) according to USP<71>. [STERILITY TEST USP<71> : Growth Promotion Test of Aerobes, Anaerobes, and Fungi] *The firm obtains the results of the growth promotion test from the manufacturer of the TSB and FTM.*	Yes
27. On site: A USP<71> method suitability test has been done with appropriate inoculum, additives and rinses. [STERILITY TEST USP<71> : Method Suitability Test] *Method suitability is outsourced to WuVi AppTec in Marietta GA. Sterility testing is done in house. There is no documentation to demonstrate that the procedure for method suitability matches the procedure for sterility testing such as rinse solutions.*	No
28. On site: TSB or SCD is incubated at 20-25 C for 14 days (2 incubators present). [STERILITY TEST USP<71> : Culture Media and Incubation Temperatures]	Yes
29. On site: FTM is incubated at 30-35 C for 14 days (2 incubators present). [STERILITY TEST USP<71> : Culture Media and Incubation Temperatures]	Yes

30. On site: Sterility testing is documented including lot numbers and expiration dates of media. [FINISHED PREPARATION RELEASE CHECKS AND TESTS]	Yes
31. On site: Sterility testing reports are reviewed and appropriate actions taken and documented. [FINISHED PREPARATION RELEASE CHECKS AND TESTS]	N/A

ENDOTOXIN TESTING

32. Endotoxin testing is conducted for High-risk level CSP's that are prepared in batches of more than 25 identical containers, or exposed longer than 12 hours at 2° to 8°, and 6 hours at warmer than 8°, before being sterilized or in multidose containers for administration to multiple patients. (excluding those for inhalation and ophthalmic administration) [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Bacterial Endotoxin (Pyrogen) Testing]	Yes
33. Endotoxin testing process indicates that it is compliant with USP<85>. [BACTERIAL ENDOTOXINS TEST USP<85>]	Yes
34. High Risk CSP's are within allowable limits for bacterial endotoxins. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Bacterial Endotoxin (Pyrogen) Testing]	N/A

IMMEDIATE USE COMPOUNDING

35. Immediate-use compounding complies with all six specified criteria. 1. Low-risk sterile nonhazardous products or diagnostic radiopharmaceutical products from the manufacturers' original containers. Anti-neoplastics shall not be prepared as immediate-use CSPs because they are hazardous drugs. 2. Unless required for the preparation, the compounding procedure is a continuous process not to exceed 1 hour. 3. During preparation, aseptic technique is followed and, if not immediately administered, the finished CSP is under continuous supervision to minimize the potential for contact with nonsterile surfaces, introduction of particulate matter or biological fluids, mix-ups with other CSPs, and direct contact of outside surfaces. 4. Administration begins not later than 1 hour following the start of the preparation of the CSP. 5. Unless immediately and completely administered by the person who prepared it or immediate and complete administration is witnessed by the preparer, the CSP shall bear a label listing patient identification information, the names and amounts of all ingredients, the name or initials of the person who prepared the CSP, and the exact 1-hour BUD and time. 6. If administration has not begun within 1 hour following the start of preparing the CSP, the CSP shall be promptly, properly, and safely discarded. [IMMEDIATE-USE CSPs]	N/A

SINGLE/MULTIPLE DOSE CONTAINER BUD

36. Beyond-use date does not exceed 28 days for multiple-dose containers after initial opening or entry, unless specified otherwise by the manufacturer. [SINGLE-DOSE AND MULTIPLE-DOSE CONTAINERS]	Yes
37. Beyond-use time does not exceed 6 hours for closure sealed single-dose containers in ISO Class 5 or cleaner air after initial opening or entry, unless specified otherwise by the manufacturer. [SINGLE-DOSE AND MULTIPLE-DOSE CONTAINERS]	Yes
38. Beyond-use time does not exceed 1 hour for closure sealed single-dose containers after being opened or entered in worse than ISO Class 5 air. [SINGLE-DOSE AND MULTIPLE-DOSE CONTAINERS]	N/A
39. Single-dose ampules are discarded immediately after use. [SINGLE-DOSE AND MULTIPLE-DOSE CONTAINERS]	N/A

HAZARDOUS DRUGS

40. A pressure indicator is installed and differential pressures are monitored and documented daily for hazardous buffer room. [HAZARDOUS DRUGS AS CSPs] *Pressures are not being documented correctly. Documentation does not designate which room pressures are assigned.*	No
41. Hazardous drug buffer room is at least 0.01 inch water column negative pressure with 30 ACPH of HEPA filtered air. [HAZARDOUS DRUGS AS CSPs]	N/A
42. At least 0.01 inch water column negative pressure and 12 air changes per hour in non-cleanrooms in which CACIs are located. FAC: USP Chapter 797 requires that: "When closed-system vial-transfer devices (CSTDs) (i.e., vial-transfer systems that allow no venting or exposure of hazardous substance to the environment) are used, they shall be used within an ISO Class 5 environment of a BSC or CACI. The use of the CSTD is preferred because of their inherent closed system process. In facilities that prepare a low volume of hazardous drugs, the use of two tiers of containment (e.g., CSTD within a BSC or CACI that is located in a non-negative pressure room) is acceptable." For purpose of said provision, a "low volume of hazardous drugs" is defined as less than 40 doses per month. [HAZARDOUS DRUGS AS CSPs]	N/A
43. Personnel compounding hazardous drugs wear appropriate personal protective equipment. [HAZARDOUS DRUGS AS CSPs] *No sterile chemo gloves*	No
44. Hazardous drugs are handled with caution at all times using appropriate chemotherapy gloves during receiving, distribution, stocking, inventorying, preparing for administration, and disposal. Spill kits are available. [HAZARDOUS DRUGS AS CSPs] *No appropriate gloves for handling hazardous drugs.*	No
45. Hazardous drugs are prepared in an ISO Class 5 environment (BSC or CACI) with protective engineering controls in place, following aseptic practices specified for the appropriate contamination risk levels. [HAZARDOUS DRUGS AS CSPs]	Yes
46. Hazardous drugs are stored separately from other inventory in a manner to prevent contamination and personnel exposure. [HAZARDOUS DRUGS AS CSPs]	Yes
47. Access to hazardous drug preparation areas is limited to authorized compounding personnel. [HAZARDOUS DRUGS AS CSPs]	Yes
48. Annual documentation of hazardous drug training of personnel regarding storage, handling, containment techniques and disposal of hazardous drugs is available. [HAZARDOUS DRUGS AS CSPs]	N/A
49. Compounding personnel of reproductive capability have confirmed in writing that they understand the risks of handling hazardous drugs. [HAZARDOUS DRUGS AS CSPs]	N/A
50. Facility maintains appropriate disposal containers for all hazardous waste. [HAZARDOUS DRUGS AS CSPs]	N/A

FACILITY DESIGN AND CERTIFICATION

51. Certification and testing of primary (LAFWs, BSCs, CAIs and CACIs) and secondary engineering controls (buffer and ante areas) have been performed by a qualified individual no less than every six months and whenever the device or room is relocated, altered, or major service to the facility is performed. Corrective action for deficiencies are documented. Certification procedures such as those outlined in the CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2006) are conducted under dynamic conditions. [ENVIRONMENTAL QUALITY AND CONTROL : Environmental Nonviable Particle Testing Program] *TMI (technical maintenance Inc,) Ft. Lauderdale 1-10-17 certified ISO 7 prep room, ante room, IV room and HD room. LAFH and BSC both ISO 5. Certification of the ISO 5 PEC is not documented as being done under dynamic conditions.*	No

52. Primary engineering controls provide unidirectional (i.e., laminar) HEPA filtered air. Air pattern analysis via smoke studies are conducted at the critical site to demonstrate unidirectional airflow and sweeping action over and away from the product under dynamic conditions.[ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls] *Smoke studies not documented on the certification report for either PEC; FIRM HAS A LYOPHYLIZER IN THE POSITIVE PRESSURE CLEAN ROOM AND TRANSFERS COMPOUNDED HCG PARTIALLY STOPPERED VIALS THROUGH ISO 7 ZONES THAT DO NOT HAVE UNIDIRECTIONAL AIRFLOW.*	No
53. The primary engineering controls are placed within a buffer area in such a manner as to avoid conditions that could adversely affect their operation. The PEC is placed out of the traffic flow and in a manner to avoid disruption from the HVAC system and room cross drafts. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
54. All HEPA filters are leak tested after installation and every six months thereafter. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes

ISOLATORS

55. CAIs are proven to maintain ISO Class 5 air when particle counts are sampled 6 to 12 inches upstream of critical site exposure areas during performance of normal inward and outward transfer of materials, and compounding manipulations when such CAIs are located in air quality worse than ISO Class 7. [ENVIRONMENTAL QUALITY AND CONTROL : Placement of Primary Engineering Controls Within ISO Class 7 Buffer Areas]	
56. Adequate recovery time for isolators to achieve ISO Class 5 air quality is allowed after material transfer before and during compounding operations. [ENVIRONMENTAL QUALITY AND CONTROL : Placement of Primary Engineering Controls Within ISO Class 7 Buffer Areas]	
57. Personnel garbing requirements are followed for CAIs unless manufacturer provides written documentation based on validated testing that any components of PPE are not required to maintain sterility of CSPs. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	

FACILITY DESIGN AND CERTIFICATION (Secondary Engineering Controls)

58. Facility has pressure gauges or velocity meters to monitor the pressure differential or airflow between the buffer area and ante-area, and the ante-area and the general environment outside the compounding area. The results are reviewed and documented on a log at least daily or by a continuous recording device. The pressures differentials meet or exceed 5 Pa (0.02 inch water column (w.c.)). Alternatively, in facilities where low- and medium-risk level CSPs are prepared, differential airflow is maintained at a minimum velocity of 0.2 meter/second (40 fpm) across a line of demarcation between buffer area and ante-area. [ENVIRONMENTAL QUALITY AND CONTROL : Pressure Differential Monitoring] *See #40*	No
59. Clean rooms for nonhazardous and nonradioactive CSPs are supplied with HEPA filtered air that enters from ceilings with return vents low on walls, and that provides not less than 30 air changes per hour or qualifies for exception in 64B16-27.797(4)(c). [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
60. Activities and tasks carried out within the buffer area are limited to only those necessary when working within a controlled environment. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
61. Only the furniture, equipment, supplies, and other material required for the compounding activities to be performed are brought into the buffer room. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
62. Surfaces and essential furniture in buffer rooms or zones and clean rooms are nonporous, smooth, non-shedding, impermeable, cleanable, and resistant to disinfectants. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
63. The surfaces of ceilings, walls, floors, fixtures, shelving, counters, and cabinets in the buffer area are smooth, impervious, free from cracks and crevices, and non-shedding, thereby promoting cleanability, and minimizing spaces in which microorganisms and other contaminants may accumulate. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls] *A beam structure that surrounds the positive pressure clean room has exposed metal bolts protruding outward; walls inside both clean rooms are not smooth and are constructed of plastic with ridges throughout; floor in ante room is tile separated with approximately quarter inch grouting.*	No
64. Ceiling tiles are caulked around each perimeter and to walls to seal them to the support frame. The exterior lens surface of ceiling lighting fixtures is smooth, mounted flush, and sealed. All other penetrations through the ceiling or walls are sealed. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls] *Ceiling tiles are not sealed. Inspector observed ceiling lens light fixture in ante room lift when the door to positive pressure clean room was opened.*	No
65. The buffer area does not contain sources of water (sinks) or floor drains. Work surfaces are constructed of smooth, impervious materials, such as stainless steel or molded plastic, so that they are easily cleaned and disinfected. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
66. Storage shelving, counters, cabinets and carts/casters in the buffer area are smooth, impervious, free from cracks and crevices, non-shedding, non-porous, cleanable, and disinfectable. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
67. When devices (e.g., computers and printers) and objects (e.g., carts and cabinets) are placed in buffer areas, air quality is verified by particle counts on certification. [ENVIRONMENTAL QUALITY AND CONTROL : ISO Class 5 Air Sources, Buffer Areas, and Ante-Areas]	Yes

QUALITY AND CONTROL

68. An appropriate environmental sampling plan has been developed for airborne viable particles based on a risk assessment of compounding activities performed. Volumetric air sampling is conducted every six months and sites include locations within each ISO Class 5 environment and in the ISO Class 7 and 8 areas, and the areas at greatest risk of contamination (e.g., work areas near the ISO Class 5 environment, counters near doors, pass-through boxes). The plan includes sample locations, method of collection, frequency of sampling, volume of air sampled, and time of day as related to activity in the compounding area and action levels. [ENVIRONMENTAL QUALITY AND CONTROL : Environmental Viable Airborne Particle Testing Program—Sampling Plan] *Action levels established by firm for ISO 7 surface sample exceed USP limits*	No
69. Evaluation of airborne microorganisms using volumetric collection methods in the controlled air environments is performed by properly trained individuals for all compounding risk levels. [ENVIRONMENTAL QUALITY AND CONTROL : Viable Air Sampling]	Yes
70. Volumetric air sampling using malt extract agar (MEA) or some other media that supports the growth of fungi is used in high-risk level compounding environments. [ENVIRONMENTAL QUALITY AND CONTROL : Growth Media]	Yes
71. For low-risk level CSPs with 12-hour or less BUD, air sampling is performed at locations inside the ISO Class 5 environment and other areas that are in close proximity to the ISO class 5 environment. [ENVIRONMENTAL QUALITY AND CONTROL : Viable Air Sampling]	N/A
72. The number of discrete colonies of microorganisms is counted and reported as colony-forming units (cfu) and documented on an environmental monitoring form. Counts from air monitoring are transformed into cfu/cubic meter of air and evaluated for adverse trends. [ENVIRONMENTAL QUALITY AND CONTROL : Incubation Period]	Yes
73. Surface sampling is accomplished in all ISO classified areas on a periodic basis using TSA contact plates with lecithin and polysorbate 80 and/or swabs and is done at the conclusion of compounding. [ENVIRONMENTAL QUALITY AND CONTROL : Surface Cleaning and Disinfection Sampling and Assessment]	Yes

74. Sampling data is collected and reviewed on a periodic basis as a means of evaluating the overall state of control of the compounding environment. [ENVIRONMENTAL QUALITY AND CONTROL : Action Levels, Documentation and Data Evaluation] *Firm conducts their own viable sampling ; Volume of air tested in PEC's is not USP <797> compliant . Documents show You are using 700 liters in your ISO 5, not 1000 L. Technician UR informed inspector that she visually observes CFU's to identify organism; No microbiologist speciates growth so there is no way of knowing if there is fungus or pathogenic bacteria growing in your PEC's and SEC's, REGARDLESS OF ACTION LEVELS.*	No
75. Competent microbiology personnel are consulted if an environmental sampling consistently shows elevated levels of microbial growth. If any mold, yeast, coagulase positive staphylococcus, or gram negative rods are detected immediate remediation and investigation into the cause and source was conducted. [ENVIRONMENTAL QUALITY AND CONTROL : Action Levels, Documentation and Data Evaluation] *Facility conducts all of their environmental monitoring however there is no identification of organisms when growth occurs; There is no way of knowing if there are pathogenic bacteria or fungi,*	No
76. Surfaces in the LAFWs, BSCs, CAIs, and CACIs are cleaned and disinfected frequently, including at the beginning of each work shift, before each batch preparation is started, every 30 minutes during continuous compounding periods of individual CSPs, when there are spills, and when surface contamination is known or suspected from procedural breaches. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
77. Cleaning and disinfecting occurs before compounding is performed. Items are removed from all areas to be cleaned, and surfaces are cleaned by removing loose material and residue from spills, e.g., water-soluble solid residues are removed with Sterile Water and low-shedding wipes. This shall be followed by wiping with a residue-free disinfecting agent, such as sterile 70% IPA, which is allowed to dry before compounding begins. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
78. Cleaning and disinfecting agents and methods of application are in accordance with written SOPs and followed by custodial and/or compounding personnel. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas] *No cleaning products used on ISO 5 surfaces or ISO 7 rooms in SOP*	No
79. Cleaning materials, such as wipes, sponges, and mops, are non-shedding, preferably composed of synthetic micro fibers, and dedicated to use in the buffer area, ante-area, and segregated compounding areas and are not removed from these areas except for disposal. If cleaning materials are reused (e.g., mops), there are procedures based on manufacturer recommendations that ensure that the effectiveness of the cleaning device is maintained and repeated use does not add to the bioburden of the area being cleaned. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas] *Four mops (2 blue and two yellow) are stored in the prep room, lying on the floor. Per UR the blue mops are used to clean the PEC's; They are stored in the prep room, not ante room*	No
80. Supplies and equipment removed from shipping cartons are wiped with a suitable disinfecting agent (e.g., sterile 70% IPA). [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
81. Disinfectant sprayed or wiped on a surface to be disinfected is allowed to dry, and during this time the item is not be used for compounding purposes. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
82. Sterile 70% IPA pads are used to disinfect the sterile entry points of packages and devices. Wetted gauze pads or other particle-generating material are not appropriate. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes

QUALITY AND CONTROL (Secondary Engineering Controls)

83. Work surfaces in ISO Class 7 and 8 areas and segregated compounding areas are cleaned at least daily. IPA (70% isopropyl alcohol) remains on surfaces to be disinfected for at least 30 seconds before such surfaces are used to prepare CSPs. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
84. Floors in ISO Class 7 and 8 areas are mopped daily by trained personnel at a time when no aseptic operations are in progress using approved agents and procedures described in written SOP's. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
85. Shelving, walls, and ceilings in ante-areas and buffer areas are cleaned and disinfected at least monthly. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes

PERSONNEL CLEANSING, GARBING & COMPETENCY EVALUATION

86. Personnel preparing CSP's are free from rashes, sunburn, weeping sores, conjunctivitis, and active respiratory infections. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	Yes
87. Compounding personnel remove personal outer garments; cosmetics; artificial nails; hand, wrist, and body jewelry that can interfere with the fit of gowns and gloves; and visible body piercing above the neck. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	Yes
88. Facility has adequate supplies to meet PPE requirements of USP<797>. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	No
89. Garbing and hand hygiene are accomplished in the ante-area in order of dirtiest to cleanest: shoes or shoe covers, head and facial hair covers, face mask, fingernail cleansing, hand and forearm washing and drying; non-shedding gown. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing] *No fingernail picks*	No
90. Sterile gloves are donned in the buffer room/isolator after hand cleansing with an alcohol-based product with persistent activity and hands are allowed to dry. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing] *No persistent activity alcohol on site.*	No
91. Gloves are routinely disinfected with sterile 70% IPA after contacting nonsterile objects. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	Yes
92. Personnel repeat garbing and hand hygiene after they are exposed to direct contact contamination or worse than ISO Class 8 air. Gowns may be hung in the anteroom and reused during the same workshift. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	Yes
93. Low/Medium Risk media-fill tests that closely simulate the most challenging or stressful conditions encountered during compounding are completed at least annually by compounding personnel. Media-filled vials are appropriately incubated for 14 days. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Medium-Risk Level CSPs]	N/A
94. High Risk Media-fill tests that closely simulate the most challenging or stressful conditions encountered during compounding have been completed at least semiannually by compounding personnel. Media-filled vials are appropriately incubated for 14 days. [CSP MICROBIAL CONTAMINATION RISK LEVELS : High-Risk Level CSPs] *Media fill simulation uses 2 ml vials X 471; No larger volume media fill within the last 6 months for either employee.*	No
95. Documentation indicates compounding personnel have successfully completed didactic training, passed written competency assessments, undergone skill assessment using observational audit tools (hand hygiene, garbing, aseptic technique) and media-fill testing annually or semiannually (high risk) and before any compounding personnel begin to prepare CSPs . [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures] *Observational assessments are overdue for UR and JG.*	No

96. Compounding personnel who fail written tests, observational audits, or whose media-fill test vials have one or more units showing visible microbial contamination, are reinstructed and re-evaluated by expert compounding personnel to ensure correction of all aseptic work practice deficiencies. Corrective action is documented. Compounding personnel pass all evaluations prior to resuming compounding of sterile preparations. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures]	N/A
97. Other cleaning personnel performing cleaning and disinfecting procedures (e.g. environmental) are thoroughly trained in proper hand hygiene, and garbing, cleaning, and disinfection procedures by a qualified aseptic compounding expert. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures]	N/A
98. Compounding personnel and other personnel responsible for cleaning routinely undergo performance evaluation of proper hand hygiene, garbing, and all applicable cleaning and disinfecting procedures conducted by a qualified aseptic compounding expert. Visual observation of hand hygiene, garbing and cleaning is documented and maintained to provide a permanent record and long-term assessment of personnel competency. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures]	No
99. Immediately after the compounder completes the hand hygiene and garbing procedure, the evaluator collects a gloved fingertip and thumb sample from both hands of the compounder onto appropriate agar plates. The plates are incubated at 30-35° for 2–3 days. All compounding personnel have successfully completed an initial competency evaluation and gloved fingertip/thumb sampling procedure (0 cfu) no less than three times before initially being allowed to compound CSPs for human use. [ENVIRONMENTAL QUALITY AND CONTROL : Gloved Fingertip Sampling]	Yes
100. Re-evaluation of glove fingertip testing onto appropriate agar plates (Trypticase soy agar (TSA) with lecithin and polysorbate 80) for all compounding personnel occurs at least annually for low- and medium-risk level CSPs and semiannually for high-risk level CSPs before being allowed to continue compounding CSPs. Gloves shall not be disinfected with sterile 70% IPA prior to testing. The cfu action level is based on the total number of cfu on both gloves and not per hand. [ENVIRONMENTAL QUALITY AND CONTROL : Gloved Fingertip Sampling]	Yes

VERIFICATION

101. Labels of CSPs contain name and address of pharmacy, correct names and amounts or concentrations of ingredients, total volumes, beyond-use dates, storage conditions, and route(s) of administration. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Identity and Strength Verification of Ingredients]	Yes
102. Facility has documentation that procedures have been followed to ensure sterility, purity, correct identities and amounts of ingredients, and stability. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Inspection of Solution Dosage Forms and Review of Compounding Procedures]	Yes
103. CSP's are visually inspected for abnormal particulate matter and color, and intact containers and seals. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Inspection of Solution Dosage Forms and Review of Compounding Procedures]	Yes
104. Beyond Use Dates are assigned using direct stability-indicating assays or authoritative literature that supports the assigned BUD. [STORAGE AND BEYOND-USE DATING : Determining Beyond-Use Dates]	Yes
105. Storage time of assembled bag and vial systems are according to the manufacturer recommendations. (eg Minibag plus, Addvantage, Add-ease) [STORAGE AND BEYOND-USE DATING : Proprietary Bag and Vial Systems]	N/A

DISPENSING/DISTRIBUTION

106. Facility has written procedures for proper packaging, storage, and transportation conditions to maintain sterility, quality, purity, and strength of CSPs. [MAINTAINING STERILITY, PURITY, AND STABILITY OF DISPENSED AND DISTRIBUTED CSPs :]	N/A
107. Modes of transport are used that maintain appropriate temperatures and prevent damage to CSPs. [MAINTAINING STERILITY, PURITY, AND STABILITY OF DISPENSED AND DISTRIBUTED CSPs : Packaging and Transporting CSPs]	N/A
108. Facility provides a multiple component formal training program to ensure patients and caregivers understand the proper storage, handling, use, and disposal of CSPs. [PATIENT OR CAREGIVER TRAINING]	N/A

POLICY/PROCEDURE

109. Written procedures detail cleaning and disinfecting the sterile compounding areas including cleansers, disinfectants, and non-shedding wipe and mop materials. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas] *Products for cleaning and disinfecting PEC's and SEC's are not included in the SOP's*	No
110. A written procedure is in place for cleaning and disinfecting the Direct Compounding Areas. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
111. Facility has written procedures to verify correct identity, quality, amounts, and purities of ingredients used in CSPs. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Identity and Strength Verification of Ingredients]	Yes
112. Policies address packaging to maintain physical integrity, sterility, stability, and purity of CSPs. [MAINTAINING STERILITY, PURITY, AND STABILITY OF DISPENSED AND DISTRIBUTED CSPs : Packaging and Transporting CSPs]	Yes
113. Written standard procedures describe means for patients to ask questions and report concerns and adverse events with CSPs, and for compounding pharmacists to correct and prevent future problems. [PATIENT MONITORING AND ADVERSE EVENTS REPORTING]	N/A

RADIOPHARMACEUTICALS

114. Facility has appropriate primary engineering controls and radioactivity containment and shielding. Location of primary engineering controls permitted in ISO Class 8 controlled environment. [RADIOPHARMACEUTICALS AS CSPs]	
115. Radiopharmaceuticals prepared as low-risk level CSPs with 12-hour or less BUD are prepared in a segregated compounding area. Segregated compounding area is designated with a line of demarcation. [RADIOPHARMACEUTICALS AS CSPs]	
116. Technetium-99m/Molybdenum-99 generators are eluted in ISO Class 8 conditions. [RADIOPHARMACEUTICALS AS CSPs]	

MISCELLANEOUS

117. Facility engaged in office use sterile compounding for human use is registered with FDA as an outsourcing facility. [FAC 64B16-27.700 (3)(g]	Yes
118. Compounding records are properly maintained. [FAC 64B16-28.140(4)] *Batch records do not have actual bubble point test documented, just simply >50psi.*	No
119. When compounding activities require the manipulation of a patient's blood-derived or other biological material, the manipulations are clearly separated from routine material-handling procedures and equipment used in CSP preparation activities, and they are controlled by specific standard operating procedures in order to avoid any cross-contamination. [ENVIRONMENTAL QUALITY AND CONTROL : Placement of Primary Engineering Controls Within ISO Class 7 Buffer Areas]	N/A

SPECIAL PARENTERAL ENTERAL & EXTENDED SCOPE

120. Pharmacy technicians properly identified and supervised. [64B16-27.420, F.A.C.]	
121. Medication properly labeled. [465.0255, F.S.] [64B16-28.108, F.A.C.]	
122. Expired medications removed from the shelves. [64B16-28.110, F.A.C.]	
123. CQI Policy and Procedures and quarterly meetings. [766.101, F.S.] [64B16-27.300, F.A.C.]	
124. Prescriptions have the date dispensed and dispensing pharmacists. [893.04(1)(c) 6, F.S.] [64B16-28.140(3)(b), F.A.C.]	
125. Pharmacy maintains patient profile records. [64B16-27.800, F.A.C.]	
126. All controlled substance prescriptions contain information required. [893.04, F.S.]	
127. Prescriptions for controlled substances are on counterfeit-proof prescription pads or blanks purchased from a Department-approved vendor and the quantity and date meet the requirements of [456.42(2), F.S.].	
128. Controlled substance inventory taken on a biennial basis and available for inspection. [893.07(1)(a), F.S.]	
129. DEA 222 order forms properly completed. [893.07, F.S.]	
130. Controlled substance records and Rx information in computer system is retrievable. [21CFR 1306.22] [64B16-28.140, F.A.C.]	
131. Controlled substance records maintained for 4 years. [465.022(12)(b), F.S.]	
132. Certified daily log OR printout maintained. [21CFR 1306.22(b)(3)] [64B16-28.140(3)(b), F.A.C.]	
133. Pharmacy is reporting to the PDMP within 7 days of dispensing controlled substance. [893.055(4), F.S.]	
134. Pharmacy maintains invoices documenting that medicinal drugs were obtained from a Florida licensed distributor. 499.005 (14)	

Remarks:

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge. I have received a copy of the Licensee Bill of Rights.

Inspector Signature:

Date:6/14/2017

Representative:

Jeff Goldrich

Date:6/14/2017

STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES
INV797-Sterile Compounding

File # 21375
Insp # 153486

NAME	PERMIT NUMBER	DATE OF INSPECTION
HYBRID PHARMA, LLC	29374	12/19/2017
DOING BUSINESS AS		
STREET ADDRESS 1015 W NEWPORT CTR DR #106-A	**TELEPHONE #**	**EXT**
CITY DEERFIELD BEACH	**COUNTY** BROWARD	**STATE/ZIP** FL/33442

Additional Information

Business Operation Hours

M-T-W-TH-F Y	Weekly Hours 10am-6pm
Monday Y	Tuesday N
Wednesday N	Thursday N
Friday N	Saturday N
Sunday N	

Registered Pharmacist / Intern / Tech

License # PS27855	Licensee Name Jeff Goldrich
License Type Registered Pharmacists	
License # RPT45465	Licensee Name Umarani Rajalingham
License Type Pharmacy Tech	

ACS Manager

Optional Information

Basic License Data - PSD

DEA Reg # FH4258706	

INV797 - Sterile Compounding

LOW RISK

1. Low risk CSP's are properly identified: Aseptic manipulations within an ISO Class 5 environment using three or fewer sterile products and no more than two entries into any container. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Low-Risk Level CSPs]	
2. Low Risk CSP's, in absence of passing sterility test, stored not more than 48 hours at controlled room temperature, 14 days at cold temperature, or 45 days in solid frozen state at -25° to -10° or colder. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Low-Risk Level CSPs]	
3. Low Risk CSP's with 12 hour BUD are properly identified and comply with all four specific criteria. 1. PEC in Segregated Compounding area 2. Away from windows, doors , high traffic areas 3. Hygiene & garbing required, sinks not adjacent to PEC. 4. Cleaning & Disinfecting, Personnel training, Competency evaluation, Garbing, Aseptic work practices, Viable and non-viable environmental sampling apply. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Low-Risk Level CSPs]	

MEDIUM RISK

4. Medium Risk CSP's are properly identified: Aseptic manipulations within an ISO Class 5 environment using prolonged and complex mixing and transfer, more than three sterile products and entries into any container, and pooling ingredients from multiple sterile products to prepare multiple CSPs. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Medium-Risk Level CSPs]	
5. Medium Risk CSP's, In absence of passing sterility test, stored not more than 30 hours at controlled room temperature, 9 days at cold temperature, or 45 days in solid frozen state at -25° to -10° or colder. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Medium-Risk Level CSPs]	

HIGH RISK

6. Presterilization procedures for high-risk level CSPs, such as weighing and mixing, are completed in no worse than an ISO Class 8 environment. [ENVIRONMENTAL QUALITY AND CONTROL : Placement of Primary Engineering Controls Within ISO Class 7 Buffer Areas]	N/A
7. High Risk CSP's are properly identified: Confirmed presence of nonsterile ingredients and devices, or confirmed or suspected exposure of sterile ingredients for more than one hour to air quality inferior to ISO Class 5 before final sterilization. [CSP MICROBIAL CONTAMINATION RISK LEVELS : High-Risk Level CSPs]	Yes

8. High Risk CSP's, in absence of passing sterility test are not stored more than 24 hours at controlled room temperature, 3 days at cold temperature, or 45 days in solid frozen state at -25° to -10° or colder. [CSP MICROBIAL CONTAMINATION RISK LEVELS : High-Risk Level CSPs]	Yes
9. A 0.2-µm certified sterilizing membrane filter is used that is chemically and physically compatible with the CSP. Filtration is completed rapidly without filter replacement. Sterilization method is verified to achieve sterility for the quantity and type of containers. [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Sterilization of High-Risk Level CSPs by Filtration] *Compounding record for Zinc sulfate 10mg/ml final volume of 300 ml was sterilized by filtration with a Baxter Supor 32 mm syringe filter. Manufacturer recommended volume for this filter is less than 150 ml.*	No
10. Sterilization method used has documentation that acceptable strength and purity of ingredients and integrity of containers is maintained. [CSP MICROBIAL CONTAMINATION RISK LEVELS : High-Risk Level CSPs]	N/A
11. The manufacturer recommended filter integrity (e.g., bubble point) test is performed and documented for all sterilizing filters after filtering CSPs. [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Sterilization of High-Risk Level CSPs by Filtration]	Yes
12. Autoclave cycle has been verified using appropriate biological indicators. Solutions are passed through a 1.2-µm or smaller filter into final containers to remove particulates before sterilization. [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Sterilization of High-Risk Level CSPs by Steam]	Yes
13. Dry heat ovens used for sterilization have filtered forced air. Only those items that will be damaged by steam are sterilized by dry heat. [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Sterilization of High-Risk Level CSPs by Dry Heat] *No sterilization of CSP's through dry heat*	N/A
14. The description of dry heat sterilization conditions and duration for specific CSPs is included in written documentation in the compounding facility. The effectiveness of dry heat sterilization is verified using appropriate biological indicators and other confirmation. [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Sterilization of High-Risk Level CSPs by Dry Heat]	N/A
15. Dry heat depyrogenation is used to render glassware or containers, such as vials free from pyrogens as well as viable microbes. The description of the dry heat depyrogenation cycle and duration for specific load items is included in written documentation in the compounding facility. The effectiveness of the dry heat depyrogenation cycle is verified using endotoxin challenge vials (ECVs). [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Depyrogenation by Dry Heat] *Firm is using distilled water to rinse glassware not sterile water ; SECOND ADVISORY.*	No
16. Sterility testing is completed for all High-risk level CSPs prepared in batches of more than 25 identical containers, or exposed longer than 12 hours at 2° to 8°, and 6 hours at warmer than 8° before being sterilized. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Sterility Testing]	Yes

USP <71> STERILITY TESTING (Outsourced)

17. Outsourced sterility testing results indicate that it is compliant with USP<71>. A method not described in the USP may be used if validation demonstrates that the alternative is at least as effective and reliable. [STERILITY TEST USP<71>]	
18. Outsourced: The number of articles tested are appropriate according to USP<71>. [STERILITY TEST USP<71> : Number of Articles to Be Tested]	
19. Outsourced: The volume/quantity tested is according to USP<71>. [STERILITY TEST USP<71> : Number of Articles to Be Tested]	
20. Outsourced: A USP<71> method suitability test has been done with appropriate inoculum, additives and rinses. [STERILITY TEST USP<71> : Method Suitability Test]	
21. Outsourced: Sterility testing reports are reviewed and appropriate actions taken and documented. [FINISHED PREPARATION RELEASE CHECKS AND TESTS]	

USP <71> STERILITY TESTING

22. On site: Membrane filtration is used if appropriate. (The technique of membrane filtration is used whenever the nature of the product permits; that is, for filterable aqueous preparations, for alcoholic or oily preparations, and for preparations miscible with, or soluble in, aqueous or oily solvents, provided these solvents do not have an antimicrobial effect in the conditions of the test.) Filters are rinsed according to USP<71>. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Sterility Testing] *The SOP the firm is using is the Pall MF (membrane filtration) technique for their sterility testing that does not match the procedure, also, the Nalgene sterile filter that was presented to inspectors indicates that it is for food and beverages and does not indicate it can be used for pharmaceutical product sterility tests; PROVIDE DOCUMENTATION THE DEVICE IS APPROPRIATE FOR USP <71> STERILITY TESTS*	No
23. On site: Direct inoculation is done only when membrane filtration cannot be carried out. Volume to be inoculated does not exceed 10% of the culture media volume. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Sterility Testing]	N/A
24. On site: The number of articles tested are appropriate according to USP<71>. [STERILITY TEST USP<71> : Number of Articles to Be Tested]	Yes
25. On site: The volume/quantity tested is according to USP<71>. [STERILITY TEST USP<71> : Number of Articles to Be Tested]	Yes
26. On site: A growth promotion test has been done on the media with the 5 specified organisms (not more than 100 CFU) according to USP<71>. [STERILITY TEST USP<71> : Growth Promotion Test of Aerobes, Anaerobes, and Fungi]	N/A
27. On site: A USP<71> method suitability test has been done with appropriate inoculum, additives and rinses. [STERILITY TEST USP<71> : Method Suitability Test] *Method suitability does not match method used for sterility tests. SECOND ADVISORY . Atlas labs conducts method suitability for HCG and uses bacteriostatic water to reconstitute the product , not SWFI ; SECOND ADVISORY Provide documentation that all rinses and methods used in the method suitability are alike ie; membrane filtration, inoculation, rinses, etc. FOR EACH PRODUCT THAT YOU TEST FOR STERILITY. The media you are using is TSB with lecithin and tween 20 and Fluid Thioglycollate that are manufactured by Hardy. Send documentation Atlas labs is using the same media and rinses for method suitability for EACH PRODUCT*	No
28. On site: TSB or SCD is incubated at 20-25 C for 14 days (2 incubators present). [STERILITY TEST USP<71> : Culture Media and Incubation Temperatures]	Yes
29. On site: FTM is incubated at 30-35 C for 14 days (2 incubators present). [STERILITY TEST USP<71> : Culture Media and Incubation Temperatures]	Yes
30. On site: Sterility testing is documented including lot numbers and expiration dates of media. [FINISHED PREPARATION RELEASE CHECKS AND TESTS]	Yes
31. On site: Sterility testing reports are reviewed and appropriate actions taken and documented. [FINISHED PREPARATION RELEASE CHECKS AND TESTS]	Yes

ENDOTOXIN TESTING

32. Endotoxin testing is conducted for High-risk level CSP's that are prepared in batches of more than 25 identical containers, or exposed longer than 12 hours at 2° to 8°, and 6 hours at warmer than 8°, before being sterilized or in multidose containers for administration to multiple patients. (excluding those for inhalation and ophthalmic administration) [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Bacterial Endotoxin (Pyrogen) Testing] *Testosterone lot #171006a 2000 ml has not been tested for endotoxins.*	No

33. Endotoxin testing process indicates that it is compliant with USP<85>. [BACTERIAL ENDOTOXINS TEST USP<85>]	Yes
34. High Risk CSP's are within allowable limits for bacterial endotoxins. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Bacterial Endotoxin (Pyrogen) Testing]	Yes

IMMEDIATE USE COMPOUNDING

35. Immediate-use compounding complies with all six specified criteria. 1. Low-risk sterile nonhazardous products or diagnostic radiopharmaceutical products from the manufacturers' original containers. Anti-neoplastics shall not be prepared as immediate-use CSPs because they are hazardous drugs. 2. Unless required for the preparation, the compounding procedure is a continuous process not to exceed 1 hour. 3. During preparation, aseptic technique is followed and, if not immediately administered, the finished CSP is under continuous supervision to minimize the potential for contact with nonsterile surfaces, introduction of particulate matter or biological fluids, mix-ups with other CSPs, and direct contact of outside surfaces. 4. Administration begins not later than 1 hour following the start of the preparation of the CSP. 5. Unless immediately and completely administered by the person who prepared it or immediate and complete administration is witnessed by the preparer, the CSP shall bear a label listing patient identification information, the names and amounts of all ingredients, the name or initials of the person who prepared the CSP, and the exact 1-hour BUD and time. 6. If administration has not begun within 1 hour following the start of preparing the CSP, the CSP shall be promptly, properly, and safely discarded. [IMMEDIATE-USE CSPs]	N/A

SINGLE/MULTIPLE DOSE CONTAINER BUD

36. Beyond-use date does not exceed 28 days for multiple-dose containers after initial opening or entry, unless specified otherwise by the manufacturer. [SINGLE-DOSE AND MULTIPLE-DOSE CONTAINERS]	N/A
37. Beyond-use time does not exceed 6 hours for closure sealed single-dose containers in ISO Class 5 or cleaner air after initial opening or entry, unless specified otherwise by the manufacturer. [SINGLE-DOSE AND MULTIPLE-DOSE CONTAINERS]	N/A
38. Beyond-use time does not exceed 1 hour for closure sealed single-dose containers after being opened or entered in worse than ISO Class 5 air. [SINGLE-DOSE AND MULTIPLE-DOSE CONTAINERS]	N/A
39. Single-dose ampules are discarded immediately after use. [SINGLE-DOSE AND MULTIPLE-DOSE CONTAINERS]	N/A

HAZARDOUS DRUGS

40. A pressure indicator is installed and differential pressures are monitored and documented daily for hazardous buffer room. [HAZARDOUS DRUGS AS CSPs]	Yes
41. Hazardous drug buffer room is at least 0.01 inch water column negative pressure with 30 ACPH of HEPA filtered air. [HAZARDOUS DRUGS AS CSPs]	Yes
42. At least 0.01 inch water column negative pressure and 12 air changes per hour in non-cleanrooms in which CACIs are located. FAC: USP Chapter 797 requires that: "When closed-system vial-transfer devices (CSTDs) (i.e., vial-transfer systems that allow no venting or exposure of hazardous substance to the environment) are used, they shall be used within an ISO Class 5 environment of a BSC or CACI. The use of the CSTD is preferred because of their inherent closed system process. In facilities that prepare a low volume of hazardous drugs, the use of two tiers of containment (e.g., CSTD within a BSC or CACI that is located in a non-negative pressure room) is acceptable." For purpose of said provision, a "low volume of hazardous drugs" is defined as less than 40 doses per month. [HAZARDOUS DRUGS AS CSPs]	N/A
43. Personnel compounding hazardous drugs wear appropriate personal protective equipment. [HAZARDOUS DRUGS AS CSPs]	Yes
44. Hazardous drugs are handled with caution at all times using appropriate chemotherapy gloves during receiving, distribution, stocking, inventorying, preparing for administration, and disposal. Spill kits are available. [HAZARDOUS DRUGS AS CSPs]	Yes
45. Hazardous drugs are prepared in an ISO Class 5 environment (BSC or CACI) with protective engineering controls in place, following aseptic practices specified for the appropriate contamination risk levels. [HAZARDOUS DRUGS AS CSPs]	Yes
46. Hazardous drugs are stored separately from other inventory in a manner to prevent contamination and personnel exposure. [HAZARDOUS DRUGS AS CSPs] *HCG stored in quarantine cabinet with non hazardous drugs.*	No
47. Access to hazardous drug preparation areas is limited to authorized compounding personnel. [HAZARDOUS DRUGS AS CSPs]	Yes
48. Annual documentation of hazardous drug training of personnel regarding storage, handling, containment techniques and disposal of hazardous drugs is available. [HAZARDOUS DRUGS AS CSPs]	Yes
49. Compounding personnel of reproductive capability have confirmed in writing that they understand the risks of handling hazardous drugs. [HAZARDOUS DRUGS AS CSPs]	Yes
50. Facility maintains appropriate disposal containers for all hazardous waste. [HAZARDOUS DRUGS AS CSPs]	Yes

FACILITY DESIGN AND CERTIFICATION

51. Certification and testing of primary (LAFWs, BSCs, CAIs and CACIs) and secondary engineering controls (buffer and ante areas) have been performed by a qualified individual no less than every six months and whenever the device or room is relocated, altered, or major service to the facility is performed. Corrective action for deficiencies are documented. Certification procedures such as those outlined in the CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2006) are conducted under dynamic conditions. [ENVIRONMENTAL QUALITY AND CONTROL : Environmental Nonviable Particle Testing Program] *July 11, 2017 TMI ; Ante ISO Class 7 , BR 1 (positive buffer room) ISO Class 7 , BR 2 (negative buffer room) ISO Class 7; ISO Class 7 PR (prep room) ; 1 X LFH ISO Class 5 TESTED UNDER AT REST CONDITIONS; 1 x BSC located in BR 2 however TMI reported the PEC is located in the lab which non viable particle counts were not collected on the BSC . There is no assurance this PEC is operating under clean ISO Class 5 standards.*	No
52. Primary engineering controls provide unidirectional (i.e., laminar) HEPA filtered air. Air pattern analysis via smoke studies are conducted at the critical site to demonstrate unidirectional airflow and sweeping action over and away from the product under dynamic conditions.[ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls] *No smoke studies available at the time of inspection. PLEASE PROVIDE SMOKE STUDIES WITHIN 72 HOURS OF THIS INSPECTION. HCG IS A HAZARDOUS DRUG COMPOUNDED IN THE HD ROOM THEN TRANSFERRED TO THE LYOPHYLIZER THAT IS LOCATED IN THE POSITIVE CLEAN ROOM; PARTIALLY STOPPERED VIALS ARE BEING TRANSFERRED FROM ISO CLASS 5 PEC THROUGH ISO CLASS 7 TO THE LYOPHYLIZER.*	No
53. The primary engineering controls are placed within a buffer area in such a manner as to avoid conditions that could adversely affect their operation. The PEC is placed out of the traffic flow and in a manner to avoid disruption from the HVAC system and room cross drafts. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
54. All HEPA filters are leak tested after installation and every six months thereafter. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes

ISOLATORS

55. CAIs are proven to maintain ISO Class 5 air when particle counts are sampled 6 to 12 inches upstream of critical site exposure areas during performance of normal inward and outward transfer of materials, and compounding manipulations when such CAIs are located in air quality worse than ISO Class 7. [ENVIRONMENTAL QUALITY AND CONTROL : Placement of Primary Engineering Controls Within ISO Class 7 Buffer Areas]	
56. Adequate recovery time for isolators to achieve ISO Class 5 air quality is allowed after material transfer before and during compounding operations. [ENVIRONMENTAL QUALITY AND CONTROL : Placement of Primary Engineering Controls Within ISO Class 7 Buffer Areas]	
57. Personnel garbing requirements are followed for CAIs unless manufacturer provides written documentation based on validated testing that any components of PPE are not required to maintain sterility of CSPs. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	

FACILITY DESIGN AND CERTIFICATION (Secondary Engineering Controls)

58. Facility has pressure gauges or velocity meters to monitor the pressure differential or airflow between the buffer area and ante-area, and the ante-area and the general environment outside the compounding area. The results are reviewed and documented on a log at least daily or by a continuous recording device. The pressures differentials meet or exceed 5 Pa (0.02 inch water column (w.c.)). Alternatively, in facilities where low- and medium-risk level CSPs are prepared, differential airflow is maintained at a minimum velocity of 0.2 meter/second (40 fpm) across a line of demarcation between buffer area and ante-area. [ENVIRONMENTAL QUALITY AND CONTROL : Pressure Differential Monitoring] *Door connecting the general area to the ISO Class 7 prep area remained ajar through most of the inspection. Pressure gauge read +0.003"w.c..*	No
59. Clean rooms for nonhazardous and nonradioactive CSPs are supplied with HEPA filtered air that enters from ceilings with return vents low on walls, and that provides not less than 30 air changes per hour or qualifies for exception in 64B16-27.797(4)(c). [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
60. Activities and tasks carried out within the buffer area are limited to only those necessary when working within a controlled environment. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
61. Only the furniture, equipment, supplies, and other material required for the compounding activities to be performed are brought into the buffer room. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
62. Surfaces and essential furniture in buffer rooms or zones and clean rooms are nonporous, smooth, non-shedding, impermeable, cleanable, and resistant to disinfectants. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
63. The surfaces of ceilings, walls, floors, fixtures, shelving, counters, and cabinets in the buffer area are smooth, impervious, free from cracks and crevices, and non-shedding, thereby promoting cleanability, and minimizing spaces in which microorganisms and other contaminants may accumulate. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls] *positive clean room has protruding , rusted bolts sticking out of the upper left side of wall; there are multiple cracks on seam of wall in clean room. SECOND ADVISORY.*	No
64. Ceiling tiles are caulked around each perimeter and to walls to seal them to the support frame. The exterior lens surface of ceiling lighting fixtures is smooth, mounted flush, and sealed. All other penetrations through the ceiling or walls are sealed. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
65. The buffer area does not contain sources of water (sinks) or floor drains. Work surfaces are constructed of smooth, impervious materials, such as stainless steel or molded plastic, so that they are easily cleaned and disinfected. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
66. Storage shelving, counters, cabinets and carts/casters in the buffer area are smooth, impervious, free from cracks and crevices, non-shedding, non-porous, cleanable, and disinfectable. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
67. When devices (e.g., computers and printers) and objects (e.g., carts and cabinets) are placed in buffer areas, air quality is verified by particle counts on certification. [ENVIRONMENTAL QUALITY AND CONTROL : ISO Class 5 Air Sources, Buffer Areas, and Ante-Areas]	Yes

QUALITY AND CONTROL

68. An appropriate environmental sampling plan has been developed for airborne viable particles based on a risk assessment of compounding activities performed. Volumetric air sampling is conducted every six months and sites include locations within each ISO Class 5 environment and in the ISO Class 7 and 8 areas, and the areas at greatest risk of contamination (e.g., work areas near the ISO Class 5 environment, counters near doors, pass-through boxes). The plan includes sample locations, method of collection, frequency of sampling, volume of air sampled, and time of day as related to activity in the compounding area and action levels. [ENVIRONMENTAL QUALITY AND CONTROL : Environmental Viable Airborne Particle Testing Program—Sampling Plan] *Not available at the time of inspection*	No
69. Evaluation of airborne microorganisms using volumetric collection methods in the controlled air environments is performed by properly trained individuals for all compounding risk levels. [ENVIRONMENTAL QUALITY AND CONTROL : Viable Air Sampling] *VAS using a general microbiological growth medium to support growth of bacteria has been used for the LFH only.*	No
70. Volumetric air sampling using malt extract agar (MEA) or some other media that supports the growth of fungi is used in high-risk level compounding environments. [ENVIRONMENTAL QUALITY AND CONTROL : Growth Media]	Yes
71. For low-risk level CSPs with 12-hour or less BUD, air sampling is performed at locations inside the ISO Class 5 environment and other areas that are in close proximity to the ISO class 5 environment. [ENVIRONMENTAL QUALITY AND CONTROL : Viable Air Sampling]	N/A
72. The number of discrete colonies of microorganisms is counted and reported as colony-forming units (cfu) and documented on an environmental monitoring form. Counts from air monitoring are transformed into cfu/cubic meter of air and evaluated for adverse trends. [ENVIRONMENTAL QUALITY AND CONTROL : Incubation Period]	Yes
73. Surface sampling is accomplished in all ISO classified areas on a periodic basis using TSA contact plates with lecithin and polysorbate 80 and/or swabs and is done at the conclusion of compounding. [ENVIRONMENTAL QUALITY AND CONTROL : Surface Cleaning and Disinfection Sampling and Assessment]	Yes
74. Sampling data is collected and reviewed on a periodic basis as a means of evaluating the overall state of control of the compounding environment. [ENVIRONMENTAL QUALITY AND CONTROL : Action Levels, Documentation and Data Evaluation]	Yes
75. Competent microbiology personnel are consulted if an environmental sampling consistently shows elevated levels of microbial growth. If any mold, yeast, coagulase positive staphylococcus, or gram negative rods are detected immediate remediation and investigation into the cause and source was conducted. [ENVIRONMENTAL QUALITY AND CONTROL : Action Levels, Documentation and Data Evaluation]	N/A
76. Surfaces in the LAFWs, BSCs, CAIs, and CACIs are cleaned and disinfected frequently, including at the beginning of each work shift, before each batch preparation is started, every 30 minutes during continuous compounding periods of individual CSPs, when there are spills, and when surface contamination is known or suspected from procedural breaches. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas] *Cleaning records do not show the BSC located in the hazardous clean room is being cleaned and/or disinfected.*	No
77. Cleaning and disinfecting occurs before compounding is performed. Items are removed from all areas to be cleaned, and surfaces are cleaned by removing loose material and residue from spills, e.g., water-soluble solid residues are removed with Sterile Water and low-shedding wipes. This shall be followed by wiping with a residue-free disinfecting agent, such as sterile 70% IPA, which is allowed to dry before compounding begins. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes

78. Cleaning and disinfecting agents and methods of application are in accordance with written SOPs and followed by custodial and/or compounding personnel. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
79. Cleaning materials, such as wipes, sponges, and mops, are non-shedding, preferably composed of synthetic micro fibers, and dedicated to use in the buffer area, ante-area, and segregated compounding areas and are not removed from these areas except for disposal. If cleaning materials are reused (e.g., mops), there are procedures based on manufacturer recommendations that ensure that the effectiveness of the cleaning device is maintained and repeated use does not add to the bioburden of the area being cleaned. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
80. Supplies and equipment removed from shipping cartons are wiped with a suitable disinfecting agent (e.g., sterile 70% IPA). [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
81. Disinfectant sprayed or wiped on a surface to be disinfected is allowed to dry, and during this time the item is not be used for compounding purposes. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
82. Sterile 70% IPA pads are used to disinfect the sterile entry points of packages and devices. Wetted gauze pads or other particle-generating material are not appropriate. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes

QUALITY AND CONTROL (Secondary Engineering Controls)

83. Work surfaces in ISO Class 7 and 8 areas and segregated compounding areas are cleaned at least daily. IPA (70% isopropyl alcohol) remains on surfaces to be disinfected for at least 30 seconds before such surfaces are used to prepare CSPs. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
84. Floors in ISO Class 7 and 8 areas are mopped daily by trained personnel at a time when no aseptic operations are in progress using approved agents and procedures described in written SOP's. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
85. Shelving, walls, and ceilings in ante-areas and buffer areas are cleaned and disinfected at least monthly. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas] *October cleaning logs reflect monthly cleaning was not done in hazardous clean room.*	No

PERSONNEL CLEANSING, GARBING & COMPETENCY EVALUATION

86. Personnel preparing CSP's are free from rashes, sunburn, weeping sores, conjunctivitis, and active respiratory infections. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	Yes
87. Compounding personnel remove personal outer garments; cosmetics; artificial nails; hand, wrist, and body jewelry that can interfere with the fit of gowns and gloves; and visible body piercing above the neck. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	Yes
88. Facility has adequate supplies to meet PPE requirements of USP<797>. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	Yes
89. Garbing and hand hygiene are accomplished in the ante-area in order of dirtiest to cleanest: shoes or shoe covers, head and facial hair covers, face mask, fingernail cleansing, hand and forearm washing and drying; non-shedding gown. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	Yes
90. Sterile gloves are donned in the buffer room/isolator after hand cleansing with an alcohol-based product with persistent activity and hands are allowed to dry. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	Yes
91. Gloves are routinely disinfected with sterile 70% IPA after contacting nonsterile objects. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	Yes
92. Personnel repeat garbing and hand hygiene after they are exposed to direct contact contamination or worse than ISO Class 8 air. Gowns may be hung in the anteroom and reused during the same workshift. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	Yes
93. Low/Medium Risk media-fill tests that closely simulate the most challenging or stressful conditions encountered during compounding are completed at least annually by compounding personnel. Media-filled vials are appropriately incubated for 14 days. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Medium-Risk Level CSPs]	N/A
94. High Risk Media-fill tests that closely simulate the most challenging or stressful conditions encountered during compounding have been completed at least semiannually by compounding personnel. Media-filled vials are appropriately incubated for 14 days. [CSP MICROBIAL CONTAMINATION RISK LEVELS : High-Risk Level CSPs] *UR RPT last high risk media fill was conducted on 2.17.17.*	No
95. Documentation indicates compounding personnel have successfully completed didactic training, passed written competency assessments, undergone skill assessment using observational audit tools (hand hygiene, garbing, aseptic technique) and media-fill testing annually or semiannually (high risk) and before any compounding personnel begin to prepare CSPs . [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures] *JG RPh is overdue for all visual assessments.*	No
96. Compounding personnel who fail written tests, observational audits, or whose media-fill test vials have one or more units showing visible microbial contamination, are reinstructed and re-evaluated by expert compounding personnel to ensure correction of all aseptic work practice deficiencies. Corrective action is documented. Compounding personnel pass all evaluations prior to resuming compounding of sterile preparations. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures]	N/A
97. Other cleaning personnel performing cleaning and disinfecting procedures (e.g. environmental) are thoroughly trained in proper hand hygiene, and garbing, cleaning, and disinfection procedures by a qualified aseptic compounding expert. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures]	N/A
98. Compounding personnel and other personnel responsible for cleaning routinely undergo performance evaluation of proper hand hygiene, garbing, and all applicable cleaning and disinfecting procedures conducted by a qualified aseptic compounding expert. Visual observation of hand hygiene, garbing and cleaning is documented and maintained to provide a permanent record and long-term assessment of personnel competency. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures] *JG Rph is assessing UR RPT and is overdue for all visual assessments.*	No
99. Immediately after the compounder completes the hand hygiene and garbing procedure, the evaluator collects a gloved fingertip and thumb sample from both hands of the compounder onto appropriate agar plates. The plates are incubated at 30-35° for 2–3 days. All compounding personnel have successfully completed an initial competency evaluation and gloved fingertip/thumb sampling procedure (0 cfu) no less than three times before initially being allowed to compound CSPs for human use. [ENVIRONMENTAL QUALITY AND CONTROL : Gloved Fingertip Sampling]	Yes
100. Re-evaluation of glove fingertip testing onto appropriate agar plates (Trypticase soy agar (TSA) with lecithin and polysorbate 80) for all compounding personnel occurs at least annually for low- and medium-risk level CSPs and semiannually for high-risk level CSPs before being allowed to continue compounding CSPs. Gloves shall not be disinfected with sterile 70% IPA prior to testing. The cfu action level is based on the total number of cfu on both gloves and not per hand. [ENVIRONMENTAL QUALITY AND CONTROL : Gloved Fingertip Sampling]	Yes

VERIFICATION

101. Labels of CSPs contain name and address of pharmacy, correct names and amounts or concentrations of ingredients, total volumes, beyond-use dates, storage conditions, and route(s) of administration. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Identity and Strength Verification of Ingredients] *DECA Ultra lot 171113A BUD 12/28/17 label does not include Benzyl Benzoate as an ingredient in the final product, however it is listed in the compounded worksheet.*	No
102. Facility has documentation that procedures have been followed to ensure sterility, purity, correct identities and amounts of ingredients, and stability. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Inspection of Solution Dosage Forms and Review of Compounding Procedures]	Yes
103. CSP's are visually inspected for abnormal particulate matter and color, and intact containers and seals. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Inspection of Solution Dosage Forms and Review of Compounding Procedures]	Yes
104. Beyond Use Dates are assigned using direct stability-indicating assays or authoritative literature that supports the assigned BUD. [STORAGE AND BEYOND-USE DATING : Determining Beyond-Use Dates]	Yes
105. Storage time of assembled bag and vial systems are according to the manufacturer recommendations. (eg Minibag plus, Addvantage, Add-ease) [STORAGE AND BEYOND-USE DATING : Proprietary Bag and Vial Systems]	N/A

DISPENSING/DISTRIBUTION

106. Facility has written procedures for proper packaging, storage, and transportation conditions to maintain sterility, quality, purity, and strength of CSPs. [MAINTAINING STERILITY, PURITY, AND STABILITY OF DISPENSED AND DISTRIBUTED CSPs :]	
107. Modes of transport are used that maintain appropriate temperatures and prevent damage to CSPs. [MAINTAINING STERILITY, PURITY, AND STABILITY OF DISPENSED AND DISTRIBUTED CSPs : Packaging and Transporting CSPs]	
108. Facility provides a multiple component formal training program to ensure patients and caregivers understand the proper storage, handling, use, and disposal of CSPs. [PATIENT OR CAREGIVER TRAINING]	

POLICY/PROCEDURE

109. Written procedures detail cleaning and disinfecting the sterile compounding areas including cleansers, disinfectants, and non-shedding wipe and mop materials. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
110. A written procedure is in place for cleaning and disinfecting the Direct Compounding Areas. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
111. Facility has written procedures to verify correct identity, quality, amounts, and purities of ingredients used in CSPs. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Identity and Strength Verification of Ingredients]	Yes
112. Policies address packaging to maintain physical integrity, sterility, stability, and purity of CSPs. [MAINTAINING STERILITY, PURITY, AND STABILITY OF DISPENSED AND DISTRIBUTED CSPs : Packaging and Transporting CSPs]	Yes
113. Written standard procedures describe means for patients to ask questions and report concerns and adverse events with CSPs, and for compounding pharmacists to correct and prevent future problems. [PATIENT MONITORING AND ADVERSE EVENTS REPORTING]	Yes

RADIOPHARMACEUTICALS

114. Facility has appropriate primary engineering controls and radioactivity containment and shielding. Location of primary engineering controls permitted in ISO Class 8 controlled environment. [RADIOPHARMACEUTICALS AS CSPs]	
115. Radiopharmaceuticals prepared as low-risk level CSPs with 12-hour or less BUD are prepared in a segregated compounding area. Segregated compounding area is designated with a line of demarcation. [RADIOPHARMACEUTICALS AS CSPs]	
116. Technetium-99m/Molybdenum-99 generators are eluted in ISO Class 8 conditions. [RADIOPHARMACEUTICALS AS CSPs]	

MISCELLANEOUS

117. Facility engaged in office use sterile compounding for human use is registered with FDA as an outsourcing facility. [FAC 64B16-27.700 (3)(g]	Yes
118. Compounding records are properly maintained. [FAC 64B16-28.140(4)] *Zinc Sulfate 10mg/ml lot 171113C BUD 12/28/17 states SWI was used in compounding the CSP however label states bacteriostatic water for injection;*	No
119. When compounding activities require the manipulation of a patient's blood-derived or other biological material, the manipulations are clearly separated from routine material-handling procedures and equipment used in CSP preparation activities, and they are controlled by specific standard operating procedures in order to avoid any cross-contamination. [ENVIRONMENTAL QUALITY AND CONTROL : Placement of Primary Engineering Controls Within ISO Class 7 Buffer Areas]	N/A

SPECIAL PARENTERAL ENTERAL & EXTENDED SCOPE

120. Pharmacy technicians properly identified and supervised. [64B16-27.420, F.A.C.]	
121. Medication properly labeled. [465.0255, F.S.] [64B16-28.108, F.A.C.]	
122. Expired medications removed from the shelves. [64B16-28.110, F.A.C.]	
123. CQI Policy and Procedures and quarterly meetings. [766.101, F.S.] [64B16-27.300, F.A.C.]	
124. Prescriptions have the date dispensed and dispensing pharmacists. [893.04(1)(c) 6, F.S.] [64B16-28.140(3)(b), F.A.C.]	
125. Pharmacy maintains patient profile records. [64B16-27.800, F.A.C.]	
126. All controlled substance prescriptions contain information required. [893.04, F.S.]	
127. Prescriptions for controlled substances are on counterfeit-proof prescription pads or blanks purchased from a Department-approved vendor and the quantity and date meet the requirements of [456.42(2), F.S.].	
128. Controlled substance inventory taken on a biennial basis and available for inspection. [893.07(1)(a), F.S.]	
129. DEA 222 order forms properly completed. [893.07, F.S.]	
130. Controlled substance records and Rx information in computer system is retrievable. [21CFR 1306.22] [64B16-28.140, F.A.C.]	
131. Controlled substance records maintained for 4 years. [465.022(12)(b), F.S.]	
132. Certified daily log OR printout maintained. [21CFR 1306.22(b)(3)] [64B16-28.140(3)(b), F.A.C.]	

133. Pharmacy is reporting to the PDMP within 7 days of dispensing controlled substance. [893.055(4), F.S.]	
134. Pharmacy maintains invoices documenting that medicinal drugs were obtained from a Florida licensed distributor. 499.005 (14)	

Remarks:

Routine High risk SSCP inspection conducted with Umarani Rajalingam RPT and Jeff Goldrich Rph PDM.

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge. I have received a copy of the Licensee Bill of Rights.

Inspector Signature:

Date:12/19/2017

Representative:

Jeff Goldrich

Date:12/19/2017

Grossman, Furlow & Bayó, LLC
ATTORNEYS AT LAW

TO: Department of Health – Attn: Marsha Boatwright

FAX # 954-202-3254

DATE: January 3, 2018

FROM: Edwin Bayó

RE: Jeffrey S. Goldrich, R.Ph.; Case No.: 2017-23346
Hybrid Pharma, LLC; Case No.: 2017-23347

COMMENTS:

TOTAL NUMBER OF PAGES INCLUDING COVER LETTER: 3

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TELEPHONE: (850) 385-1314 **FACSIMILE: (850) 385-4240**

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Grossman, Furlow & Bayó, LLC
ATTORNEYS AT LAW

January 3, 2018

Marsha Boatwright, Investigator
Florida Department of Health
Division of MQA
1400 W. Commercial Blvd.
Ft. Lauderdale, FL 33309

VIA FAX: (954) 202-3254

Re: Jeffrey S. Goldrich, R.Ph., DOH Case No. 2017-23346

Dear Investigator Boatwright:

This firm and undersigned counsel have been retained to represent Jeffrey S. Goldrich, R.Ph., and to provide legal advice in relation to the subject investigation. Our client received your notice of investigation on or about December 29, 2017. Please direct any future contact with our client through me.

I returned to the office today after an extended holiday absence and am catching up on a number of matters. I briefly discussed with our client and have confirmed that a corrective action plan is being prepared and implemented. I expect to be able to file a supplemental response by early next week. In the meantime, please consider this letter as our request, pursuant to subsection 456.073(10), F.S., for a complete copy of the investigative file at the conclusion of the investigation. Our client agrees to maintain the confidentiality of all documents provided pursuant to this request and further agrees to pay appropriate costs for the copies provided.

Sincerely,

Edwin A. Bayó

cc: Jeffrey S. Goldrich, R.Ph.

HYBRID PHARMA PRODUCTION SHE

ASCORBIC ACID 500mG/mL SOLUTION INJECTABLE
PREPARATION DATE
BATCH SIZE
LOT#/ BATCH#
BEYOND USE DATE /Maximum BUD*
RPH INITIALS
RPT INITIALS

***Labelled BUD may be less than the Maxim**

MATERIALS REQUIRED:

Calibrated balance –
Stir plate /electric
Beakers with mark in it or suitable glas
Calibrated pH meter / pH indicator tape
Bubble point tester/filter integrity tester
Depyrogenated 30ml or 50ml amber via
Sterile rubber stoppers,

000054

Exhibit #5

ASCORBIC ACID 500mG/mL SOLUTION INJECTABLE		**ISO 7 Buffer Room**	
PREPARATION DATE	11/21/17	Temperature F [Range 68 -77F]	73
BATCH SIZE	10,000 ml	Humidity % [Range 30 -65%]	34
LOT#/ BATCH#	171121A	Particle Count /ft^3/ min [below 100]	1
BEYOND USE DATE /Maximum BUD*	5/21/18	Pressure Gauge [>0.02]" w.c	0.05
RPH INITIALS		**ISO 5 HOOD**	
RPT INITIALS		Pressure Gauge 0.5" w.c	0.5

***Labelled BUD may be less than the Maximum BUD**

MATERIALS REQUIRED:

Calibrated balance –	Weigh boats/ weighing beakers/ spatulas
Stir plate /electric	
Beakers with mark in it or suitable glassware	Depyrogenate all the glasswares and sterilize the tubes and accessories
Calibrated pH meter / pH indicator tape	Sterile 0.2micron membrane filters/ sterile capsule filter
Bubble point tester/filter integrity tester	Dose pump / Calibrated transfer pump/dispenser pump
Depyrogenated 30ml or 50ml amber vials	Sterile transfer tubes
Sterile rubber stoppers,	Wash with tap water, 2% disodium edetate solution, rinsing with distilled water. Autoclave stoppers.

ASCORBIC ACID 500MG/ML
LOT 171121A BUD 05/21/18
MFG 11/21/17

ASCORBIC ACID 500mG/mL SOLUTION INJECTABLE

	FORM	MEASURE	UNITS	NDC	LOT NUMBER	EXPIRY DATE	MEASURE	WEIGHT TAKEN	
TOTAL QUANTITY MADE	Liquid	**1000**	**mL**		17F29-U04-039329		10000		mL
ASCORBIC ACID, USP	Crystalline powder	**500**	**gm**	51552-0163-05 Fagron ✓	17E04-U04-037958 ✓	~~05/14/2019~~ 12/17/19 ✓	5000	5.000 kg	gm
BENZYL ALCOHOL, USP	Liquid	**9**	mL	38779-10298-04 Medisca ✓	140195C ✓	11/30/2018 ✓	90	90	mL
SODIUM HYDROXIDE NF	Powder	**112**	**GM**	62991-2061-022 LETCO ✓	1609060009 ✓	08/24/2018 ✓	1120	1.120 kg	gm
STERILE WATER FOR INJECTION USP	No color, clear liquid	**1000 [700]**	**mL**	0338001306 Baxter ✓	Y247353 ✓	9/30/2018 ✓	[6660] 10000ML	6.690 kg.	Ml,qs
Mixing speed	250 - 400 rpm	400	rpm		Mixing time	45 minutes	45 min		
Clarity in ~30 minutes	then mixed for 45 minutes								

1 gm ascorbic acid is in 1.125gm of ascorbic acid sodium.

COMPOUNDING/ PRODUCTION DIRECTIONS:

1. Measure and/or weigh accurately the required quantity for the total amount to be prepared.
2. Incorporate the solid into water and dissolve items and allowing complete dissolution for about 45 minutes.
3. Check pH 5.5 -7.0 and record pH; may adjust with dilute hydrochloric acid 10% or dilute sodium hydroxide 1% solution when the pH above 7.0 or below 5.5. Record the details.

DILUTE HYDROCHLORIC ACID 10% Fagron 15108U05026696 9/8/2018	SOLUTION	**QS, ml**
DILUTE SODIUM HYDROXIDE	SOLUTION	**Qs, ml**
pH OF THE FINISHED ASCORBIC ACID 500MG/ML SOLUTION	pHmeter 6.5	indicator strip

ASCORBIC ACID 500MG/ML
LOT 171121A BUD 05/21/18
MFG 11/21/17

MEMBRANE FILTRATION:

2. After pH adjustment, filter the solution through a 0.45 micron prefilter and a sterilized 0.22micron filter into a sterilized staging assembly- [sterile empty iv bag or suitable sterile container, 2 lit depyrogenated sterile bottle.] Sample and submit to qc.
3. Sterile 0.22micron filter and record the details below in the tables which represent during filtration.

ISO 7 Buffer Room			
Pressure Gauge [>0.02]" w.c	0.05	Temperature F [Range 68 -77F]	73
ISO 5 HOOD		Humidity % [Range 30 -65%]	34
Pressure Gauge 0.5" w.c	0.5	Particle Count /ft3/ min [below 100]	1

DETAILS OF 0.2 MICRON FILTER	MANFACTURER/LOT # MDI DKS-S Asepticap KS – gamma PES capsule Filter 1" (0.45 +0.2 micron) DK 82961 2018-10	BUBBLE POINT /FILTER INTEGRETY AFTER FILTRATION, PSI	53 psi Bes E

DISPENSING/ DOSING INTO VIALS:

4. After qc approval for pH, dispense into depyrogenated amber vials using the dispenser pump & sterile transfer tubes or using sterile and depyrogenated glass funnel and depyrogenated graduated jar.
5. Make sure the dispenser pump is calibrated to dispense the required volume before dispensing. An allowance of extra 3 % is allowed.
6. Use butyl or latex rubber stoppers previously sterilized in an autoclave to stopper the vials.
7. Sterile fill and stopper within ISO 5 designated hood under HEPA filter and the preparation should be prepared using strict aseptic techniques.
8. At the finish of compounding, take gloved fingertip sampling and gown sampling of the compounding personnel and submit for qc testing.
9. Record the number of vials made.
10. Storage: protect from light.
11. storage: refrigerate

CONFIDENTIAL

ASCORBIC ACID 500MG/ML
LOT 171121A BUD 05/21/18
MFG 11/21/17

HYBRID PHARMA PRODUCTION SHEET ASCORBIC ACID 500MG/ML INJECTABLE NDC: 26436-5001-50

000058

PROCESS DETAILS

GLASSWARES, TUBES & ACCESSORIES: AUTOCLAVED / DEPYROGENATED	✓	DISPENSING INTO VIALS; volume	50 mL
WEIGHING	~ 20 min	STOPPERING	~ 2hrs 30min
MIXING / MIXING TIME	~ 30+45min	CAPPING	
MEMBRANE FILTRATION /TRANSFER	Sterile 0.2μm	LABEL PRINTING	~ 15 min
FILTER INTEGRITY TESTING, HOLD PRESSURE		LABELLING IN THE VIALS	

Total hours 4 hrs 45 minutes. One edit during mixing. B

LABELS PRINTED WITH THE NOTE: STORAGE: PROTECT FROM LIGHT STORE AT +36° to 46° F (2° to 8° C)
10% of the total vials made will be submitted for Quality control and they will be divided into two portions. One half will be retained as retention samples.

INSPECTION STATION COMPLETED ✓
PARTICULATE CHECK ✓
VISUAL CONTAINER CLOSURE ✓
LABEL ACCURACY/PRINTING ✓
LABEL COUNT ✓

ASCORBIC ACID 500MG/ML
LOT 171121A BUD 05/21/18
MFG 11/21/17

CONFIDENTIAL

HYBRID PHARMA PRODUCTION SHEET ASCORBIC ACID 500MG/ML INJECTABLE NDC: 26436-5001-50

	Batch#	
TOTAL NUMBER OF FINISHED VIALS	199---x50ML	
NUMBER OF VIALS SUBMITTED FOR STERILITY TESTING.	10---x50ML	
NUMBER OF VIALS SUBMITTED FOR ENDOTOXIN ASSAY, pH	---1---x50ML	
REJECTED SAMPLES	8 5---x50ML	Reason:
RETAINED SAMPLES AT +36° to 46° F (2° to 8° C)	-5---x50ML	
NUMBER OF VIALS IN INVENTORY FOR SALES/DISPENSING –	-------x50ML	

(183)

QUALITY CONTROL:

		Centiel	BATCH #	
APPEARANCE	50 ml amber	Redcap	CLARITY	clear
COLOR	No color		PARTICLES	None.
		Limit:		DATE
pH	6.5	5.5 -7.0	PASS /FAIL	
ENDOTOXIN	<0.01EU/ml	2EU/mg	PASS /FAIL	
ASSAY	103%.	90 – 110%	PASS /FAIL	
STERILITY TEST			PASS /FAIL	
STERILITY TEST PREPARATION	11/21/17		STERILITY TEST BATCH RELEASING	12/4/17
BATCH RELEASED / BY			PASS	

CONFIDENTIAL

ASCORBIC ACID 500MG/ML
LOT 171121A BUD 05/21/18
MFG 11/21/17

Quality *Control*

Product Specification:	*Compounded*
Drug Form	*Injectable*
Sample Lot Number	
Preservative	*YES* NO
Storage	*2 – 8⁰ C*

Test Parameters	***Product Specification***
Appearance	Liquid
Packing Size	Amber Glass Vial 30ml 50mL --------ml
Appearance	
Color	
Clarity	Clear ✓
Particulate Matters	None ✓
Leak Proof/Cap Tight	Yes ✓
Quality & Purity: Grade Active Pharmaceutical Ingredients	USP NF
pH	
In house / Theoretical Calculated Assay	90 – 110 %
Label /BUD	2months 3 months 6months ----------
Custom Compounding/Drug Shortage/Dosage Form/Strength	----------/Yes/ same/ same
Manufacturer / Literature Reference / In house Testing Assay / Third party Testing	

Testing conducted in accordance with current Good Laboratory Practices.

Signed by Quality Control Date

ASCORBIC ACID 500MG/ML
LOT 171121A BUD 05/21/18
MFG 11/21/17
000060

ITEMS CHECK LIST	Batch Number	DEPYROGENATE OR AUTOCLAVE CYCLE
SPATULA		
OVERHEAD STIR ROD		
10000 ML FLASK		DP LB 152
100 ML CYLINDER		DP LB 146
250 ML BEAKER		DP LB 139
~~1000~~ 4000 ML BEAKER		DP LB 139
STERILE TRANSFER SET		Sterile Repeater Pump Fluid Transfer Tube set, Universal Spike –Luer Lock , REF: H93811 1225264 2020-03-31 ✓
0.2 µ STERILE FILTER		DKS-S Asepticap KS – gamma PES capsule Filter 1" (0.45 +0.2 micron) DK DK 82961 2018-10 ✓
50 ML VIAL AMBER		DP LB 150
FORCEPS/ TWEEZER		
RUBBER STOPPERS		20mm Ac 256
VIAL CAPS		Center Tear Red aluminum cap
CRIMPER		
TSA PLATES AIR		Hardy W64 26ML 15 X100mm, USP W64 H401705 2018-01-13 ✓
TSA PLATES SURFACE		Hardy P34 15X60mm TSA/Lec/Tween H402195 2017-12-31 ✓

CONFIDENTIAL

ASCORBIC ACID 500MG/ML
LOT 171121A BUD 05/21/18
MFG 11/21/17 00061

Label Printing, Tracking & Verification Log

Date:

Batch /Lot: ASCORBIC ACID 500MG/ML LOT 171121A BUD 05/21/18 MFG 11/21/17

Name: Size:

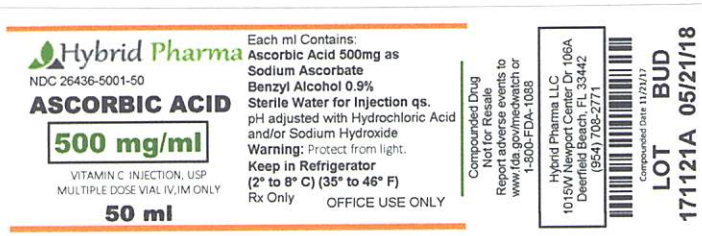
Total Labels Required = 199+3

Pre-Label Design check _____ (Signature)

Label Element	Checked
lot or batch number;	✓
dosage form and strength;	✓
quantity or volume	✓
date compounded;	✓
expiration date;	✓
storage and handling instructions;	✓

Total Labels Printed 202 Verified By _____

Complete after labeling operation



Label audit: Left over or short Labels NO_____ YES_____

If Yes Explain:

_____

Final Inspection by _____

Pass ✓ Fail _____

PALL Medical

Pall *PharmAssure* Pharmacy Filtration Devices

Syringe Filter (32 mm)

Pore Size Availability	0.2 µm, 0.45 µm, 1.2 µm, 5 µm
Housing	Acrylic
Membrane	Supor (hydrophilic polyethersulphone)
Effective Filtration Area	6.8 cm²
Connections	ISO Female Luer Lock Inlet ISO Male Luer Lock Outlet
Priming Volume	<1.0 mL
Typical Fluid Retention (with air purge)	<100 µL
Recommended Filtration Volume	<100 mL
Maximum Operating Temperature	50°C
Maximum Operating Pressure	75 psi (5.2 bar)
Endotoxin Level	<0.25 EU/mL (Limulus Amebocyte Lysate (LAL) test)
Biocompatibility	Components in fluid pathway meet USP Biological Reactivity Testing *in vivo* <88>
Sterilisation Method	Gamma irradiation

Typical Water Flow Rate at 45 psi (3.1 bar)	
HP4642	690 mL/min
HP4643	700 mL/min
HP4644	1700 mL/min
HP4645	2500 mL/min

Reorder Information

Product Code	Pore Size	Colour	Packaging
HP4642	0.2 µm	Blue/Blue	50/pkg
HP4643	0.45 µm	Red/Clear	50/pkg
HP4644	1.2 µm	Clear/Blue	50/pkg
HP4645	5 µm	Green/Green	50/pkg

Baxter

Supor® 32 mm 0.2 Micron Syringe Filter

REF H93824642

STERILE R

LOT 2016-629101

2019-10

Baxter Healthcare Corporation
14445 Grasslands Dr.
Englewood, CO 80112 USA

EC REP
Baxter Healthcare SA
8010 Zurich
Switzerland

Made in the UK. Manufactured by Pall Corporation for Baxter Healthcare Corporation.

PALL Medical

[illegible]
Telephone
Fax
Email

CE

*Filtration. Separation. Solution.*sm

Visit us on the web at www.pall.com

International Offices

HYBRID PHARMA

Air Temperature and Humidity, Differential Pressure — Documentation Form 47

Controlled Room Temperature: 20 - 25 deg.C (68- 77degF): Relative Humidity: 30 – 65%

October Date 2017	Air Temperature & Humidity % Clean Room F /%	Air Temperature & Humidity % Ante Room F /%	Air Temperature & Humidity % Prep/Staging Room F/%	Differ. Pressure >0.02"w.c			By
1.							
2.	70/40	72/35	74/32	5	5	7	B
3.	70/40	72/35	74/32	5	5	7	B
4.	70/41	72/35	74/32	5	5	7	B
5.	70/41	72/35	74/32	5	5	7	B
6.	70/41	72/35	74/32	5	5	7	B
7.							
8.							
9.	70/41	72/35	74/32	5	5	7	B
10.	70/41	72/35	74/31	5	5	7	B
11.	70/41	72/34	74/31	5	5	7	B
12.	70/41	72/35	74/31	5	5	7	B
13.	71/41	72/35	74/31	5	5	7	B
14.							
15.							
16.	70/41	72/35	74/31	5	5	7	B
17.	70/41	72/36	74/30	5	5	7	B
18.	70/40	72/34	74/30	5	5	7	B
19.	71/39	72/33	75/30	5	5	7	B
20.							
21.							
22.							
23.	70/40	72/35	75/30	5	5	7	B
24.	70/39	72/35	75/30	5	5	7	B
25.	70/39	71/35	74/29	5	5	7	B
26.	70/37	71/32	73/31	5	5	7	B
27.	70/36	71/32	71/31	5	5	7	B
28.							
29.							
30.	69/35	71/32	71/33	5	5	7	B
31.	70/35	71/32	73/30	5	5	7	B

APPROVED BY [signature] DATE 10/31/17

HYBRID PHARMA

Cleaning Maintenance Log: Laminar Hood/Buffer Room /Ante Room. FORM 73

Check Activity as completed

Month/ Year	Daily						Weekly	Monthly	Comments	By
Date	Waste Removal	Hood/ SST #1 & 2		Dry/ Wet Mop Floor	SST #3	Tacky Mat/as usage& soiled	Lyophilizer	Stationary Cart Walls/ Ceiling		
1.										
2.	✓	✓	✓	✓	✓	✓			Peridoxon	B
3.	✓	✓	✓	✓	✓	✓			↓	B
4.	✓	✓	✓	✓	✓	✓				B
5.	✓	✓	✓	✓	✓	✓				B
6.	✓	✓	✓	✓	✓	✓	✓			B
7.										
8.										
9.	✓	✓	✓	✓	✓	✓				B
10.	✓	✓	✓	✓	✓	✓				B
11.	✓	✓	✓	✓	✓	✓				B
12.	✓	✓	✓	✓	✓	✓				B
13.	✓	✓	✓	✓	✓	✓	✓			B
14.										
15.										
16.	✓	✓	✓	✓	✓	✓				B
17.	✓	✓	✓	✓	✓	✓				B
18.	✓	✓	✓	✓	✓	✓				B
19.	✓	✓	✓	✓	✓	✓	✓			B
20.										
21.								↑		
22.									Peridoxon	
23.	✓	✓	✓	✓	✓	✓		↓		B
24.	✓	✓	✓	✓	✓	✓				B
25.	✓	✓	✓	✓	✓	✓				B
26.	✓	✓	✓	✓	✓	✓				B
27.	✓	✓	✓	✓	✓	✓	✓			B
28.										
29.										
30.	✓	✓	✓	✓	✓	✓				B
31.	✓	✓	✓	✓	✓	✓				B

Cleaning Maintenance Log: Laminar Flow Hood / SST #1 /SST #2

APPROVED BY **DATE** 10/31/17

HYBRID PHARMA

Cleaning Maintenance Log: Preparation/Staging Room. Check Activity as completed FORM 78

Month/ Year	Daily				Weekly	External	Monthly	Comments	By
Date	Waste Removal/Sink	SST#4 SINK COUNTER		Dry/Wet Mop Floor	Tacky Mat/as usage& soiled	Autoclave Isolator	Stationary Cart Walls/ Ceiling		
1. 2	✓	✓	✓	✓	✓			Peridex	B
2.								↓	
3.	✓	✓	✓	✓	✓				B
4.	✓	✓	✓	✓	✓				B
5.	✓	✓	✓	✓	✓				B
6.	✓	✓	✓	✓	✓	✓			B
7.									
8. 9	✓	✓	✓	✓	✓				B
9. 10	✓	✓	✓	✓	✓				B
10. 11	✓	✓	✓	✓	✓				B
11. 12	✓	✓	✓	✓	✓				B
12.	✓								
13.	✓	✓	✓	✓	✓	✓			B
14.									
15.									
16.	✓	✓	✓	✓	✓				B
17.	✓		✓	✓	✓				B
18.	✓	✓	✓	✓	✓				B
19.	✓	✓	✓	✓	✓	✓			B
20.									
21.									
22.									
23.	✓	✓	✓	✓	✓				B
24.	✓	✓	✓	✓	✓				B
25.	✓	✓	✓	✓	✓				B
26.	✓	✓	✓	✓	✓				B
27.	✓	✓	✓	✓	✓	✓			B
28.									
29.									
30.	✓	✓	✓	✓	✓				B
31.	✓	✓	✓	✓	✓			Peridex	B

APPROVED BY JAL **DATE** 10/31/17

Cleaning Maintenance Log: Biological Safety Cabinet/ Buffer Room 2. **FORM 73A**

Check Activity as completed

Month/ Year				Daily			Weekly	Monthly	Comments	By
Date	**Temp °F**	**% Humidity**	**Br "w.c Pressure**		**Dry/ Wet mop Floor**	**Waste removal**	**Balance enclosure**	**Stationary cart walls/ ceiling**		
1.										
2.	70	35	-0.03		✓	✓			Pendant	B
3.	70	35	-0.03		✓	✓			↓	B
4.	70	35	-0.03		✓	✓				B
5.	70	35	-0.03		✓	✓				B
6.	70	35	-0.03		✓	✓	✓			B
7.										
8.										
9.	70	35	-0.03		✓	✓				B
10.	70	35	-0.03		✓	✓				B
11.	70	35	-0.03		✓	✓				B
12.	69	38	-0.03		✓	✓				B
13.	68	36	-0.03		✓	✓	✓			B
14.										
15.										
16.	69	36	-0.03		✓	✓				B
17.	69	35	-0.03		✓	✓				B
18.	68	36	-0.03		✓	✓				B
19.	68	35	-0.03		✓	✓	✓			B
20.										
21.										
22.										
23.	68	35	-0.03"		✓	✓				B
24.	69	35	-0.03"		✓	✓				B
25.	68	35	-0.03"		✓	✓				B
26.	68	35	-0.03"		✓	✓				B
27.	69	33	-0.03"		✓	✓	✓			B
28.										
29.										
30.	69	33	-0.03"		✓	✓				B
31.	70	33	-0.03"		✓	✓				B

490000

HYBRID PHARMA

10/31/17

Compounded zinc sulfate 10mg/ml injectable

NDC# 26436-0102-15

Master Formula Sheet

Total Quantity made

RPT initials

Date	11/13/17
Lot Number	1711 13C
BUD	12/28/17
RPh initials	

		100	ml	Manufacturer /NDC	Lot#	Expiry Date	300	ml	
Zinc Sulfate,usp [monohydrate]	Powder	1	gm	38779010289/Medisca	14203A	10/31/2018	3	gm	2.977gm
Benzyl alcohol	Liquid	0.9	ml	3877910298	140195C	11/30/2018	2.7	ml	2.7ml
Sterile water for Injection	liquid	100	ml, qs	0338001304/Baxter	Y240903	7/31/2018	300	ml	300ml

Method of Preparation:

1. Calculate the required quantity of each ingredient for the total amount to be prepared.
2. Accurately weigh and/or measure each ingredient
3.[Incorporate benzyl alcohol in about 95% of sterile water for injection and mix well if you use benzyl alc
4. Adjust the pH with sodium bicarbonate if need to adjust.
5. Sterile filter through an appropriate 0.22micron filter into suitable sterile containers
6. QS to total volume , Record pH
7. Dispense sterile amber vials.
8. Stopper within ISO 5 designated Work space.
9. Record the number of vials made.
10. autoclave at 121 deg.C For 15 minutes for batches more than 25 vials.

INSPECTION STATION COMPLETED
PARTICULATE CHECK
VISUAL CONTAINER CLOSURE
LABEL ACCURACY/PRINTING
LABEL COUNT

All glassware, glass and ceramic mortars and pestles should be sterilized.

This preparation should be prepared in a laminar flow hood in a cleanroom using strict aseptic technique.

Sterile depyrogenated Glass vials BUD 45 Days

Storage: Frozen

Color	No color	Temperature F	72
Clarity	clear	Humidity %	37
Appearance	30 mlamb	Particle count/ft3/min	1
Cap		ISO 5 hood"w.c	0.5
Filter Integrity		BR "w.c	0.05

Red cookie tear

Wipe the items brought into ISO 5 Hood with 70% sterile IPA
Wipe the ISO 5 Hood surface with sterile 70% IPA before start of compounding, between batches and during compounding every 30 minutes.
Filter Details: 0.2 micron Supor Sterile 2017 632801 2020 02 Bubble Point 57 psi Pass
Baxter H93824642
Number of vials Made: 10X 30 ml
Depyrogenation/Autoclave Cycles: DPLB1465 AC260

Compounded zinc sulfate 10mg/ml injectable

NDC# 26436-0102-15

Master Formula Sheet

Total Quantity made RPT initials

Date	11/13/17
Lot Number	171113C
BUD	12/28/17
RPh initials	Joel

		100	ml	Manufacturer /NDC	Lot#	Expiry Date	300	ml	
Zinc Sulfate,usp [monohydrate]	Powder	1	gm	38779010289/Medisca	14203A	10/31/2018	3	gm	2.977gm
Benzyl alcohol	Liquid	0.9	ml	3877910298	140195C	11/30/2018	2.7	ml	2.7ml
Sterile water for Injection	liquid	100	ml, qs	0338001304/Baxter	Y240903	7/31/2018	300	ml	300ml

Method of Preparation:

1. Calculate the required quantity of each ingredient for the total amount to be prepared.
2. Accurately weigh and/or measure each ingredient
3.[Incorporate benzyl alcohol in about 95% of sterile water for injection and mix well if you use benzyl alc
4. Adjust the pH with sodium bicarbonate if need to adjust.
5. Sterile filter through an appropriate 0.22micron filter into suitable sterile containers
6. QS to total volume , Record pH
7. Dispense sterile amber vials.
8. Stopper within ISO 5 designated Work space.
9. Record the number of vials made.
10. autoclave at 121 deg.C For 15 minutes for batches more than 25 vials.

INSPECTION STATION COMPLETED
PARTICULATE CHECK
VISUAL CONTAINER CLOSURE
LABEL ACCURACY/PRINTING
LABEL COUNT

All glassware, glass and ceramic mortars and pestles should be sterilized.

This preparation should be prepared in a laminar flow hood in a cleanroom using strict aseptic technique.

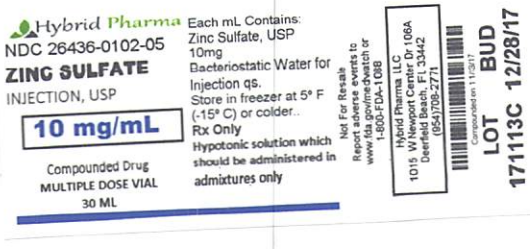
Sterile depyrogenated Glass vials BUD 45 DAYS

Storage: Frozen

Color	No color	Temperature F	72
Clarity	clear	Humidity %	37
Appearance	30 lamb	Particle count/ft3/min	1
Cap	Red centre tear	ISO 5 hood"w.c	0.5
Filter Integrity		BR "w.c	0.05

Wipe the items brought into ISO 5 Hood with 70% sterile IPA
Wipe the ISO 5 Hood surface with sterile 70% IPA before start of compounding, between batches and during compounding every 30 minutes.
Filter Details: 0.2 micron Supor Sterile 2017 632801 2020 02
Baxter H93824642
Number of vials Made: 10X 30 ml
Depyrogenation/Autoclave Cycles: DPLB1465 AC260

Bubble Point 57 psi Pass



Compounded Nandrolone decanoate 200mg/ml in oil injectable

26436-5022-XX (05 & 10)

RPT initials

Date	11/13/17
Lot#	171113A
BUD	12/28/17
RPh Initials	

Temperature deg.F	70
Humidity %	33
Biological Safety Cabinet, ISO 5 Hood	✓

B. R "w.c - 0.03

	100	ml	Lot #	Exp.Date	Manufacturer/NDC	50	ml	
Nandrolone Decanoate	20	gm	110316-1	9/21/2021	58597-0081-6/API	10	gm	9.98gm
Oil mixture stock solution:	90	gm	171107Y	5/10/18	HP	45	gm	45gm

1. Dissolve all the powders in benzyl alcohol and oil mixture.

Filter through 0.2 micron.

Use Sterile glass vials for the preparation and the preparation is carried out in Sterile compounding Room BR2 , Hood.

Use sterile rubber stoppers.

Dispense 10 ml in each amber vial and seal them

All the activities are carried out asceptically in ISO 5 hood in Biological safety cabinet.

Oil mixture stock solution: for 100ml Nan.deca 200mg solution

Benzyl Benzoate	30	gm	Medisca/3877910311	140026A	8/30/2018	
Benzyl alcohol	0.945	gm	Medisca 38779102984	140195C	11/30/2018	
Grapeseed oil	54	gm	Medisca/3877920891	138715A	9/30/2018	

All the activities are carried out asceptically in ISO 5 hood

Store frozen 45 Days

Membrane Filteration Syringe Filter:

0.2 micron sterile

~~Asepticap KS gamma IKS-S~~

Sterile Baxter 2017 632801

B

~~2016429101 2019/10~~

2020 02

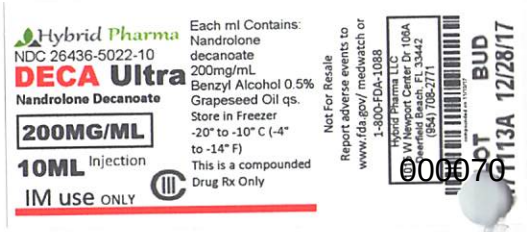
Bubble point 57 psi Pass B

Autoclave
Depyrogenation DP-B146; AC 260
5x 10ml amber green cerise team
Finished Product
Filter Integrity

Wipe the items brought into ISO 5 Hood with 70% sterile IPA

Wipe the ISO 5 Hood surface with sterile 70% IPA before start of compounding, between batches and during compounding every 30 minutes.

INSPECTION STATION COMPLETED ✓
PARTICULATE CHECK ✓
VISUAL CONTAINER CLOSURE ✓
LABEL ACCURACY/PRINTING ✓
LABEL COUNT



Enviro-Air Viable Microorganism Monitoring: Collection of samples **FORM 69Rev1**

DATE 7/10/17	Air collection for viable microorganism monitoring	
LOCATION (circle)	Buffer Room1 /Buffer Room 2/Ante Room/ Prep Room/ LAFH/ Biosafety Hood	Particle count/ft3/min
TEMPERATURE, F 74	HUMIDITY, % 35%	Differential Pressure reading "w.c -0.03 in BR2

		FORCED AIR PUMP	
PUMP READING (A)	29--Litres/min	A6 Viable Microbial Partial Sampler 29 LPM Pump	35 minutes
Collection Time (T)	35 minutes		Incubator Temp
Details of the Plate	Malt Extract Agar	17146 P 2017 08 24	26°C
Incubator Temp	26-30°C	79-86 F (26)	Cfu = 0 7/17/17
Number of occupants during testing		(1)	
Activities			
No compounding			
INCUBATION (circle)	IN-HOUSE	THIRD PARTY LAB	

Total volume of air collected = Pump reading (A) lit/min X collection Time(T)

$$\text{Total cfu/1000 lit} = \frac{\text{Cfu in plate X 1000lit}}{\text{Total volume of air collected in lit.}} = 0 \text{ cfu}$$

Enviro-Air Viable Microorganism Monitoring: Collection of samples by Impaction Air Sampler and Action levels for air microbial contamination.

Location		ISO CLASS 5	ISO CLASS 7	ISO CLASS 8
Action Level Cfu		>1	>10	>100
cfu			0	
Pass/Fail			Pass	
Air volume collected.			1015 lit	

Negative MEA Plate 17146P 2017 08 24 (27)
at 26°C

B
7/17/17

Enviro-Air Viable Microorganism Monitoring: Collection of samples **FORM 69**Rev1

DATE 7/10/17	Air collection for viable microorganism monitoring	
LOCATION (circle)	Buffer Room1 /Buffer Room 2/Ante Room/ Prep Room/ LAFH/ Biosafety Hood	Particle count/ft3/min
TEMPERATURE, F	HUMIDITY, %	Differential Pressure reading "w.c
75	35	−0.03 in BR2

		FORCED AIR PUMP	
PUMP READING (A)	29 --Litres/min	A6 Viable Microbial Partial Sampler 29 LPM Pump	
Collection Time (T)	35 minutes		35 minutes
Details of the Plate	Malt Extract Agar	17146 P 2017 08 24	Hardy 440
Incubator Temp:	26-30°C 5-7 days	79-86F (21)	at 26°C
Number of occupants during testing		(1)	cfu = ∅ 7/17/17
Activities			
No compounding			
INCUBATION (circle)	IN-HOUSE	THIRD PARTY LAB	

Total volume of air collected = Pump reading (A) lit/min X collection Time(T)

Total cfu/1000 lit = Cfu in plate X 1000lit / Total volume of air collected in lit.

∅ cfu in 29 x 35 lit

Enviro-Air Viable Microorganism Monitoring: Collection of samples by Impaction Air Sampler and Action levels for air microbial contamination.

Location		ISO CLASS 5	ISO CLASS 7	ISO CLASS 8
Action Level Cfu		>1	>10	>100
cfu		∅		
Pass/Fail		Pass		
Air volume collected.		1015 lit		

B. 7/17/17

Enviro-Air Viable Microorganism Monitoring: Collection of samples **FORM 69Rev1**

DATE 7/10/17	Air collection for viable microorganism monitoring	
LOCATION (circle)	Buffer Room1 /Buffer Room 2/Ante Room/ Prep Room/ LAFH/ Biosafety Hood	Particle count/ft3/min 3 in BR1
TEMPERATURE, F 75	HUMIDITY, % 35	Differential Pressure reading "w.c 0.03 in BR1

		FORCED AIR PUMP	
PUMP READING (A)	29--Litres/min	A6 Viable Microbial Partial Sampler 29 LPM Pump	
Collection Time (T)	35 minutes		35 minutes
Details of the Plate	Malt Extract Agar	17146 P 2017 0824	Hardy 440
Incubator Temp:	26 - 30°C 5-7 days	79 - 86F (22)	at 26°C
Number of occupants during testing		(1)	cfu's = Ø 7/17/17
Activities			
No compounding			
INCUBATION (circle)	IN-HOUSE	THIRD PARTY LAB	
Total volume of air collected = Pump reading (A) lit/min X collection Time(T)			
Total cfu/1000 lit = Cfu in plate X 1000lit / Total volume of air collected in lit.			Ø

Enviro-Air Viable Microorganism Monitoring: Collection of samples by Impaction Air Sampler and Action levels for air microbial contamination.

Location		ISO CLASS 5	ISO CLASS 7	ISO CLASS 8
Action Level Cfu		>1	>10	>100
cfu		Ø		
Pass/Fail		Pass		
Air volume collected.		1015 lit		

E
7/17/17

Enviro-Air Viable Microorganism Monitoring: Collection of samples **FORM 69**Rev1

DATE 7/10/17	Air collection for viable microorganism monitoring	
LOCATION (circle)	Buffer Room1 /Buffer Room 2/Ante Room/ Prep Room/ LAFH/ Biosafety Hood	Particle count/ft3/min 3
TEMPERATURE, F	HUMIDITY, %	Differential Pressure reading "w.c
75	35	0.04

		FORCED AIR PUMP	
PUMP READING (A)	29--Litres/min	A6 Viable Microbial Partial Sampler 29 LPM Pump	
Collection Time (T)	35 minutes		35 minutes
Details of the Plate	Malt Extract Agar	17146 P 2017 08 24	Hardy 440
Incubator Temp:	26 - 30°C 5 - 7 days	(23)	at 26°C
Number of occupants during testing		(1)	Cfu = ø 7/17/17
Activities			
No compounding. few times		Open the door and entry & exit	
INCUBATION (circle)	IN-HOUSE	THIRD PARTY LAB	

Total volume of air collected = Pump reading (A) lit/min X collection Time(T)

Total cfu/1000 lit = $\frac{\text{Cfu in plate X 1000lit}}{\text{Total volume of air collected in lit.}}$ ø

Enviro-Air Viable Microorganism Monitoring: Collection of samples by Impaction Air Sampler and Action levels for air microbial contamination.

Location		ISO CLASS 5	ISO CLASS 7	ISO CLASS 8
Action Level Cfu		>1	>10	>100
cfu			ø	
Pass/Fail			Pass	
Air volume collected.			1015 lit	

7/17/17

Enviro-Air Viable Microorganism Monitoring: Collection of samples **FORM 69**Rev1

DATE 4/10/17	Air collection for viable microorganism monitoring		
LOCATION (circle)	Buffer Room1 /Buffer Room 2/Ante Room/ Prep Room/ LAFH/ Biosafety Hood		Particle count/ft3/min 6
TEMPERATURE, F	HUMIDITY, %	Differential Pressure reading "w.c	
75	35	0.03	

		FORCED AIR PUMP	
PUMP READING (A)	29 --Litres/min	A6 Viable Microbial Partial Sampler 29 LPM Pump	
Collection Time (T)	35 minutes		35 minutes
Details of the Plate	Malt Extract Agar	171468 2017 08 24	Hardy 440.
Incubator Temp.	26 – 30°c 5 – 7 days	(24)	at 26°C
Number of occupants during testing		(1)	0 cfu 7/17/17
Activities			
No activities; Just pass through the doors few times.			
INCUBATION (circle)	IN-HOUSE	THIRD PARTY LAB	
Total volume of air collected = Pump reading (A) lit/min X collection Time(T)			
Total cfu/1000 lit = Cfu in plate X 1000lit / Total volume of air collected in lit.			0 cfu Pass 7/17/17

Enviro-Air Viable Microorganism Monitoring: Collection of samples by Impaction Air Sampler and Action levels for air microbial contamination.

Location		ISO CLASS 5	ISO CLASS 7	ISO CLASS 8
Action Level Cfu		>1	>10	>100
cfu			0	
Pass/Fail			Pass	
Air volume collected.			1015 lit	

7/17/17

Enviro-Air Viable Microorganism Monitoring: Collection of samples **FORM 69**Rev1

DATE 7/10/17	Air collection for viable microorganism monitoring		
LOCATION (circle)	Buffer Room1 /Buffer Room 2/Ante Room/ (Prep Room)/LAFH/ Biosafety Hood		Particle count/ft3/min
TEMPERATURE, F	HUMIDITY, %	Differential Pressure reading "w.c	
75	31%.	0.07"	

		FORCED AIR PUMP	
PUMP READING (A)	~~29~~ --Litres/min	A6 Viable Microbial Partial Sampler 29 LPM Pump	
Collection Time (T)	35 minutes		35 minutes
Details of the Plate	Malt Extract Agar	171468 2017-08-	24 Hardy 440
Temperature of Incubator 26-30°C 5-7days		(25) at	26°C
Number of occupants during testing		One, sometimes two.	Cfu's = 0
Activities			7/11/17
No compounding activities. Organising the shelving items.			
INCUBATION (circle)	(IN-HOUSE)	THIRD PARTY LAB	
Total volume of air collected = Pump reading (A) lit/min X collection Time(T)			
Total cfu/1000 lit = Cfu in plate X 1000lit / Total volume of air collected in lit.		0 cfu	

Enviro-Air Viable Microorganism Monitoring: Collection of samples by Impaction Air Sampler and Action levels for air microbial contamination.

Location		ISO CLASS 5	ISO CLASS 7	ISO CLASS 8
Action Level Cfu		>1	>10	>100
cfu				0
Pass/Fail				Pass
Air volume collected.				1015 lit

HYBRID PHARMA **ENVIRONMENTAL MONITORING / SAMPLING FOR VIABLE**

FORM: ENV70A **AIR SAMPLING FOR VIABLE USING SETTLE PLATES**

Date	**Details of Plate, Lot#, Expiry** TSA 26ml, USP, W64	H-17159 2017-09-26 ✓	**Details of Collection Settle air**		**Incubation 30- 35 ^{0} C 86-95 ^{0} F 48-72 hrs.**		**Pass** / **Fail**
Location			**By**	8	**CFU**	**Date**	By
Laminar flow hood	16	ISO 5 ✓		7/10/17	ø	7/13/17	
Top of lyophilizer front door		Buffer room 1		38°C	ø		
Stainless steel table #2	17	Buffer room 1 ✓			ø		
Next to wall grid #1		Buffer room 1			ø		
Stainless steel table #5	18	Buffer room 2 ✓			ø		
Stainless steel table #3	19	Ante room ✓			ø		
Next to wall grid #3		Ante room			ø		
Stainless steel table #4	20	Prep./staging room ✓			ø		
Counter		Prep./staging room					

	Gloved fingertips L		Post sample collection		
	Gloved Fingertip R		Post sample collection		
	Negative		Post sample collection		

APPROVED BY

HYBRID PHARMA

ENVIRONMENTAL

	Date	Details of Plate, Lot#, Expiry	H-TSA w/ L/T H-17118 2017-08-16 ✓	Su	co	By
	Location					
1	Laminar flow hood ✓		ISO 5, Buffer room 1			
2	Stainless steel table #2 ✓		Buffer room 1			
3	Stainless steel table #1 ✓		Buffer room 1			
4	Entrance Floor ✓		Buffer room 1			
5	Stainless steel table #5, ✓		Buffer room 1			
6	Stainless steel table #3 ✓		Ante room			
7	Traffic Floor ✓		Ante room			
8	Stainless steel table #4 ✓		Prep./staging room			
9	Entrance Floor ✓		Prep./staging room			
10	Biosafety Hood ✓		ISO 5, Buffer room 2			
11	Entrance Floor ✓		Buffer room 2			
12	Stainless Steel Table #6	Buffer room 2				
13	✓ Gloved fingertips L	H-TSA w/ L/T H-17118 2017-08-1				
14	✓ Gloved Fingertip R	H-TSA w/ L/T H-17118 2017-08-1				
15	✓ Negative	H-TSA w/ L/T H-17118 2017-08-1				

FORM 70E

APPROVED BY

000078

HYBRID PHARMA

ENVIRONMENTAL MONITORING

	Date / Location	Details of Plate, Lot#, Expiry	H-TSA w/ L/T H-17118 2017-08-16	Surface sampling- contact/ swab/ By	Incub. Temp.	Incubation 30-35 °C / 86 -95 °F 48-72 hrs CFU/ plate	Start Date	End Date	Pass / Fail By
1	Laminar flow hood ✓		ISO 5, Buffer room 1			Ø		7/13/17	
2	Stainless steel table #2 ✓		~~Buffer room 1~~			Ø			
3	Stainless steel table #1 ✓		Buffer room 1			Ø			
4	Entrance Floor ✓		Buffer room 1			Ø			
5	Stainless steel table #5, ✓		Buffer room 1			Ø			
6	Stainless steel table #3 ✓		Ante room			Ø			
7	Traffic Floor ✓		Ante room			Ø			
8	Stainless steel table #4 ✓		Prep./staging room			Ø			
9	Entrance Floor ✓		Prep./staging room			1			
10	Biosafety Hood ✓		ISO 5, Buffer room 2			Ø			
11	Entrance Floor ✓		Buffer room 2			1			
12	Stainless Steel Table #6 ✓		Buffer room 2						
13	Gloved fingertips L ✓		H-TSA w/ L/T H-17118 2017-08-16		Post sample collection			Ø	
14	Gloved Fingertip R ✓		H-TSA w/ L/T H-17118 2017-08-16		Post sample collection			Ø	
15	Negative ✓		H-TSA w/ L/T H-17118 2017-08-16		Post sample collection			Ø	

7/10/17 33°C 7/10/17 33°C 7/10/17

FORM 70E

APPROVED BY

EMLab P&K
6301 NW 5th way, Suite#: 1410, Ft. Lauderdale, FL 33309
(866) 871-1984 Fax (954) 776-8485 www.emlab.com

Client: Hybrid Pharma
C/O: Dr. Ponswamy Ragalingam
Re: Form 69 Rev. 1; LAFH, ISO 5 Environmental
Air
Sampling

Date of Sampling: 08-10-2017
Date of Receipt: 08-11-2017
Date of Report: 08-15-2017

USP 797 - Summary of Sample Analysis Results

The summary information for each sample includes a Pass/Fail result with respect to the USP 797 action level guidelines for concentration of colony forming units (see *Table 1*) and actionable microorganisms (United States Pharmacopeia, 2014). Actionable microorganisms are defined here as Gram-negative bacteria, coagulase-positive Staphylococcus, molds, and yeasts.

Table 1: Recommended Action Levels for Viable Particles in Air and from Surfaces

ISO Class	Active Airborne (cfu*/m3)	Inanimate Surfaces** (cfu/plate)
5	>1	>3
7	>10	>5
8+	>100	>100

* cfu = colony forming units
** Contact plate areas vary from 24 to 30 cm2. When swabbing is used in sampling, the area covered should be at least 24 cm2 but no larger than 30 cm2.

Pass Acceptable concentrations and absence of actionable microorganisms
Fail Unacceptable concentrations and/or presence of actionable microorganisms
N/A Not applicable. Blank Sample and/or no ISO Class area designation provided¥

Location	Media	Type	Total CFU†	Colony Identification§	ISO Class	Performance vs. USP 797 Guidelines‡
HP0810A:Hood Air	TSA	Air	< 1	No colonies detected	5	Pass
HP0810S:Hood Surface	TSA w/ Lecithin & Tween	Surface	ND	No colonies detected	5	Pass

REFERENCE: United States Pharmacopeia and National Formulary Chapter <797> (USP 35-NF 30). Rockville, MD: United States Pharmacopeial Convention; 2014:40-84.
¥ Samples that would otherwise pass in relationship to concentration and actionable microorganisms will always report as N/A when one or more bacterial colonies in the sample are identified as Other Bacteria.
† The Total CFU value reported in this column is the Total CFU/unit value for the entire sample. For details, refer to the detailed results page of each sample in this report. In order to calculate Total CFU/unit values for air sample types, an air volume must be provided. Air samples without air volumes provided are reported as N/A (Not Applicable). A reported value of ND indicates none detected.
§ Actionable microorganisms reported in Bold font when detected.
‡ As stated in USP 797, the recommended action level table and actionable microorganism list are for guidance purposes only.

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Client: Hybrid Pharma
C/O: Dr. Ponswamy Ragalingam
Re: Form 69 Rev. 1; LAFH, ISO 5 Environmental Air Sampling

Date of Sampling: 08-10-2017
Date of Receipt: 08-11-2017
Date of Report: 08-15-2017

USP 797 - Detail Sample Analysis Results

Location:	HP0810A:Hood Air	
Comments (see below)	A	
Area Designation	ISO Class 5	
Sample type	Andersen sample	
Media used	TSA	
Lot#/Expiration date	H17159/9-26-2017	
Lab ID-Version‡:	8296042-1	
Analysis Date	8-15-2017	
Incubation	30° - 35°C for 2-3 days	
	raw ct.	cfu*/m3
§Total	ND	< 1
Sample size	1015 liter	
Positive Hole	0	

*cfu = colony forming units Positive hole correction chart used for all calculations ND = none detected
Comments: A) No impaction marks detected.

Identifiers listed without a count or data entry were not detected during the course of the analysis for the respective sample.

Note: Interpretation is left to the company and/or persons who conducted the field work. Some rare strains of Staphylococcus produce free (unbound) coagulase exclusively. The applied coagulase test only measures bound coagulase.

The limit of detection is a raw count of 1. The analytical sensitivity for air samples is equal to 1 raw count divided by sample size and multiplied by the positive hole correction factor. The analytical sensitivity for surface samples is equal to 1 raw count divided by a sample size of 1 plate.

‡ A "Version" indicated by -"x" after the Lab ID# with a value greater than 1 indicates a sample with amended data. The revision number is reflected by the value of "x".
§ Total cfu/unit has been rounded to two significant figures to reflect analytical precision.

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Client: Hybrid Pharma
C/O: Dr. Ponswamy Ragalingam
Re: Form 69 Rev. 1; LAFH, ISO 5 Environmental Air Sampling

Date of Sampling: 08-10-2017
Date of Receipt: 08-11-2017
Date of Report: 08-15-2017

USP 797 - Detail Sample Analysis Results

Location:	HP0810S:Hood Surface	
Comments (see below)	None	
Area Designation	ISO Class 5	
Sample type	Contact plate	
Media used	TSA w/ Lecithin & Tween	
Lot#/Expiration date	H17205/10-22-2017	
Lab ID-Version‡:	8296043-1	
Analysis Date	8-15-2017	
Incubation	30° - 35°C for 2-3 days	
	raw ct.	cfu*/plate
§Total	ND	ND

*cfu = colony forming units ND = none detected

Comments:

Identifiers listed without a count or data entry were not detected during the course of the analysis for the respective sample.

Note: Interpretation is left to the company and/or persons who conducted the field work. Some rare strains of Staphylococcus produce free (unbound) coagulase exclusively. The applied coagulase test only measures bound coagulase.

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‡ A "Version" indicated by -"x" after the Lab ID# with a value greater than 1 indicates a sample with amended data. The revision number is reflected by the value of "x".
§ Total cfu/unit has been rounded to two significant figures to reflect analytical precision.

EMLab P&K
A TestAmerica Company

Report for:

Dr. Ponswamy Ragalingam
Hybrid Pharma
1015 W Newport Center Drive #106A
Deerfield Beach, FL 33442

Regarding: Project: Form 69 Rev. 1; LAFH, ISO 5 Environmental Air Sampling
EML ID: 1775246

Approved by:

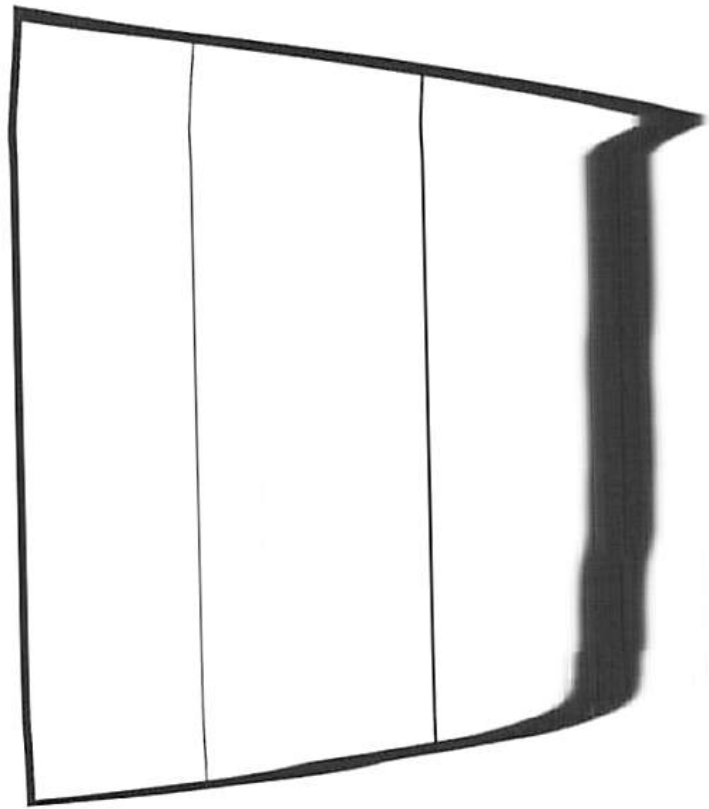
Technical Manager
Balu Krishnan

Dates of Analysis:
USP 797 Count & ID 30-35C: 08-15-2017

Service SOPs: USP 797 Count & ID 30-35C (EM-USP-S-2082, EM-USP-S-2081, EM-BT-S-1576)

All samples were received in acceptable condition unless noted in the Report Comments portion in the body of the report. Due to the nature of the analyses performed, field blank correction of results is not applied. The results relate only to the items tested.

EMLab P&K ("the Company") shall have no liability to the client or the client's customer with respect to decisions or recommendations made, actions taken or courses of conduct implemented by either the client or the client's customer as a result of or based upon the Test Results. In no event shall the Company be liable to the client with respect to the Test Results except for the Company's own willful misconduct or gross negligence nor shall the Company be liable for incidental or consequential damages or lost profits or revenues to the fullest extent such liability may be disclaimed by law, even if the Company has been advised of the possibility of such damages, lost profits or lost revenues. In no event shall the Company's liability with respect to the Test Results exceed the amount paid to the Company by the client therefor.



CHAIN OF CUSTODY

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EMLab P&K
A TestAmerica Company

New Jersey: 3000 Lincoln Drive East, Suite A, Marlton, NJ 08053 * **(866) 871-1984**
Phoenix, AZ: 1501 West Knudsen Drive, Phoenix, AZ 85027 * **(800) 651-4802**
SSF, CA: 6000 Shoreline Court, Suite 205, South San Francisco, CA 94080 * **(866) 888-6653**

Weather		Fog	Rain	Snow	Wind	Clear
Level	None	☐	☐	☐	☐	☐
	Light	☐	☐	☐	☐	
	Moderate	☐	☐	☐	☐	
	Heavy	☐	☐	☐	☐	

CONTACT INFORMATION

Company:	Hybrid Pharma	Address:	1015 W Newport Center Drive #106A Deerfield Beach, FL 33442
Contact:	Dr. Ponswamy Rajalingam	Special Instructions:	
Phone:	954-708-2771		

PROJECT INFORMATION

Project ID:	Form 69 Rev.1		
Project Description:	LAFH, ISO 5 Environmental air sampling.		
Project Zip Code:		Sampling Date & Time:	8/10/17 10:30 a.
PO Number:		Sampled By:	U.R

TURN AROUND TIME CODES (TAT)

STD – Standard (DEFAULT)
ND – Next Business Day
SD – Same Business Day Rush
WH – Weekend / Holiday

Rushes received after 2pm or on weekends, will be considered received the next business day. Please alert us in advance of weekend analysis needs.

Sample ID	Description	Sample Type (Below)	TAT (Above)	Total Volume / Area (as applicable)	Notes (Time of day, Temp, RH, etc.)
HP0810S	Hood Surface	CP	STD		72F, 36%
HP0810A	Hood Air	A1S	STD	1015 L	72F, 36%

REQUESTED SERVICES
(Use checkboxes below)

Non-Culturable				Culturable											Other Requests			
Spore Trap		Tape Swab Bulk		BioCassette™ , Andersen, SAS, Swab, Water, Bulk, Dust, Soil, Contact Plates														
Fungi – Spore Trap Analysis	Spore Trap Analysis – Other particles	Direct Microscopic Exam (Qualitative)	Quantitative Spore Count Direct Exam	1-Media Surface Fungi (Genus ID + *Asp.* spp.)	2-Media Surface Fungi (Genus ID + *Asp.* spp.)	3-Media Surface Fungi (Genus ID + *Asp.* spp.)	Culturable Air Fungi (Genus ID + *Asp.* spp.)	Gram Stain & Counts (Culturable Air & Surface Bacteria)	*Legionella* culture	Total Coliform, *E. coli* (Presence/Absence)	Membrane Filtration (specify organism):	MPN Bacteria (specify organism):	QuantiTray – Sewage Screen		Asbestos Analysis – PCM Airborne Fiber Count (NIOSH 7400)	Asbestos Analysis – PLM (EPA method 600/R-93-116)	PCR (specify test):	USP 797 30-35°C
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SAMPLE TYPE CODES			
BC – BioCassette ™	**ST** – Spore Trap: Zefon, Allergenco, Burkard …	**T** – Tape	**D** – Dust
A1S – Anderson		**SW** – Swab	**SO** – Soil
SAS – Surface Air Sampler	**P** – Potable Water	**B** – Bulk	
CP – Contact Plate	**NP** – Non-Potable Water	**O** – Other:	

RELINQUISHED BY	DATE & TIME	RECEIVED BY	DATE & TIME

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Enviro-Air Viable Microorganism Monitoring: Collection of samples **FORM 69**Rev1

DATE	Air collection for viable microorganism monitoring		8/10/17
LOCATION (circle)	Buffer Room1 /Buffer Room 2/Ante Room/ Prep Room/(LAFH)/ Biosafety Hood		Particle count/ft3/min
TEMPERATURE, F	HUMIDITY, %	Differential Pressure reading "w.c	
72F	36%	0.5"w.c in LAFH	

		FORCED AIR PUMP	
PUMP READING (A)	29 Litres/min	A6 Viable Microbial Partial Sampler 29 LPM Pump	
Collection Time (T)	35 minutes		35 minutes
Details of the Plate	TSA	Hardy 26ml USP	
Sample # HP0810A		H17159 2017 09 26	
Number of occupants during testing		1	
Activities		Bringing in the items for the compounding from Prep room to Buffer Room 1	
INCUBATION (circle)	IN-HOUSE	THIRD PARTY LAB	
Total volume of air collected = Pump reading (A) lit/min X collection Time(T)			
Total cfu/1000 lit = Cfu in plate X 1000lit / Total volume of air collected in lit.			

Enviro-Air Viable Microorganism Monitoring: Collection of samples by Impaction Air Sampler and Action levels for air microbial contamination.

Location		ISO CLASS 5	ISO CLASS 7	ISO CLASS 8
Action Level Cfu		>1	>10	>100
cfu				
Pass/Fail		Pass		
Air volume collected.		1015 lit		

Buffer Room 1 ISO 5 Hood Surface Contact # HP0810S
TSA H17205 2017 10 22 Pass

HYBRID PHARMA ENVIRONMENTAL LOG

DATE	TEST TYPE	PASS/FAIL
2/17/'16	Surface contact-	Pass
4/11/'16	Surface Contact-	Pass
6/24/'16	Surface Contact	Pass
8/29/'16	Surface contact	Pass
10/28/'16	Surface contact	Pass
11/23/'16	Surface Contact	Pass
12/16/'16	Surface Contact	Pass
12/29/'16	Surface Contact	Pass
7/10/'17	Surface contact	Pass.
8/10/'17	Surface Contact-	Pass

E 9/7/16

Cleanroom - Suite

HYBRID PHARMA ENVIRONMENTAL LOG

DATE	TEST TYPE	PASS/FAIL
1/4/16	Air sampler	Pass
6/24/16	Air Sampling	Pass
12/31/16	Air Sampling	Pass
7/10/17	Air Sampling	Pass
8/10/17	Air Sampling	Pass

ATLAS ANALYTICAL

CERTIFICATE OF ANALYSIS

Client:	Hybrid Pharma 1015 W Newport Center Dr #106a Deerfield Beach, FL 33442
Contact:	Dr. Raja Drraja@hybridpharma.com P (954) 708-2771
Atlas Sample ID No.:	17-0066
Atlas Report No.:	17-0066
Original Issue Date:	January 24, 2017
Test:	USP <71> Sterility: Method Suitability Test
Product Name:	HCG 11000IU Lyophilized
Lot Number:	170113C
Samples Tested:	35 vials with lyophilized product in each were received. 5 vials were suspended in 11 ml bacteriostatic water each, 55mL filtered and the filter was placed into 100 mL of TSB in triplicate (for 3 organisms). 5 vials were suspended in 11 mL bacteriostatic water each, 55mL filtered and the filter was placed into 100 mL of FTM in triplicate (for 3 organisms). A total of 30 vials (330 mL suspension) was tested with 55 mL used for each organism listed.

Method Summary:

In order for a USP <71> Sterility Test to be considered valid, the enrichment scheme used to recover contaminants must be shown to be able to recover various test species introduced to separate enrichments at low levels (<100 colony forming units). These enrichments are incubated for no more than five days at prescribed temperatures. Turbidity in the growth media is confirmation of growth and therefore validates the test.

Product Enrichment:

55 mL of suspended product was filtered through a 0.45 micron filter. The filter was rinsed with <100 cfu of test species and the filter was transferred to 100 mL of TSB. This process was repeated except the filter was transferred to 100 ml of FTM.

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ATLAS ANALYTICAL

Results:

Media	Organism	Inoculation Level	Incubation	Growth
Tryptic Soy Broth	*Bacillus subtilis*	21 cfu	20° - 25°C	Yes
Tryptic Soy Broth	*Candida albicans*	66 cfu	20° - 25°C	Yes
Tryptic Soy Broth	*Aspergillus brasiliensis*	69 cfu	20° - 25°C	Yes
Fluid Thioglycolate Medium	*Clostridium sporogenes*	8 cfu	30° - 35°C	Yes
Fluid Thioglycolate Medium	*Staphylococcus aureus*	56 cfu	30° - 35°C	Yes
Fluid Thioglycolate Medium	*Pseudomonas aeruginosa*	26 cfu	30° - 35°C	Yes

Conclusion:

Filtering 55 mL of suspended HCG 11000IU and placing the filter in 100 mL of TSB, and repeating with filtering another 55 mL and placing in FTM is a valid method for confirming sterility of manufactured product.

Approved by:

Kim Dix

Kim Dix
Quality Assurance

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ATLAS ANALYTICAL

CERTIFICATE OF ANALYSIS

Client:	Hybrid Pharma 1015 W Newport Center Dr #106a Deerfield Beach, FL 33442
Contact:	Dr. Raja Drraja@hybridpharma.com P (954) 708-2771
Atlas Sample ID No.:	17-0065
Atlas Report No.:	17-0065
Original Issue Date:	January 24, 2017
Test:	USP <71> Sterility: Method Suitability Test
Product Name:	Testosterone Cypionate 200mg/mL
Lot Number:	170112D
Samples Tested:	7 vials containing 50mL product in each were received. 50mL of product was filtered and the filter was placed into 100 mL of TSB in triplicate (for 3 organisms). 50mL of product was filtered and the filter was placed into 100 mL of FTM in triplicate (for 3 organisms). A total of 300mL of product was tested with 50mL used for each organism listed.

Method Summary:

In order for a USP <71> Sterility Test to be considered valid, the enrichment scheme used to recover contaminants must be shown to be able to recover various test species introduced to separate enrichments at low levels (<100 colony forming units). These enrichments are incubated for no more than five days at prescribed temperatures. Turbidity in the growth media is confirmation of growth and therefore validates the test.

Product Enrichment:

50 mL of product was filtered through a 0.45 micron filter. The filter was rinsed with <100 cfu of test species and the filter was transferred to 100 mL of TSB. This process was repeated except the filter was transferred to 100 ml of FTM.

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ATLAS ANALYTICAL

Results:

Media	Organism	Inoculation Level	Incubation	Growth
Tryptic Soy Broth	*Bacillus subtilis*	21 cfu	20° - 25°C	Yes
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Tryptic Soy Broth	*Aspergillus brasiliensis*	69 cfu	20° - 25°C	Yes
Fluid Thioglycolate Medium	*Clostridium sporogenes*	8 cfu	30° - 35°C	Yes
Fluid Thioglycolate Medium	*Staphylococcus aureus*	56 cfu	30° - 35°C	Yes
Fluid Thioglycolate Medium	*Pseudomonas aeruginosa*	26 cfu	30° - 35°C	Yes

Conclusion:

Filtering 50 mL of Testosterone Cypionate 200mg/mL and placing the filter in 100 mL of TSB, and repeating with filtering another 50 mL and placing in FTM is a valid method for confirming sterility of manufactured product.

Approved by:

Kim Dix

Kim Dix
Quality Assurance

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SOP FOR THE GENERAL PROCEDURE FOR STERILITY TESTING BY MEMBRANE FILTRATION TECHNIQUE

Approved **Date**

Membrane Filter Technique

Membrane Filter Technique

The Membrane Filter (MF) Technique was introduced in the late 1950s as an alternative to the Most Probable Number (MPN) procedure for microbiological analysis of water samples. The MF Technique offers the advantage of isolating discrete colonies of bacteria, whereas the MPN procedure only indicates the presence or absence of an approximate number or organisms (indicated by turbidity in test tubes).

The MF Technique was accepted by the U.S. EPA for microbiological testing of potable water in the 11th edition of *Standard Methods for the Examination of Water and Wastewater*. In the 1978 publication, *Microbiological Methods for Monitoring the Environment*, the U.S. EPA stated that the MF Technique is preferred for water testing because it permits analysis of larger samples in less time.

- Comparative Benefits
- Uses of the MF Technique
- Conclusion
- Advantages of the MF Technique
- Step-by-step Procedures
- Application Guide for Membrane and Nutrient Media
- Ordering Information

Comparative Benefits

The concentration of larger samples on a membrane filter is a key benefit of the technique over the MPN procedure as well as over Pour Plate and Spread Plate techniques.

Many industry and U.S. EPA test procedures require samples of 100 mL or more to be analyzed for the presence of bacteria. The Pour Plate technique is limited to a sample volume of 2 mL and the Spread Plate technique has a limit of 0.5 mL.

Using the MF Technique, a 100 mL sample is passed through a 47 mm membrane using a filter funnel and vacuum system. Any organisms in the sample are concentrated on the surface of the membrane. The filter is then placed in a petri dish with nutrient medium. The passage of nutrients through the filter facilitates the growth of organisms on the upper surface of the membrane. The discrete colonies that form on the surface of the membrane can be easily transferred to confirmation media.

Top

Uses of the MF Technique

Municipal water treatment plants monitor drinking, waste, and surface water for the presence of coliform bacteria by the MF Technique. The key organism monitored in water treatment facilities is *E. coli*. The U.S. EPA considers this organism the leading indicator of fecal contamination.

In addition to its use by government labs for monitoring drinking water, the MF Technique is also used for microbial monitoring in the pharmaceutical, cosmetics, electronics, and food and beverage industries. The MF Technique is used in these industrial labs to monitor the presence of microorganisms in process waters and final product.

The pharmaceutical and cosmetics industries typically focus on monitoring their process water for *Pseudomonas* species. The electronics industry monitors for any and all microorganisms because they must keep their process water free from even the smallest organisms. Microbial monitoring in the food and beverage industry typically employs several types of techniques because of the variety of samples that are encountered. Beverage samples can typically be monitored for microorganisms by the MF Technique, but when solid samples cannot be liquefied, alternative methods must be used.

Top

Conclusion

The MF Technique is an effective, accepted technique for testing fluid samples for microbiological contamination. It involves less preparation than many traditional methods, and is one of a few methods that will allow the isolation and enumeration of microorganisms. The MF Technique also provides presence or absence information within 24 hours.

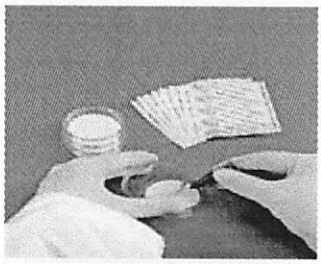
Top

Advantages of the MF Technique

- Permits testing of large sample volumes.
- Reduces preparation time as compared to many traditional methods.
- Allows isolation and enumeration of discrete colonies of bacteria.
- Provides presence or absence information within 24 hours.
- Effective and acceptable technique. Used to monitor drinking water in government laboratories.
- Useful for bacterial monitoring in the pharmaceutical, cosmetics, electronics, and food and beverage industries.
- Allows for removal of bacteriostatic or cidal agents that would not be removed in Pour Plate, Spread Plate, or MPN techniques.

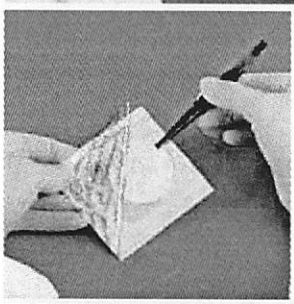
Top

Step-by-step Procedures



1. Collect the sample and make any necessary dilutions.

2. Select the appropriate nutrient or culture medium. Dispense the broth into a sterile Petri dish, evenly saturating the absorbent pad.



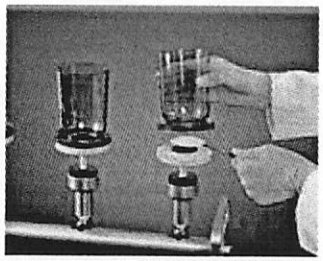
3. Flame the forceps, and remove the membrane from the sterile package.

4. Place the membrane filter into the funnel assembly.

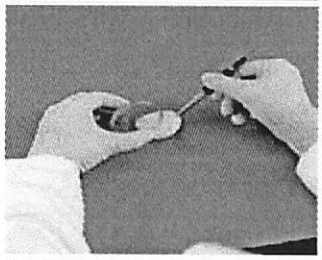
5. Flame the pouring lip of the sample container and pour the sample into the funnel.

6. Turn on the vacuum and allow the sample to draw completely through the filter.

7. Rinse funnel with sterile buffered water. Turn on vacuum and allow the liquid to draw completely through the filter.

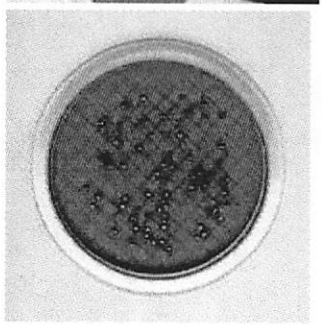


8. Flame the forceps and remove the membrane filter from the funnel.



9. Place the membrane filter into the prepared Petri dish.

10. Incubate at the proper temperature and for the appropriate time period.



11. Count the colonies under 10 - 15 X magnification.

12. Confirm the colonies and report the results.

Note: Observe aseptic technique throughout the procedure.

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Application Guide for Membrane and Nutrient Media

Media Broth	Total Coliform	Fecal Coliform	Yeast and Mold	Total Bacteria	*Pseudomonas* Species	Fecal *Streptococcus*	*Lactobacillus* acid resistant bacteria
MF-Endo	*						
M-FC		*					
M-TGE				*			
Trypticase Soy-USP				*			
M-Green YM			*				
KF Streptococcal						*	
Pseudomonas					*		
Orange Serum							*
HPC with TTC indicator				*			

Membrane Filtes	Total Coliform	Fecal Coliform	Yeast and Mold	Total Bacteria	*Pseudomonas* Species	Fecal *Streptococcus*	*Lactobacillus* acid resistant bacteria
0.45 µm (white)	*	*	*	*	*	*	*
0.45 µm (black)			*				
0.8 µm (black)			*				
0.2 µm (white)				*	*		

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Ordering Information

GN-6 Metricel® Membrane Disc Filters - Individual Sterile Packages (S-Packs)
GN-6 Metricel Membrane Disc Filters - Non-sterile Packages
GN-6 Metricel Membrane Disc Filters - Autoclave Packages
Metricel Black Membrane Disc Filters
Supor® 200 Membrane Disc Filter

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"CONFIDENTIAL INFORMATION"

ISU LABEL/SEALED CD

RECORDS SEALED*

CASES NO.: PH2017-23347

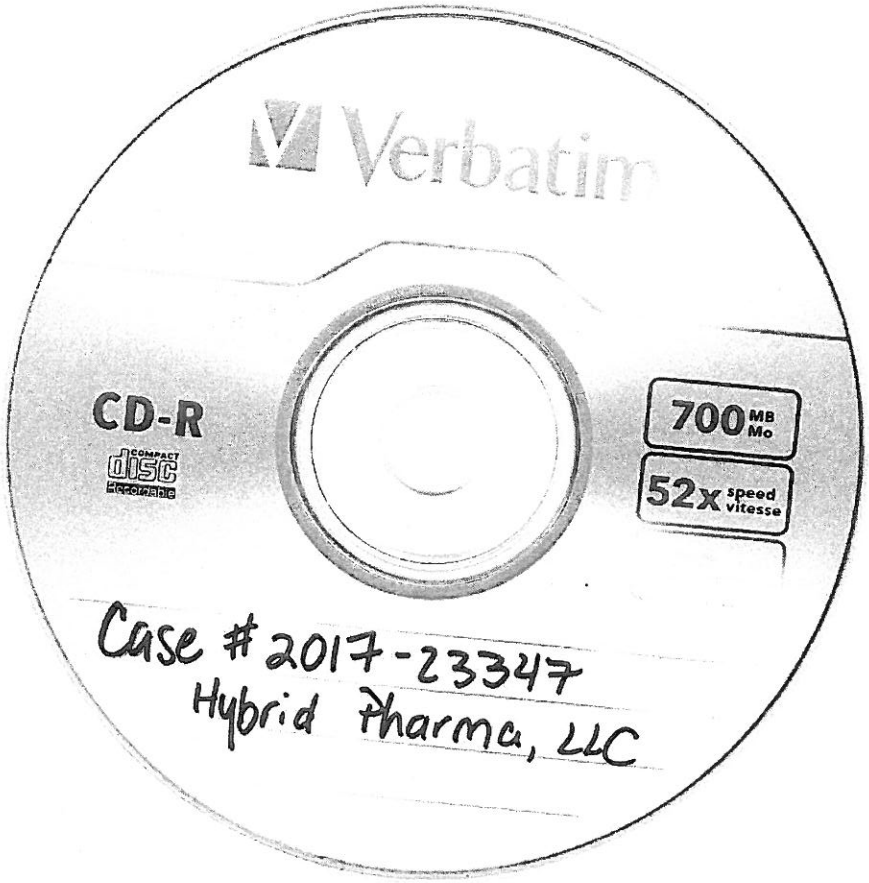
SUBJECT: HYBRID PHARMA

INVESTIGATOR: Marsha Boatwright

EXHIBIT: #6

-One (1) CD with 82 Photos of pharmacy taken by BOWER

THE CD WILL BE FORWARDED IN A SEPARATE PACKAGE TO PSU, VIA FEDERAL EXPRESS.


Verbatim
CD-R
COMPACT disc Recordable
700 MB Mo
52x speed vitesse
Case #2017-23347
Hybrid Pharma, LLC

660000