STATE OF FLORIDA

DEPARTMENT OF HEALTH

INVESTIGATIVE REPORT

Office: TAMPA VI	Date of Complaint: 9/6/2024	Case Number: 202435310
Subject: OUSIA PHARMACY CORP. 34609 MARINER BOULEVARD SPRING HILL, FL 34609 813-252-4076	Source: DEPARTMENT OF HEALTH/INVESTIGATIVE SERVICES UNIT/TAMPA	
Profession: 2205 PHARMACY	License Number and Status: 29616/ACTIVE	
Related Case(s): 202436663	Period of Investigation and Type of Report: 9/10/2024 Thru 10/31/2024 **FINAL**	

Alleged Violation: Possible violation of ss. 456.0341, 456.072(1)(j)(k)(o)(dd), 465.016(1)(e)(r), 465.023(1)(c), F.S. and Rules 64B16-27.100(2), 64B16-27.300, 64B16-27.410, 64B16-27.420, 64B16-27.700(3)(g), 64B16-27.4001, 64B16-28.102, 64B16-28.108, 64B16-28.109, 64B16-28.110, 64B16-28.118, 64B16-28.120, 64B16-28.140(3)(d), 64B16-28.140(4), 64B16-28.1191, 64B16-28.10801, F.A.C.

Synopsis: This investigation is predicated upon receipt of a complaint (Exhibit 1) submitted by DEPARTMENT OF HEALTH/INVESTIGATIVE SERVICES UNIT/TAMPA regarding OUSIA PHARMACY CORP. This complaint alleges that on 8/15/2024, OUSIA PHARMACY CORP, located at 5194 Mariner Blvd., Spring Hill, Florida 34609 failed a community pharmacy inspection. The following discrepancies were identified: Certified daily log not signed; pharmacist not wearing a badge or proper identification; Trizepatide powder is stored in freezer outside of a cleanroom suite, prescription department was unsafe/unsanitary; no warm water to wash hands prior to compounding or donning gloves; injectable medications intended for dispensing were not properly labeled; pharmacy does not have the minimal amount of continuous quality improvement documentation; patient profile information is incomplete; pharmacy does not maintain records of compounded injectable medication; invoices of purchase of Semaglutide and Tirzepatide not available, and the pharmacy is shipping injections to California but is not licensed in California. The facility is allegedly compounding high risk Category 3 compounds such as Semaglutide injection but has not received a passing new business inspection. A sterile compounding new business inspection was also performed at the address and failed. Pharmacy is practicing outside of scope by compounding sterile product without a compounding permit.

☒ 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: N/A
☐ Involved Agency:

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

Investigator/Date: 10/31/2024  Veronica L. Gibson-Ray Medical Quality Assurance Investigator, TI202	Approved By/Date: 10/31/2024  Christopher Wright Investigation Supervisor, TI174

Distribution: HQ/ISU

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INVESTIGATIVE DETAILS

INVESTIGATOR NOTE: No recorded interviews taken. Due to a tip that the facility was compounding without a permit, Senior Pharmacist MALA CULLIPHER requested this investigator accompany her to conduct the inspection on 8/15/2024 as a witness.

INTERVIEW WITH A[redacted] H[redacted], RPH (WITNESS)

EMPLOYMENT
[redacted]
OUSIA PHARMACY CORP
5194 MARINER BOULEVARD
SPRING HILL, FLORIDA 34609
813-893-5445

On August 15, 2024, Investigator VERONICA L. GIBSON-RAY interviewed A[redacted] H[redacted], RPH via in person, H[redacted] essentially stated:

- H[redacted] was instructed to compound medications by the owner.
- H[redacted] is the only pharmacist on site.
- H[redacted] only compounded because she was instructed to by the owner.
- [redacted] is not going to return to OUSIA PHARMACY.

INVESTIGATOR NOTE: On the day of the inspection, H[redacted] appeared to be very nervous from the moment DOH employees walked in. H[redacted]'s hands were shaking continuously.

INTERVIEW WITH DENISE SCHRADE (WITNESS)

EMPLOYMENT
OWNER
OUSIA PHARMACY CORP
5194 MARINER BOULEVARD
SPRING HILL, FLORIDA 34609
320-405-9504

On October 4, 2024, Investigator VERONICA L. GIBSON-RAY interviewed DENISE SCHRADE via telephone, SCHRADE essentially stated:

- SCHRADE was told by A[redacted] H[redacted], RPh that everything went fine with the inspection.
- SCHRADE did receive a copy of the inspections via email from the DOH Inspector and forwarded them to her attorney.
- SCHRADE did not actually look over the inspections.
- SCHRADE was unaware that the inspection failed.
- As soon as the DOH inspectors left the day of the inspection, H[redacted] resigned.
- The day of the inspection, H[redacted] told other staff that the owner could not come in for the inspection.
- Since the inspection, all compounding equipment has been removed from the facility.
- All compounded products were also disposed of.

INVESTIGATOR NOTE: On 10/28/2024, this investigator visually inspected the facility to ensure all compounding has ceased. No compounding equipment or materials were found.

CASE SUMMARY

CONFIDENTIAL

Case No: 202435310
Please use this number in all correspondence with the Department concerning this matter.

RESPONDENT INFORMATION

License: 29616 Profession: 2205 Pharmacy
Name: OUSIA PHARMACY CORP.
Address: 34609 MARINER BLVD
SPRING HILL, FL 34609
Home Phone: 813-252-4076

SOURCE OF INFORMATION

Name: Department Of Health/Investigative Services Unit/Tampa
Address:

Home Phone:

REPORTED INFORMATION

Receive Date: 09/06/2024 Source Code: 5 Form Code: 7
Responsible Party: ha151 Status Code: 10
Classification Code: 20 Incident Date: 07/30/2024 Complexity: Regular

Patient Name(s):

Possible Code(s): 34, 4, 41, 10, 15, 18

Summary:
Possible violation of ss. 456.0341, 456.072(1)(j)(k)(o)(dd), 465.016(1)(e)(r), 465.023(1)(c), F.S. and Rules 64B16-27.100(2), 64B16-27.300, 64B16-27.410, 64B16-27.420, 64B16-27.700(3)(g), 64B16-27.4001, 64B16-28.102, 64B16-28.108, 64B16-28.109, 64B16-28.110, 64B16-28.118, 64B16-28.120, 64B16-28.140(3)(d), 64B16-28.140(4), 64B16-28.1191, 64B16-28.10801, F.A.C.
Fail to comply with community pharmacy requirements; fail to display required sign; fail to comply with safety/sanitary requirements; fail to maintain records; practice beyond the scope of license; aid/abet unlicensed activity; violate Chapter 499, 893, or federal laws/regulations; fail to perform statutory/legal obligation; violate statute/rule.

Complaint alleges that the owner of Subject pharmacy at 5194 Mariner Blvd., Spring Hill, Florida 34609 is releasing compounded sterile product without passing a second new business inspection for their application for an affiliated sterile compounding license at the same location. The facility is allegedly compounding high risk Category 3 compounds such as Semaglutide injection but has not received a second passing new business inspection. A community pharmacy inspection was conducted at Subject pharmacy on 08/15/24. The following discrepancies were identified: Prescription Department Closed sign not displayed, certified daily log not signed, pharmacist not wearing a badge or proper identification, after weighing the active pharmaceutical powder in an unclassified hood it is transferred to a freezer for which no data of appropriate temperatures is maintained, prescription department was unsafe/unsanitary, no sterilization of equipment used in compounding, no warm water to wash hands prior to compounding or donning gloves, injectable medications intended for dispensing were not

properly labeled, pharmacy does not have the minimal amount of continuous quality improvement documentation, patient profile information is incomplete, pharmacy does not maintain records of compounded injectable medication, records of receipt and dispensing to patients not provided, pharmacy rx # was the zip code of the patient, invoices of purchase of Semaglutide and Tirzepatide not available, human trafficking sign was too small, pharmacist had no knowledge if controlled substances are reported to PDMP, and the pharmacy is shipping injections to California but is not licensed in California. A sterile compounding new business inspection was also performed at the address. Inspectors collected evidence that the facility is compounding and dispensing Semaglutide and Tirzepatide injection assigned a one year beyond use date without any testing before release or a properly certified compounding environment or competency assessments for the pharmacist establishing proper aseptic technique, hand hygiene, garbing were followed. There was a lack of sterility assurance as equipment has not been calibrated or validated and the pharmacy does not use filters to sterilize after placing open beakers in the unclassified hood. Several anticipatory finished product vials and amber bottles with physician names were also found in the refrigerator on the drug testing side of the firm, some vials with physician names.

Analyzed by Miles Hardison ha151

DOH-Form200

September 10, 2024

CONFIDENTIAL TO:
OUSIA PHARMACY CORP
34609 MARINER BLVD
SPRING HILL, FL 34609

Case Number: **202435310**

Dear OUSIA PHARMACY CORP,

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**; **or**
- **email your response** to veronica.gibson-ray@flhealth.gov

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 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 integrated state, county and community efforts. If you have any questions, please call us at 813-710-8343

Sincerely,

Veronica L. Gibson-Ray
Medical Quality Assurance Investigator

Enclosure: ☒ **Case Summary,** ☒ **Initiating Documents,** ☐ **Voluntary Relinquishment**

STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES
INV359 - Community Requirements

File # 23078
Insp # 194855

NAME	PERMIT NUMBER	DATE OF INSPECTION
OUSIA PHARMACY CORP.	29616	08/15/2024
DOING BUSINESS AS OUSIA PHARMACY CORP.		
STREET ADDRESS 5194 Mariner Blvd	**TELEPHONE #**	**EXT**
CITY SPRING HILL	**COUNTY** HERNANDO	**STATE/ZIP** FL/34609

Additional Information

Business Operation Hours

M-T-W-TH-F Y	Weekly Hours 9:00 AM to 5:00 PM
Monday Y	Monday Hours
Tuesday Y	Tuesday Hours
Wednesday Y	Wednesday Hours
Thursday Y	Thursday Hours
Friday Y	Friday Hours
Saturday Y	Saturday Hours CLOSED
Sunday N	Sunday Hours CLOSED

Registered Pharmacist / Intern / Tech

License # PS35231	Licensee Name Amy Hamilton
License Type Registered Pharmacists	

ACS Manager

Optional Information

Basic License Data - PSD

DEA Reg # FO5808297	

License Relations

Pharmacy Affiliate

SCHRADE, DENISE	License #

RX DPT MGR/COR/POR

H[redacted]	License #[redacted]

Special Sterile Compounding

OUSIA PHARMACY CORP.	License #

INV 359 - Community Requirements

Signage Requirements Section

Signage stating the hours the pharmacy department is open. [64B16-28.1081(2), F.A.C.]	Yes
"Prescription Department Closed" sign with bold letters not less than 2 inches in width and height is displayed in a prominent place where it is easily read by patrons. [64B16-28.109, F.A.C.] *No sign noted when door was locked to make it accessible to the public.*	No
Patient Consultation Area sign is posted. [64B16-30.003, F.A.C] [64B16-28.1035, F.A.C.]	Yes

Community Requirements General Section

Exhibit 3

INV359 - Community Requirements

Insp # 194855 **OUSIA PHARMACY CORP.** **File # 23078**

Outdated medications removed from active stock. [64B16-28.110, F.A.C.] [64B16-28.1191, F.A.C.] *Pharmacy is not permitted to dispensed compounded sterile products-there is no confirmation these have been sterility tested or manufactured in a sanitary environment suitable for the injection route and beyond use date assigned of 30 days.* *Lot SH159077 Semaglutide 2.5mg/1ml compounded on 8-3-24 label states use within 30 days of first penetration, keep refrigerated, expiration date assigned is 8-2-25 (1 year BUD)-no sterility testing.*	No
Prescription Department is open for a minimum of 20 hours per week. [64B16-28.1081(1), F.A.C.]	Yes
All controlled substance prescriptions (electronic, faxed, verbal and written) contain required information. [893.04(a)(b)(c), F.S.] [21CFR1306.05]	Yes
Certified daily log or signed printout maintained. [21CFR1306.22(f)(3)] [64B16-28.140(3)(d), F.A.C.] *Pharmacy has dispensed Semaglutide and Tirzepatide and NAD Plus injections but has not signed the daily log sine 7/21/24.*	No
Prescription department has current copy of laws and rules, references and equipment necessary to the professional practice of pharmacy. [64B16-28.102(5)(a), F.A.C.] *Pharmacist present for the day AH was able to pull up laws and rules from the DOH website.*	Yes
Technicians properly identified. [64B16-27.100(2), F.A.C.] [64B16-27.4001, F.A.C.] [64B16-27.410, F.A.C.] [64B16-27.420, F.A.C.] *No technicians at this time in the pharmacy. Pharmacist not wearing a badge to identify as Amy Hamilton.*	No
Legend drugs properly stored within confines of pharmacy department and maintained at appropriate temperature to preserve therapeutic activity. [64B16-28.118, F.A.C.]; [64B16-28.120, F.A.C.]; [64B16-28.102, F.A.C.] *Trizepatide powder is stored in freezer outside of a cleanroom suite, preweighed in Isolator and taken out and placed in freezer for future use, however currently not labeled, except for 1 bag-no strength indicated or lot # or date weighed.* *No documented temperature log for freezer where API is stored outside of C-SCA*	No
Documentation of destruction or return of controlled substances. [64B16-28.303, F.A.C.] *Last reverse distribution of CS from Rx Reverse distributors 6-4-24*	Yes
Generic equivalent sign is posted. [465.025(7), F.S.]	Yes

Additional Community Requirements

Prescription department is operating under clean, sanitary, and uncrowded health conditions. [64B16-28.102, F.A.C.] *Cluttered, insanitary conditions for compounding injectable medications.*	No
Prescription department has a sink with running water easily accessible to the prescription counter. [64B16-28.102, F.A.C.] *No warm water to wash hands prior to compounding.*	No
Pharmacist is on the premises and on duty when the prescription department is open. [64B16-28.109, F.A.C.]	Yes
Pharmacy maintains a written policy and procedure manual regarding the number of registered pharmacy technician positions and the pharmacy operates within the established ratio as defined by rule. [64B16-27.410(2)(a), F.A.C.] *No technicians at this pharmacy*	N/A
Pharmacists, technicians, and interns are licensed in the State of Florida. [465.015(1)(a), F.S.]	N/A
Upon receipt of a new or refill prescription, a verbal and printed offer to counsel is made to the patient or the patient's agent. [64B16-27.820(1), F.A.C.]	Yes
Medication is properly labeled for dispensing to patient. [64B16-28.108, F.A.C.] *Semaglutide injection multi dose vials noted in back room in refrigerator along with several vials of Tirzepatide Inj and NAD plus Inj incorrectly labeled. Pharmacy was waiting on owner in order to release the batch records. Unlabeled vials noted.*	No
Unclaimed prescriptions are maintained in stock for no more than one year past dispensing date. [64B16-28.1191, F.A.C.]	N/A
Manufacturer containers are properly labeled. [499.003(26), F.S.] *Inner bag of Semaglutide from Rochem not properly labeled to indicate components are ascertained.*	No
Customized medication packages are labeled properly with beyond use date of not more than 120 days from the date of preparation but not later than the beyond use date for any of the medications in the package. [64B16-28.108(6)9., F.A.C.] *Pharmacy has Dispil and does dispense and expiration date assigned is based on manufacturer's bottle.*	Yes
Continuous Quality Improvement Program described in the Pharmacy policy and procedure manual and quarterly summarization of Quality-Related Events are available for inspection. [64B16-27.300, F.A.C.] [766.101(1)(a)(l), F.S.] *Last CQI's 5/16/24 and 12/29/23, The firm is Missing all of 2022 CQI's and most of 2023 CQI's (present pharmacist AH was not with the firm in 2022 and started Oct 2023), 8/7/19.*	No
Pharmacy maintains patient profile with allergy information and medications dispensed. [64B16-27.800, F.A.C.] *No allergy documented for Tirzepatide 7.5mg/0.5ml*	No
Compounding records include compounding date, lot number, expiration date, name and manufacturer of ingredients, package size, number of units, technician compounding and pharmacist verifying the final compound. [64B16-28.140(4), F.A.C.] *Not provided during inspection for Semaglutide 0.25mg/0.5ml (no volume on vial) Lot SH159063, Semaglutide 0.5mg/0.5ml (no volume on vial) lot SH159064, Tirzepatide 2.5mg/0.5ml (no volume on vial) Lot SH159078.*	No
The pharmacy maintains an audit trail for all drugs from receipt or acquisition to sale or disposition [499.005, F.S.] [61N-1.012, F.A.C.] *No audit trail of sterility studies or stability for injectable medications released to patients.*	No
Invoices for medications purchased from a Florida licensed wholesaler/distributor are retrievable for inspection. [499.005(14), F.S.] *No invoices provided for purchase of API Trizepatide, Semaglutide or NAD plus API.*	No
Facility engaged in non-sterile office use compounding for human use is registered with FDA as an outsourcing facility. [64B16-27.700(3)(g), F.A.C.] *Pharmacy engaged in office use compounding, however not registered with FDA.*	No
Signage indicating that any patient receiving testing, screening, or treatment services is advised to seek follow-up care from his or her primary care physician. [465.1895(9), F.S.]	N/A
Human Trafficking signage is posted in a conspicuous place accessible to employees that is at least 11 inches by 15 inches in size, printed in a clearly legible font and in at least a 32-point type which gives instructions in English and Spanish on how to report to the National Human Trafficking Resource Center. [456.0341, F.S.] *not 11X15 inches-posted on bath room wall.*	No

Requirements for Dispensing Controlled Substances

Controlled substance inventory taken on a biennial basis and available for inspection. [893.07(1)(a), F.S.] [21CFR1304.11] *Close of business 10-31-23 CII's are separated from CIII-CV's.*	Yes

INV359 - Community Requirements

Insp # 194855 **OUSIA PHARMACY CORP.** **File # 23078**

DEA 222 forms properly completed or records of CSOS orders electronically completed, linked to the original order, archived and retrievable. [893.07(2), F.S.] [21CFR 1305.13(e)] [21CFR1305.22(g)] *DEA 222 forms filled out by pharmacist when CII's purchased from Cardinal.*	Yes
Controlled substance records and prescription information in computer system are retrievable and maintained for 4 years. [465.022(12)(a), F.S.] [64B16-28.140, F.A.C.] [21CFR1306.22] [21CFR1304.04]	Yes
Pharmacy is reporting to law enforcement any instance of fraudulent prescriptions within 24 hours or close of business on next business day of learning of instance. Reports include all required information. [465.015(3), F.S.]	N/A
Record of theft or significant loss of all controlled substances is being maintained and reported to the sheriff and board within 24 hours of discovery. [893.07(5)(b), F.S.] [465.022(11)(b), F.A.C.]	N/A
Pharmacy is reporting to the PDMP within 24 hours of dispensing controlled substance. [893.055(4)(3)(a), F.S.] *No PMP Clearing house notifications or zero reports received by pharmacist in email, not clear if Best Rx reports daily.*	No

Pharmacy Ships Medicinal Drugs to Patients [64B16-28.10801, F.A.C]

Pharmacy has policies and procedures in place to provide instructions to the patient on reporting concerns with delivery and storage of medicinal drugs. *Not allowed to dispense to states pharmacy is not licensed in-example Goleta, California Rx#93117-2041.*	No
Pharmacy has policies and procedures in place to ensure that medicinal drugs are not adulterated at the time of receipt by the patient or their agent. *Shipping to states without an active license.* *Not allowed to dispense to states pharmacy is not licensed in-example Goleta, California Rx#93117-2041.*	No

Automated Pharmacy System [465.0235, F.S.]

Pharmacy maintains a record of the medicinal drugs dispensed, including the identity of the pharmacist responsible for verifying the accuracy of the dosage and directions and providing patient counseling.	
Pharmacy maintains written policies and procedures to ensure the proper, safe, and secure functioning of the automated pharmacy system for a minimum of 4 years.	

Pharmacy engages in Centralized Prescription Filling [64B16-28.450, F.A.C.]

Pharmacies have the same owner or have a written contract specifying the services to be provided by each pharmacy.	
Current P&P Manual available for inspection designating at minimum: types of medications that may be filled, procedures for communicating orders, procedures for securely transporting the filled prescriptions.	
The central fill pharmacy is identified by name and address or a by a code available at the originating pharmacy.	
If a controlled substance, the word "central fill" appears on the face of the original prescription.	
The originating pharmacy keeps a record of receipt of the filled prescription, including the date of receipt, method of delivery and the name of the originating pharmacy's employee accepting delivery.	

Internet Pharmacy

A toll-free telephone number is provided to facilitate communication between patients in this state and a pharmacist at the pharmacy who has access to the patient's records. [465.0197 (3)(e), F.S.]	
Toll free number is disclosed on the label affixed to each container of dispensed medicinal drugs. [465.0197(3)(e), F.S.]	
Documentation of a valid, unexpired pharmacy license, permit or registration in the state in which the dispensing facility is located and from which the medicinal drugs shall be dispensed. [465.0197(3)(a) F.S]	

HIV Infection Prevention Drugs

Pharmacists are screening, ordering or dispensing HIV postexposure prophylaxis drugs under a written Collaborative Practice Agreement. [465.1861, F.S.]	
An access-to-care plan has been submitted to the board office and is in place to assist patients in gaining access to appropriate care settings when they present to a pharmacist for HIV screening and indicate that they lack regular access to primary care. [465.1861, F.S.]	

Remarks:

Inspectors Mala Cullipher and Veronica Gibson-Ray have provided the Florida Statute to personnel of 465.017 stating Inspectors have the authority to inspect a licensed facility.
Inspectors were concerned since non-licensed personnel have access to the pharmacy from both the front and back of the pharmacy.
Tirzepatide injection dispensed to several patients starting 8/11/24, ex 228944-0 sequentially to 228968-0.
Pharmacy does not have a sterile compounding permit with the State of Florida, just a file #29867 and has not passed the final inspection to be able to release injectables to patients. Pharmacist was educated in prior inspection on 64B16-27.797. F.A.C.
Pharmacist advised to not release or dispense any injectable medication until has passed an initial licensure for sterile compounding. Pharmacy has a Community permit PH29616.

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.

Inspector Signature

CULLIPHER, MALA

Date:8/15/2024

Representative:

[redacted]

Date:8/15/2024

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

File # 29867
Insp # 198462

NAME	PERMIT NUMBER	DATE OF INSPECTION
Ousia Pharmacy Corp.		08/15/2024
DOING BUSINESS AS		
OUSIA PHARMACY CORP		
STREET ADDRESS	**TELEPHONE #**	**EXT**
5194 MARINER BLVD	813-252-4076	
CITY	**COUNTY**	**STATE/ZIP**
SPRING HILL	HERNANDO	FL/34609

Additional Information

Business Operation Hours

M-T-W-TH-F Y	Weekly Hours 9 am to 5pm
Monday Y	Monday Hours 9 am to 5 pm
Tuesday Y	Tuesday Hours 9 am to 5 pm
Wednesday Y	Wednesday Hours 9 am to 5 pm
Thursday Y	Thursday Hours 8 am to 5 pm
Friday Y	Friday Hours 9 am to 5 pm
Saturday N	Saturday Hours closed
Sunday N	Sunday Hours closed

Registered Pharmacist / Intern / Tech

License # [redacted]	Licensee Name A[redacted] H[redacted] PDM
License Type Registered Pharmacists	

ACS Manager

Optional Information

Basic License Data - PSD

DEA Reg # FO5808297	

License Relations

Pharmacy Affiliate

SCHRADE, DENISE	License #

Special Sterile Compounding

OUSIA PHARMACY CORP.	License # 29616

INV797 - USP Sterile Compounding

A. INTRODUCTION & SCOPE – ALL CATEGORIES

DESIGNATED PERSON: A designated person(s) is identified who is responsible and accountable for the performance and operation of the facility and personnel involved in the preparation of CSPs. [USP 797 Section 1.1.3] *Designated Person: Amy Hamilton*	Yes
IMMEDIATE USE COMPOUNDING: When preparing immediate use preparations, written SOPs are in place for all requirements and all criteria are met including 1. aseptic technique, processes, and procedures; and, 2. personnel are trained and demonstrate competency in aseptic processes as they relate to assigned tasks and SOP's, 3. the preparation is performed in accordance with evidence-based information for physical and chemical compatibility of the drugs, 4. the preparation involves not more than 3 different sterile products, 5. Any unused starting component from a single-dose container is discarded, 6. Administration begins within 4 hours following the start of preparation and, 7. Unless directly administered by the preparer or administration is witnessed by the preparer, the CSP is labeled with the names and amounts of all active ingredients, the name or initials of the preparer and the 4 hour period within which administration must begin. [USP 797 Section 1.3] *Pharmacy does not have a cleanroom suite to be able to compound and release injections of Semaglutide, Tirzepatide and NAD plus. Only a CACI in a SCA.*	No

BAG & VIAL SYSTEM: Docking of vial and bag systems for future activation and administration is performed in an ISO 5 environment and BUDs are not longer than those specified in the manufacturer's labeling. [USP 797 Section 1.4] *ISO 5 classification of CACI has not been completed as per last inspection*	No
REPACKAGING: Repackaging of sterile products or preparations from its original container into another container are prepared according to all applicable USP 797 requirements. [USP 797 Section 1.1.2]	N/A
BLOOD-DERIVED OR BIOLOGICAL MATERIAL MANIPULATIONS: Compounding activities that require the manipulation of a patient's blood-derived or other biological material (e.g., autologous serum), are clearly separated from other compounding activities and equipment used in CSP preparation activities and controlled by specific SOPs to avoid cross-contamination. [USP 797 Section 1.1.2]	N/A

B. COMPONENT BUDs (Single and Multi-dose Containers) – ALL CATEGORIES

SINGLE DOSE CONTAINERS (SDCs): SDCs are entered or punctured only in an ISO Class 5 or cleaner air and are used up to 12 hours after initial entry or puncture if the labeled storage requirements during that 12-hour period are maintained. [USP 797 Section 15.1]	N/A
AMPULES: Opened SINGLE DOSE AMPULES are used immediately and not stored for any time period. [USP 797 Section 15.1]	N/A
MULTIDOSE CONTAINERS (MDCs): Upon initially entering or puncturing a conventionally manufactured MDC, the MDC is not used for more than 28 days unless otherwise specified by the manufacturer on the labeling. [USP 797 Section 15.2]	N/A
PHARMACY BULK PACKAGES: Conventionally manufactured pharmacy bulk packages are entered or punctured only in an ISO Class 5 PEC and must be used according to the manufacturer's labeling. [USP 797 Section 15.3]	N/A
SINGLE DOSE COMPONENT CSPs & STOCK SOLUTIONS: When single-dose CSPs or CSP stock solutions are used as a component to compound additional CSPs, the original compounded single-dose component CSP or CSP stock solution is entered or punctured in ISO Class 5 or cleaner air and is stored under the conditions upon which its BUD is based (e.g., refrigerator or controlled room temperature). Once punctured, the component CSP is used for sterile compounding for up to 12 hours or its assigned BUD, whichever is shorter, and any remainder is discarded. [USP 797 Section 16.2]	N/A
MULTI-DOSE CSPs USED AS A COMPONENT: Meet the criteria for anti-microbial effectiveness testing (see <51>) if aqueous, are stored under the conditions upon which the BUD is based, Multiple-dose CSP after initially entered or punctured, are not used for longer than the assigned BUD or 28 days, whichever is shorter. [USP 797 Sections 14.5 & 16.1] *No USP <51> antimicrobial effectiveness testing of mixed components or final solution.* *Several vials not even crimped, specifically Semaglutide 2.5mg/1ml Inj Dr. Justin bulk vial Lot SH159087 intended to pull off future doses. Pharmacist is removing contents from this vial to further pipette into smaller vials.*	No

C. CSP LABELING – ALL CATEGORIES

IMMEDIATE CONTAINER LABEL REQUIREMENTS: Immediate label of CSPs prominently and legibly display 1) assigned internal identification number; 2) active ingredient(s) and their amount(s), or concentration(s); 3) storage conditions if other than controlled room temperature; 4) BUD; 5) dosage form; 6) total amount or volume; 7) statement if CSP is a single dose container or multi-dose container. [USP 797 Section 13] *No dosage form indicated on immediate container labels, no volume. Each vial states multi-dose container.*	No
ADDITIONAL REQUIREMENTS FOR A CLASS II OR III FACILITY: 1) Identification of responsible compounding personnel and/or dispensing pharmacist;2) labels for batch-prepared CSPs must also include: Control or lot number, auxiliary labeling (including precautions); and device-specific instructions. Patient specific medications must also include patient's name, location the medication is to be delivered to and directions for use. [USP 797 Section 13] [F.A.C.64B16-28.108(10)]	N/A
LABELING REQUIREMENTS: Labeling of CSP displays 1) route of administration, 2) special handling instructions, 3) warning statements, and the compounding facility name and contact information if the CSP is sent outside of the facility in which it was compounded. [USP 797 Section 13] *Clear vials used to compound and store Semaglutide 2.4mg/7.5ml injection lot SH 159088 assigned a 1 year BUD, do have a protect from light statement however, not stored in amber vials.*	No
LABELING SOPs: Labeling procedures, as described in facility SOPs, are followed to prevent labeling errors and CSP mix-ups. [USP 797 Section 13] *Not following policy-Unlabeled vials observed in refrigerator in amber vials, was stated to be NAD plus test-per pharmacist not dispensed.*	No
LABEL VERIFICATION: CSP labels are verified to ensure that they conform with the prescription or medication order, MFR (if required), and the CR. [USP 797 Section 13] *SOP reflects the language, but since pharmacy started compounding and dispensing Semaglutide, Tirzepatide and NAD plus, has not prepared a Compounding record, of master formulation record.*	No

D. PERSONNEL PREPARATION & OBSERVATION – ALL CATEGORIES

CONTROLLED ACCESS: Access to the SEC is restricted to authorized personnel and required materials. [USP 797 Section 4.2.1] *SCA is accessible to all staff including non-licensed personnel SR(Office Manager), CC(IT person) and owners (DS)*	No
UNNECESSARY ITEMS: Items not necessary for compounding (e.g., food, drinks, mints, gum, earbuds, headphones) are not introduced into the compounding environment. Accommodations are documented. [USP 797 Section 3.1] *In SCA, inspectors noted a lid for unsterilized rubber stoppers*	N/A
UNNECESSARY PERSONAL ITEMS: Personnel remove outer garments (e.g., bandanas, coats, hats, jackets, sweaters, vests); cosmetics, and all hand, wrist, and other exposed jewelry, including piercings that may interfere with effectiveness of garbing. [USP 797 Section 3.1]	Yes
NAILS: Nails are clean and trimmed. Nail products (e.g., polish, artificial nails, and extenders) are not worn. [USP 797 Section 3.1]	Yes
REQUIRED PPE & GARBING ORDER: Personnel garb (don and doff) in an order that reduces risk of contamination per SOP. Required garb, manner of storage, and order or garbing is documented in SOP's. The minimum required PPE when preparing CSPs includes a garment with sleeves that fit around wrists and enclosed neck, shoe covers, head/facial hair cover, face mask, and sterile powder-free gloves. All PPE is low lint for Category 1 & 2 compounding or sterile if Category 3. [USP 797 Section 3.3] *Pharmacist AH was not able to demonstrate proper garbing technique*	No
NAIL PICK USE: Personnel clean under nails under warm running water with a disposable nail cleaner. Hands and forearms are washed with soap and water for at least 30 seconds prior to entering a compounding area. [USP 797 Section 3.2] *Not used to demonstrate hand hygiene, no warm running water, nail picks not used during observation of garbing*	No
INAPPROPRIATE HAND HYGIENE PRACTICES: Brushes and hand dryers are not used, and soap containers are not refilled or topped off. [USP 797 Section 3.2] *Hand hygiene not demonstrated prior to donning gown*	No
ALCOHOL-BASED HAND RUB: Hands are sanitized with alcohol-based hand rub prior to donning gloves. Handrub is used prior to donning garb when hand hygiene is done outside of a classified area. [USP 797 Section 3.3] *Not used during demonstration*	No
STERILE GLOVES USED: Sterile gloves are donned in classified room or SCA. Skin is not exposed inside ISO 5 PEC (e.g., gloves are not donned or doffed). [USP 797 Section 3.3] *Dynarex sterile gloves used during compounding*	Yes

GARB STORAGE: Gowns and other garb are stored in a manner that minimizes contamination (e.g., away from sinks) and within a classified area or SCA. [USP 797 Section 3.3] *Pharmacist observed to reuse the same gown to demonstrate garbing, CACI in SCA*	No
SANITIZATION OF STERILE GLOVES: Sterile 70% IPA is applied to gloves prior to compounding and regularly throughout the compounding process. [USP 797 Section 3.3] *Expired Alcohol noted from 6/2022 in hood*	No
SANITIZATION OF ITEMS INTRODUCED INTO PEC: Items are wiped with sterile 70% IPA and sterile low-lint wipers just prior to being introduced into the PEC and allowed to dry before use. [USP 797 Section 8.2] *Kimtech lint-guard wipes are low-linting but not sterile. SOP states to use sporicidal prior to introducing items into the CACI followed by SIPA, but this is not the process used.*	No
CRITICAL SITES (e.g., vial stoppers, ampule necks, and intravenous bag septum's) are wiped with sterile 70% IPA in the PEC to provide both chemical and mechanical actions to remove contaminants. The sterile 70% IPA is allowed to dry before personnel enter or puncture stoppers and septum's or break the necks of ampules. [USP 797 Section 8.3]	No
EQUIPMENT DISINFECTION PRIOR TO ENTRY: Equipment brought into classified areas is wiped with a sporicidal disinfectant, EPA-registered disinfectant, or sterile 70% IPA using low-lint wipers. [USP 797 Section 9.1] *Portable weighing equipment used to weigh upto 50 grams of Semaglutide API or Tirzepatide API is not wiped down between compounds.*	No

E. EQUIPMENT, SUPPLIES, & COMPONENTS – ALL CATEGORIES

DAILY ACD ACCURACY ASSESSMENT: An accuracy assessment is conducted for Automated Compounding Devices (ACDs) or similar equipment before the first use and again each day the equipment is used to compound CSPs. A daily record of accuracy measurements is maintained. Corrective actions are implemented if accuracy measurements are outside of manufacturer's specifications. [USP 797 Section 9.1] *Tirzepatide is pre-weighed and stored in the freezer in weigh boats but there are no records of weight documentation or accuracy assessment for this API.*	No
EQUIPMENT SOPs: Written SOPs for the calibration, maintenance, cleaning, and use of equipment are established and are based on the manufacturer's recommendations. Procedures are followed and records are maintained. [USP 797 Section 9.1] *No record of PEC /CACI certification. Aseptic Enclosures PEC or CACI was installed March 2024, but has not been maintained or certified. No autoclave or dry heat oven, weighing scale not calibrated, no certificate of calibration.*	No
COMPOUNDING EQUIPMENT & SUPPLIES: Equipment and supplies used in compounding (e.g., needles, syringes, filters, tubing sets, beakers, utensils) are of suitable composition that surfaces in direct contact with components are not reactive or sorptive and surfaces in direct contact with CSPs are sterile and depyrogenated. [USP 797 Section 9.2] *No tubing, but using non-sterile pipettes to draw up from beaker into vials final product, such as Tirzepatide 5mg/0.5ml lot SH159090 assigned a BUD of 8/8/2025 (1 year BUD from date or preparation).*	No
COMPONENT STORAGE: Components are handled and stored in a manner that prevents contamination, mix-ups, and deterioration and under temperature, humidity, and lighting conditions consistent with those indicated in official monographs or specified by the suppliers and/or manufacturers. [USP 797 Section 9.3.4] *No monitoring of humidity or temperature. API's are prone to contamination since glassware such as beakers are not sterilized but rinsed with Isopropyl alcohol in a non-controlled environment.*	No

F. SEGREGATED COMPOUNDING AREA: Category 1

CATEGORY 1 MAXIMUM BUDs & COMPOUNDING AREA REQUIREMENTS: Only Category 1 CSPs are compounded in an ISO class 5 PEC located within a SCA and are assigned a BUD of 12 hours or less at controlled room temperature or 24 hours or less when refrigerated. [USP 797 Section 1.5, 4.2.1] *Injectable compounded products are being assigned a 1 year BUD, that were compounded in a CACI in an SCA*	No
DEDICATED AREA FOR SCA: The SCA is separated from areas not directly related to compounding, and all surfaces (walls, floors, counters, and equipment) are clean, uncluttered, and dedicated to compounding. [USP 797 Section 4.2.1] *Yes dedicated SCA, however no documented maintenance*	No
SCA LOCATION: The SCA is located away from unsealed windows, doors that connect to the outdoors, and traffic flow, all of which may adversely affect the air quality in the PEC. SCA is not located where environmental control challenges (e.g., restrooms, warehouses, or food preparation areas) could negatively affect the air quality of the PEC within the SCA. A sink is not located within 1 meter of PEC. [USP 797 Section 4.2.1] *Door remained open throughout the day when inspectors arrived and the PEC was turned off.*	No
ITEMS WITHIN SCA: Only furniture, equipment, and other materials necessary for performing compounding activities are located within the SCA. [USP 797 Section 4.2.1] *Cardboard boxes observed next to hood on the left on a cart.*	No

G. FACILITIES & SECONDARY ENGINEERING CONTROLS – Categories 2 and 3

STERILE SUITE CONSTRUCTION: The ISO-classified anteroom and buffer room are separated from the surrounding unclassified areas of the facility by fixed walls and doors, and controls are in place. [USP 797 Section 4.2.1] *Pharmacy is compounding Categ 3 injectable medications and dispensing to patients, but has not completed sterile suite construction or received a license from the Board of pharmacy.*	No
HEPA FILTERED AIR: Air supplied to the cleanroom suite is introduced through HEPA filters located in the ceiling of the buffer room and anteroom. [USP 797 Section 4.2.1] *No ceiling hepa filters. Pharmacy is compounding Categ 3 injectable medications in a CACI in SCA assigning a 1 year BUD and dispensing to patients, clinics, but has not completed sterile suite construction*	No
AIR RETURNS: Air returns in the cleanroom suite are low on the wall unless a visual smoke study demonstrates an absence of stagnant airflow. [USP 797 Section 4.2.1] *Ceiling return only, smoke studies not conducted*	No
LINE OF DEMARCATION: The anteroom has a line of demarcation to separate the clean side from the dirty side. [USP 797 Section 4.2.1] *Not a sterile suite however used to compound and dispense injectable medication -specifically novel weight loss drugs-various strengths.*	No
SURFACES & WALLS: The surfaces of ceilings, walls, floors, doors, door frames, fixtures, shelving, work surfaces, counters, and cabinets in the classified area are smooth, impervious, free from cracks and crevices, and non-shedding. Walls are constructed of/or covered with durable material. [USP 797 Section 4.3.1] *Walls are textured and not cleanable. Inspector completed the initial New Business inspection April 2024 and notified attendees during the inspection, if they were to compound injectable medication labeled as Cat 3, a cleanroom suite was necessary.*	No
CEILINGS & FLOORS: Inlaid panels of ceilings are caulked around each panel to seal them to the support frame. Junctures between the ceiling and the walls and between the walls and the floor are sealed to eliminate cracks and crevices where dirt can accumulate. Floors include coving to the sidewall, or the juncture between the floor and the wall are caulked. [USP 797 Section 4.3.1] *Baseboard is wood in SCA where Cat 3 compounding occurs in the uncertified CACI.*	No

LEDGES & OVERHANGS: Overhangs and ledges are easily cleanable, and the exterior lens surface of ceiling light fixtures are smooth, mounted flush, and sealed. [USP 797 Sections 4.3.1] *Not a cleanroom suite suitable for compounding and releasing Cat 3 injectables, baseboards are wood.*	No
FURNITURE, EQUIPMENT, & MATERIALS: Only furniture, equipment, and other materials necessary for performing compounding activities are permitted in a classified area or SCA. Tacky mats are not placed within ISO-classified areas. [USP 797 Sections 4.2.1 & 4.5] *This is not a cleanroom suite suitable for compounding and releasing Cat 3 compounds rx 34275 Semaglutide Inj, Tirzepatide Inj SH159091*	No
CARTS: Carts used to transport components or equipment into classified areas are constructed from nonporous materials with cleanable casters and wheels. [USP 797 Section 4.5]	Yes
TEMPERATURE & HUMIDITY MONITORING: Temperature and humidity in the cleanroom suite are controlled through a heating, ventilation, and air conditioning (HVAC) system. The temperature and humidity are monitored in each room of the cleanroom suite each day that compounding is performed, either manually or by a continuous recording device. They are documented at least once daily or stored in the continuous recording device and are retrievable and are reviewed as described in the facility's SOP. [USP 797 Section 4.2] *No device for temp or humidity monitoring in C-SCA.*	No
PRESSURE DIFFERENTIATION MONITORING & DOCUMENTATION: Facility maintains a minimum differential positive pressure of 0.020-inch water column between the buffer room and anteroom and anteroom and unclassified area. A pressure differential monitoring device is used to continuously monitor the pressure differentials. Quantitative results from the pressure monitoring device are reviewed and documented at least daily on the days when compounding is occurring. [USP 797 Sections 4.2.5] *No cleanroom suite. The CACI is reading negative pressure and ventilated to the outside and is located in a C-SCA and this environment is being used to compound and dispense injectable non-hazardous medication with no cascading pressure reaching a minimum of + 0.02 inches water column.*	No
PEC LOCATION: PECs are located in a buffer room in a manner that minimizes conditions that could increase the risk of microbial contamination (strong air currents, personnel traffic, or air streams from HVAC system(s)) and allows for cleaning around the PEC. [USP 797 Sections 4.2.2 & 4.2.3] *Negative pressure CACI in SCA is the compounding environment used to prepare Cat 3 injectable compounds with a BUD of 1 year*	No
INTEGRATED VERTICAL LAMINAR FLOW ZONES: IVLFZ is separated from ISO Class 7 area with a physical barrier and there is full coverage of HEPA filters above the work surface. [USP 797 Section 4.2.3]	N/A

H. CERTIFICATION AND RECERTIFICATION – ALL CATEGORIES

PEC CERTIFICATION: The PEC is certified initially and every 6 months to meet ISO Class 5 or better conditions, during dynamic operating conditions. [USP 797 Sections 4.1 & 5.0] *Aseptic Enclosures CACI in SCA is not certified but was installed March 14, 2024. Pharmacy is compounding Categ 3 injectable medications in a CACI in SCA assigning a 1 year BUD and dispensing to patients, clinics, but has not completed sterile suite construction.*	No
SEC CERTIFICATION: SECs are certified initially and every 6 months to meet ISO Class 7 or 8 or better conditions, during dynamic operating conditions (including presterilization activities if applicable). Anterooms providing access to positive-pressure buffer rooms are at least ISO 8 and at least ISO 7 for anterooms providing access to negative-pressure buffer rooms. Classified areas are recertified when changes occur that could affect airflow or air quality [USP 797 Sections 4.1, 4.2.6, & 5.0] *Compounding without an issued license and dispensing compounded products,*	No
ISO CLASS 7 & 8 REQUIREMENTS: ISO Class 7 rooms maintain a minimum of 30 total HEPA-filtered ACPH during dynamic operating conditions, at least 15 ACPH come from the HVAC through HEPA filters located in the ceiling. ISO Class 8 rooms maintain a minimum of 20 total HEPA-filtered ACPH during dynamic operating conditions; 15 ACPH must come from the SEC. The ACPH from HVAC, ACPH contributed from the PEC, and the total ACPH are documented on the certification report. [UPS 797 Section 4.2.4] *No cleanroom suite suitable for compounding injectable weight loss medications assigned a BUD of 1 year.*	No
DOCUMENTATION OF PERSONNEL PRESENT DURING CERTIFICATION: The number of personnel present in each PEC and SEC during total particle counts and dynamic airflow smoke-pattern tests is documented on the certification report. [USP 797 Section 5.0] *No formal certification of the compounding environment.*	No
PEC DYNAMIC SMOKE PATTERN TEST: Smoke pattern tests are performed under dynamic conditions initially to demonstrate minimal disruption in airflow and repeated if equipment is placed in a different location. Smoke pattern tests are performed under dynamic conditions every 6 months to demonstrate unidirectional airflow and sweeping action over and away from the preparation(s). [USP 797 Section 5.0] *Not documented or provided to inspector.*	No
ROBOTICS / ROBOTIC ENCLOSURES: Robotic enclosures used as a PEC or placed within a PEC have a dynamic airflow smoke pattern test is performed initially and at least every 6 months that confirms 1) the robotic device is properly integrated into the facility, 2) there is no turbulence or refluxing at any critical site(s), 3) room air does not enter the PEC where sterile products and/or preparations may be exposed, and 4) all processes can be performed without introducing contamination to the DCA(s). [USP 797 Section 4.2.3]	N/A
HEPA FILTER INTEGRITY TESTING: HEPA filter integrity testing for both SECs & PECs is conducted initially and every 6 months as part of total particle testing. [USP 797 Section 5.0] *None documented*	No
MONITORING DEVICE CERTIFICATION: Temperature and humidity monitoring devices are verified for accuracy at least every 12 months or as required by the manufacturer. [USP 797 Section 4.2] *Not documented*	No
CONTAINMENT DEVICES USED FOR PRESTERILIZATION PROCEDURES: CVEs, BSCs, or CACIs used for presterilization procedures are certified at least once every 6 months. [USP 797 Section 4.2.6] *Cat 3 compounding warrants a CVE be used in a Cleanroom suite to weigh API.*	No
CERTIFICATION REPORT REVIEW BY DESIGNATED PERSON: All certification and recertification records are reviewed by the designated person(s). A corrective action plan is implemented and documented in response to any out-of-range results on certification report and data reviewed to confirm that the actions taken have been effective. [UPS 797 Section 5.0] *Not documented*	No

I. RABS

LOCATION: If used to prepare Category 2 or Category 3 CSP's RABS are located in a cleanroom suite with an ISO Class 7 or better buffer room with an ISO Class 8 or better anteroom. [USP 797 Section 4.2.3]	
RECOVERY TIME: When a RABS is used, the recovery time after opening the transfer chamber to achieve ISO Class 5 air is documented and internal procedures are developed to ensure that adequate recovery time is allowed after opening and closing the RABS. [USP 797 Section 4.2.3]	
STERILE GLOVES: are worn over gloves attached to RABS sleeves. [USP 797 Section 3.3]	

J. CATEGORY 2 CSPs WITHOUT STERILITY TESTING

CATEGORY 2 COMPOUNDING ENVIRONMENT: Category 2 CSPs are compounded in an ISO class 5 PEC located within an ISO classified anteroom and buffer room. [USP 797 Sections 4.1 & 14.3] *Not a certified PEC*	No

CATEGORY 2 BUDs FROM STERILE COMPONENTS WITHOUT STERILITY TESTING: Category 2 CSPs compounded aseptically from all sterile starting components and in the absence of sterility testing do not exceed the following BUDs: 4 days room temperature, 10 days refrigerated, or 45 days frozen. [USP 797 Section 14.3]	N/A
CATEGORY 2 BUDs FROM NONSTERILE COMPONENTS WITHOUT STERILITY TESTING: Category 2 CSPs compounded aseptically from one or more nonsterile starting components and in the absence of sterility testing do not exceed the following BUDs: 1 day room temperature, 4 days refrigerated, or 45 days frozen. [USP 797 Section 14.3] *Non-sterile compounding falling into Cat 3 due to BUD of 1 year*	No

K. CATEGORY 2 EXTENDED BUD REQUIREMENTS

CATEGORY 2 BUDs FOR ASEPTICALLY PROCESSED CSPs WITH STERILITY TESTING: Category 2 CSPs compounded aseptically, and which have passed sterility testing do not exceed the following BUDs: 30 days room temperature, 45 days refrigerated, or 60 days frozen. [USP 797 Section 14.3]	
CATEGORY 2 BUDs FOR TERMINALLY STERILIZED CSPs WITHOUT STERILITY TESTING: Category 2 CSPs terminally sterilized and in the absence of sterility testing do not exceed the following BUDs: 14 days room temperature, 28 days refrigerated, or 45 days frozen. [USP 797 Section 14.3]	
CATEGORY 2 BUDs FOR TERMINALLY STERILIZED CSPs WITH STERILITY TESTING: Category 2 CSPs terminally sterilized, and which have passed sterility testing do not exceed the following BUDs: 45 days room temperature, 60 days refrigerated, or 90 days frozen. [USP 797 Section 14.3]	
ANTIMICROBIAL EFFECTIVENESS TESTING FOR MULTI-DOSE CSPs: Aqueous multiple-dose CSPs (e.g., injectables and ophthalmics) pass USP <51> compliant antimicrobial effectiveness testing once for each unique formulation and each container closure system in which it is packaged. Bracketing studies are allowed. [USP 797 Section 14.5 & 16.1]	
CONTAINER CLOSURE TESTING: Container closure integrity testing is performed once for each unique CSP formulation and container closure system in which it is packaged. For multi-dose (i.e., preserved CSPs), container integrity testing is performed per fill volume for each unique CSP formulation and container closure system. [USP 797 Sections 14.3.3 & 14.5]	
MULTI-DOSE, NON-PRESERVED AQUEOUS CSPs: Multi-dose, non-preserved aqueous CSPs (i.e., topical, or ophthalmic solutions) are assigned are prepared as a Category 2 CSP, for use by a single patient, and labeled to indicate that once opened, the CSP must be discard after 24 hours if stored at controlled room temperature or 72 hours when stored under refrigeration. [USP 797 14.5]	
OUTSOURCED STERILITY TESTING: Sterility testing is performed for all Category 2 CSPs assigned a BUD requiring sterility testing according to USP <71> or a validated alternative and noninferior method. Membrane Filtration as described in USP <71> is the preferred method when the formulation allows. [USP 797 Section 12.2]	
INHOUSE STERILITY TESTING: Sterility testing is according to USP <71> or a validated alternative and noninferior method. Membrane filtration is used if appropriate and filters are rinsed according to USP <71>. Direct inoculation is done only when membrane filtration cannot be carried out. Volume inoculated does not exceed 10% of the culture media volume. Growth promotion test has been done on the media with the 5 specified organisms (not more than 100 CFU) according to USP <71>. TSB or SCD is incubated at 20-25C for 14 days; FTM is incubated at 30-35C for 14 days. (2 incubators present).	
METHOD SUITABILITY TEST: A Method Suitability Test (or equivalent validation for alternative testing methods) is performed to validate suitability of the sterility testing method. [USP 797 Section 12.2]	
MAXIMUM BATCH SIZE: The maximum batch size for all CSPs requiring sterility testing is 250 final yield units. [USP 797 Section 12.2]	
STERILITY TESTING QUANTITY & VOLUME DETERMINATION: The minimum quantity of each container tested for sterility is per USP <71> Table 2 and the number of containers tested in relation to the batch size is per USP <71> Table 3. For 1-39 CSPs compounded as single batch, sterility testing is performed on a number of containers or units equal to 10% of the number of CSPs prepared rounded to the next whole number. [USP 797 Section 12.2]	
INVESTIGATION OF STERILITY TEST FAILURES: Sterility tests resulting in failure undergo prompt investigation into possible causes and requires identification of the microorganism(s) as well as evaluation of sterility testing procedure, compounding facility, process, and/or personnel that may have contributed to the failure. Impact to other CSPs is assessed. Investigation and resulting corrective actions are documented. [USP 797 Section 12.2]	
ENDOTOXIN TESTING: Category 2 injectable CSPs compounded from one or more nonsterile component(s) and assigned a BUD that requires sterility testing are tested for bacterial endotoxins. [USP 797 Section 12.3]	
ENDOTOXIN LIMITS: In the absence of a bacterial endotoxin limit in an official USP–NF monograph or other CSP formula or scientifically supported source, the CSP does not exceed the endotoxin limit calculated as described in USP <85> for the appropriate route of administration for humans or largest recommend dose per weight for nonhuman species. [USP 797 Section 12.3]	

L. CATEGORY 3 CSPs, BUDs, & RELATED REQUIREMENTS

CATEGORY 3 REQUIREMENTS: All requirements associated with Category 3 compounding (e.g., garbing, cleaning, environmental monitoring) apply to all personnel entering the buffer room where Category 3 CSPs are compounded and always apply regardless of whether Category 3 CSPs are compounded on a given day. [USP 797 Section 14.4.2] *Not meeting requirements for dispensing Cat 3 compounds injectable peptides*	No
STERILE/SINGLE USE GARB: When compounding Category 3 CSPs, skin is not exposed in buffer room (i.e., face and neck are covered) and all low lint outer garb is sterile, including sterile sleeves over RABS gauntlet sleeves. Disposable garb items are not reused. [USP 797 Section 3.3] *Gown is not noted to be sterile prior to garbing and compounding in CACI in SCA*	No
STERILIZED/REUSABLE GARB: Non-disposable garb is not reused without being laundered and resterilized with a validated cycle. Disinfection procedures described in facility SOPs are followed before reusing goggles, respirators, and other equipment. [USP 797 Section 3.3] *Currently reusing gown, no goggles, skin exposed during compounding in SCA*	No
CATEGORY 3 BUDs FOR ASEPTICALLY PROCESSED CSPs: Category 3 CSPs aseptically processed, sterility tested, and passing all applicable tests (including stability indicating assay, endotoxin, and other dosage form appropriate tests) do not exceed the following BUDs: 60 days room temperature, 90 days refrigerated, or 120 days frozen. Shorter BUDs are assigned when physical or chemical stability of the CSP is less than the maximum allowable Category 3 BUDs for aseptically processed CSPs. [USP 797 Section 14.4.3] *Injectable Semaglutide and Tirzepatide is assigned a 1 year BUD (exceeds what the USP <797> chapter allows) and dispensed by courier to patients without a confirmation of sterility, stability or endotoxin testing.*	No
CATEGORY 3 BUDs FOR TERMINALLY STERILIZED CSPs: Category 3 CSPs aseptically processed, sterility tested, and passing all applicable tests (including stability indicating assay, endotoxin, and other dosage form appropriate tests) do not exceed the following BUDs: 90 days room temperature, 120 days refrigerated, or 180 days frozen. Shorter BUDs are assigned when physical or chemical stability of the CSP is less than the maximum allowable Category 3 BUDs for terminally sterilized CSPs. [USP 797 Section 14.4.3] *No autoclave-not terminally sterilizing, however assigning injectable compounds a 1 year BUD.*	No
MAXIMUM BATCH SIZE: Category 3 CSP batch sizes do not exceed 250 final yield units. [USP 797 Section 12.2] *Compounds a maximum of 50 vials, no license to compound injectable medications.*	No

STABILITY INDICATING ASSAYS: All Category 3 CSP formulations are supported by data obtained using a validated stability-indicating analytical method that can distinguish active ingredients from degradants and impurities and quantify the amount of active ingredient. CSPs are prepared according to the exact formulation, components, and packaged in a container closure system of the same materials of composition. Facilities have documentation of the stability study, its results, and the method validation available for review. [USP 797 Section 14.3.3] *Not provided*	No
STERILITY TESTING: All category 3 CSPs and batches undergo sterility testing performed according to USP <71> or a validated alternative and noninferior method. [USP 797 Sections 12.2 & 14.4.4] *No sterility testing document provided prior to release to patients.*	No
METHOD SUITABILITY TEST: A Method Suitability Test (or equivalent validation for alternative testing methods) is performed to validate suitability of the sterility testing method for each formulation. [USP 797 Section 12.2] *Not completed prior to releasing products.*	No
STERILITY TESTING QUANTITY & VOLUME DETERMINATION: The minimum quantity of each container tested for sterility is per USP <71> Table 2 and the number of containers tested in relation to the batch size is per USP <71> Table 3. For 1-39 CSPs compounded as single batch, sterility testing is performed on a number of containers or units equal to 10% of the number of CSPs prepared rounded to the next whole number. [USP 797 Section 12.2] *Not completed on injectable medications released to patients.*	No
INVESTIGATION OF STERILITY TEST FAILURES: Sterility tests resulting in failure undergo prompt investigation into possible causes and requires identification of the microorganism(s) as well as evaluation of sterility testing procedure, compounding facility, process, and/or personnel that may have contributed to the failure. Impact to other CSPs is assessed. Investigation and resulting corrective actions are documented. [USP 797 Section 12.2] *Not documented.*	No
ENDOTOXIN TESTING: Category 3 injectable CSPs compounded from one or more nonsterile component(s) are tested for bacterial endotoxins. [USP 797 Section 12.3] *No contract lab used per pharmacist for endotoxin testing*	No
ENDOTOXIN LIMITS: In the absence of a bacterial endotoxin limit in an official USP–NF monograph or other CSP formula or scientifically supported source, the CSP does not exceed the endotoxin limit calculated as described in USP <85> for the appropriate route of administration for humans or largest recommend dose per weight for nonhuman species. [USP 797 Section 12.3] *Nothing documented prior to releasing and dispensing to patients.*	No
PARTICULATE MATTER TESTING: Category 3 injectable CSPs undergo USP <788> (Particulate Matter in Injections) and ophthalmic solutions undergo USP <789> (Particulate Matter in Ophthalmic Solutions) test once per formulation with acceptable results. [USP 797 Section 14.3.3] *Not done on released dispensed Semaglutide or Tirzepatide injection*	No
ANTIMICROBIAL EFFECTIVENESS TESTING FOR MULTI-DOSE CSPs: Aqueous multiple-dose CSPs (e.g., injectables and ophthalmic) pass USP <51> compliant antimicrobial effectiveness testing once for each unique formulation and each container closure system in which it is packaged. Bracketing studies are allowed. [USP 797 Section 14.5 & 16.1] *Several vials of Semaglutide vials lot SH159063 noted in back room under 5196 Mariner Blvd (Drug testing side)-different address where they are stored. Inspector currently at 5194 Mariner Blvd where pharmacy is located.*	No
CONTAINER CLOSURE TESTING: Container closure integrity testing is performed once for each unique CSP formulation and container closure system in which it is packaged. For multi-dose (i.e., preserved multi-dose CSPs), container closure integrity testing is also performed per fill volume for each unique CSP formulation and container closure system. [USP 797 Sections 14.3.3 & 14.5] *Not provided. Several vials not even crimped, specifically Semaglutide 2.5mg/1ml Inj Dr. Justin bulk vial Lot SH159087 intended to pull off future doses. Pharmacist is removing contents from this vial to further pipette into smaller vials.*	No
MULTI-DOSE, NON-PRESERVED AQUEOUS CSPs: Multi-dose, non-preserved aqueous CSPs (i.e., topical, or ophthalmic solutions) are prepared for use by a single patient, and labeled to indicate that once opened, the CSP must be discard after 24 hours if stored at controlled room temperature or 72 hours when stored under refrigeration. [USP 797 14.5]	N/A
MULTI-DOSE COMPONENT CSPs: Multiple-dose CSP after initially entered or punctured, are not used for longer than the assigned BUD or 28 days, whichever is shorter. [USP 797 Section 16.1] *Each vial states 30 days, specifically Semaglutide 2.5mg/1ml Inj Dr. Justin bulk vial Lot SH159087 intended to pull off future doses. Pharmacist is removing contents from this vial to further pipette into smaller vials.*	No

M. PERSONNEL TRAINING & COMPETENCIES - ALL CATEGORIES

TRAINING PROGRAM & SOP: Facility maintains a written training program and corresponding SOP which defines required trainings, frequency of training and the process for evaluating the performance of individuals who compound, have direct oversight of compounding personnel, perform in-process checks, final verification and dispensing of CSP's. [USP 797 Section 2] *Designated Person is now a compounder, however has no documented training and is compounding injectable Semaglutide and Tirzepatide.*	No
INITIAL CORE SKILLS KNOWLEDGE & COMPETENCY ASSESSMENT: Before beginning to compound CSPs independently or have direct oversight of compounding personnel, personnel complete training and can demonstrate knowledge of principles and competency of skills for performing sterile manipulations and achieving and maintaining appropriate environmental conditions as applicable to their assigned job functions. [USP 797 Section 2.1] *No visually observed knowledge assessment prior to compounding Cat 3 injectables assigned a 1 year BUD.*	No
INITIAL GLOVED FINGERTIP & HAND HYGIENE/GARBING COMPETENCY: Before beginning to compound independently or have direct oversight of compounding personnel, personnel successfully complete an initial gloved fingertip (GFT) competency no fewer than 3 separate times, with a documented visual audit while performing hand hygiene and garbing procedures. GFT samples are collected before applying sterile 70% IPA to gloves. [USP 797 Section 2.2] *Not documented or provided.*	No
GLOVED FINGERTIP INCUBATION: Documentation includes the name of the person evaluated; evaluation date and time; media and components used to include manufacturer, expiration date, and lot number; starting temperature for each interval of incubation; dates of incubation; results and identification of the observer and personnel reading and documenting the results. USP 797 Section 2.2] *No calibrated incubators, since not gloved fingertip provided for documented assesments. Refrigerated TSA plates have not been used.*	No
INITIAL MEDIA FILL & ASEPTIC TECHNIQUE ASSESSMENT: Before beginning to compound independently or have direct oversight of compounding personnel, personnel who compound or have direct oversight of compounding successfully complete an initial aseptic manipulation competency evaluation which consists of a visual observation, media-fill testing followed by a gloved fingertip and thumb sampling on both hands, and surface sampling of the direct compounding area. [USP 797 Section 2.3] *Not completed for pharmacist compounding.*	No
MEDIA INCUBATION: Documentation includes the name of the person evaluated, evaluation date and time, media and components used to include their manufacturer or supplier, expiration dates and lot numbers, starting temperature for each interval of incubation, dates of incubation, the results, and the names or other identification of the observer and the person who reads and documents the results. [USP 797 Section 2.3] *No incubator noted. Media fill not conducted prior to compounding.*	No
CATEGORY 1 AND 2-ONGOING GFT & GARBING ASSESSMENT: After initial garbing competency evaluations, compounding personnel complete garbing competency evaluation and GFT every 6 months for Category 1 and Category 2 CSP's. Direct oversight personnel who do not compound complete garbing competency and GFT every 12 months. GFTs are appropriately incubated. [USP 797 Section 2.2] *Never done.*	No

CATEGORY 1 AND 2-ONGOING MEDIA FILL & ASSESSMENT: After initial aseptic manipulations competency evaluations, compounding personnel complete aseptic technique competency, media fill, GFTs, and surface sampling of DCA every 6 months for Category 1 and Category 2 CSP's. Direct oversight personnel who do not compound complete media fill every 12 months. GFTs and surface samples are appropriately incubated. [USP 797 Section 2.3] *Never done*	No
ONGOING KNOWLEDGE & COMPENTENCY OF CORE SKILLS: Training and knowledge assessment of sterile compounding principles or core skills is completed at least every 12 months. [USP 797 Section 2.1] *Insufficient skills: Only documented CEs were Practice makes perfect: a guide to mastering, garbing, hand hygiene 1 CE, Sterile Compounding 101 1 CE: Stability, sterility and BUD 1 CE, Sterile Compounding navigating Revise USP 797 from free CE 1 hr. Other compounding CE not provided to inspectors such as Master formulation records, Compounding records, Aseptic technique, surface sampling.*	No
FAILED COMPETENCY INVESTIGATION: Initial and ongoing competency assessment failures are investigated, remediated, and documented in a Corrective Action Plan. [USP 797 Sections 2.2 & 2.3] *Only 1 pharmacist at firm, no one to assess.*	No
STAFF TRAINING IN VIABLE AIR AND SURFACE SAMPLING: Personnel are trained and competent in air and surface sampling procedures to ensure accurate and reproducible sampling. [USP 797 Section 6.1] *Not available*	No

FACILITY COMPOUNDS CATEGORY 3

CATEGORY 3-ONGOING GFT & GARBING ASSESSMENT: After initial garbing competency evaluations, compounding personnel complete garbing competency and GFT every 3 months for Category 3 CSP's. Direct oversight personnel who do not compound complete garbing competency and GFT every 12 months. GFTs are appropriately incubated. [USP 797 Section 2.2] *Cat 3 compounds such as Semaglutide and Tirzepatide have been dispensed, however, not a single assessment of garbing available.*	No
CATEGORY 3-ONGOING ASEPTIC PROCESSING COMPETENCY: Aseptic competency is repeated at least one time every 3 months for personnel compounding Category 3 CSPs. The simulation must capture elements that could potentially affect the sterility of the CSP. Immediately following the media-fill test, gloved fingertip and thumb sampling is performed on both hands and surface sampling of the direct compounding area. Direct oversight personnel who do not compound must complete media fill every 12 months. [USP 797 Section 2.3] *Sole pharmacist and compounder has not completed aseptic technique competency.*	No

N. MICROBIOLOGICAL AIR AND SURFACE MONITORING: ALL CATEGORIES

ENVIRONMENTAL MONITORING PROGRAM & SOPs: The microbiological air and surface monitoring program is clearly described in the facility's SOPs, which includes a diagram of the sampling locations, procedures for collecting samples, frequency of sampling, size of samples (e.g., surface area, volume of air), time of day of sampling in relation to activities in the compounding area, and action levels that trigger corrective action. [USP 797 Section 6] *Frequency must be every 30 days for Category 3 compounds-never completed at the firm.*	No
VIABLE AIR SAMPLING: Volumetric active air sampling using an impaction air sampler collecting at least 1000L of air is conducted in each classified area [e.g., ISO Class 5 PEC and ISO Class 7 and 8 room(s)] during dynamic operating conditions and is completed at least every 6 months. [USP 797 Section 6.2] *No viable air ever completed.*	No
AIR IMPACTION DEVICE: Device is serviced and calibrated according to the manufacturer's recommendations. [USP 797 Section 6.1] *No certification documented for CACI in SCA*	No
SURFACE SAMPLING: Microbiological surface sampling is conducted in all classified areas and pass-through chambers under dynamic operating conditions and performed at least once monthly. [USP 797 Section 6.3] *Plates are present but monthly sampling has never been completed and the pharmacist is compounding Cat 3 CSP's.*	No
GROWTH MEDIA: A general microbiological growth media that supports the growth of bacteria and fungi is used and a COA from the manufacturer is available. Growth media used for surface sampling contains neutralizing agents (e.g., lecithin and polysorbate 80). [USP 797 Sections 6.2 & 6.3] *Not used, however pharmacy has Hardy TSA with L&T plates in the refrigerator*	No
INCUBATION: Samples are incubated at 30°C - 35°C for 48 hours and 20°C - 25°C for an additional 5 days; if dual growth media are used, incubate one media device at 30°C - 35°C for 48 hours and the second media device at 20°C - 25°C for 5 days. The incubator temperature is monitored during incubation, either manually or by a continuous recording device, and results are reviewed and documented as described in the facility's SOPs. Incubators are placed in a location outside of the sterile compounding area. [USP Sections 6.2.2 (Box 5) & 6.3.2 (Box 6)] *No incubators calibrated or in use*	No
ENVIRONMENTAL MONITORING TREND ANALYSIS: Regular review of sampling data is performed to detect trends and review of trending data is documented. [USP 797 Section 6.1] *Never certified CACI in SCA where firm compounds Semaglutide and Tirzepatide inj*	No
CORRECTIVE ACTION: When microbial growth exceeds action levels, the cause is investigated, and corrective action is taken; corrective actions taken are reviewed for effectiveness. An attempt to identify microorganisms at the genus level is made. [USP Sections 6.2.3 & USP 6.3.3] *Since last inspection of April 2024, no corrections in place*	No

FACILITY COMPOUNDS CATEGORY 3

CATEGORY 3-VIABLE AIR SAMPLING: Volumetric air sampling is completed within 30 days prior to the commencement of any Category 3 compounding and at least monthly thereafter regardless of the frequency of compounding Category 3 CSPs.Air sampling sites are selected in all classified areas. [USP 797 6.2.1] *Never completed, but is compounding Cat 3 compounds injectables released to patients.*	No
CATEGORY 3-SURFACE SAMPLING: Surface sampling for any Category 3 CSPs, is completed in all classified areas, and pass-through chambers connecting to classified areas, prior to assigning a BUD longer than BUD limits for Category 2 CSPs (defined in Table 13 of USP 797) and at least weekly on a regularly scheduled basis regardless of the frequency of compounding Category 3 CSPs. [USP 797 6.2.2] *No documentation provided, per pharmacist never been done*	No
CATEGORY 3-BATCH SURFACE SAMPLING: Surface sampling is conducted within the PEC used to prepare Category 3 CSPs, at the end of each batch before cleaning and disinfection occurs, unless a self-enclosed robotic device is used. When a self-enclosed robotic device is used as the PEC, surface sampling is conducted at least once daily at the end of compounding operations before cleaning and disinfection occurs. [USP 797 Section 6.3.2] *Not completed at the conclusion of a batch-no batch records provided.*	No

O. CLEANING AND DISINFECTING: ALL CATEGORIES

CLEANING SOPS: The frequency, method(s), documentation requirements, and location(s) of cleaning, disinfecting, and applying sporicidal disinfectants are described in written SOPs; use of agents is in accordance with manufacturer's instructions, procedures, and in adherence with minimum wet contact times. [USP 797 Section 7] *Not adhering to SOP "Cleaning of classified areas"*	No

CLEANING PERSONNEL: Cleaning and disinfecting activities are performed by trained and appropriately garbed personnel using facility-approved agents and procedures. Cleaning personnel demonstrate knowledge and competency of core skills related to cleaning, disinfection, and maintenance of environmental conditions initially and at least once every 12 months. [USP 797 Sections 7 & 2.1] *No cleaning training documented*	No
REUSABLE GARB: Disinfection procedures described in facility SOPs are followed before reusing goggles, respirators, and other equipment used. [USP 797 Section 3.3] *Garb should not be reused as observed in this environment*	No
DAILY PEC CLEANING & DISINFECTION: Equipment and all interior surfaces of the PEC are cleaned and disinfected daily on days when compounding occurs and when surface contamination is known or suspected. [USP 797 Section 7] *Not documented, however compounding Semaglutide and Tirzepatide is compounded Mon-Wed. Hood had particles noted and no documented under tray cleaning.*	No
CATEGORY 1 AND 2-MONTHLY PEC SPORICIDAL DISINFECTION: Equipment and all interior surfaces of the PEC, including underneath of removable work trays, are cleaned with a sporicidal agent monthly. [USP 797 Section 7] *Peridox still in owerwrap, not used, not documented, only sterile alcohol wipes used daily*	No
DAILY SEC & SCA CLEANING & DISINFECTION: Work surfaces, floors, sink surfaces, and pass-through chambers are cleaned and disinfected daily on days when compounding occurs. [USP 797 Section 7] *No documentation of SCA cleaning*	No
CATEGORY 1 AND 2 -MONTHLY SEC & SCA SPORICIDAL DISINFECTION: A sporicidal disinfectant is applied to work surfaces, pass-through chambers, storage shelving and bins, equipment outside of PEC's, sink surfaces, floors, ceilings*, walls, doors, and doors frames at least once monthly. *SCA ceilings are only cleaned, disinfected, and have sporicidal agents applied when visibly soiled and when surface contamination is known or suspected. [USP 797 Section 7] *SCA not documented as cleaned*	No
CLEANING & DISINFECTING AGENTS: Cleaning and disinfecting agents are EPA-registered. If a one-step disinfectant cleaner is not used, surfaces are cleaned prior to being disinfected. [USP 797 Section 7]	Yes
STERILE AGENTS USED INSIDE PECs: Cleaning, disinfecting and sporicidal agents used within PECs are sterile. Written SOPs describe the time period during which, once opened, sterile cleaning and disinfecting agents, supplies, and sterile 70% IPA may be reused sterile water is used to dilute concentrated cleaning agents used inside of PECs (if applicable). [USP 797 Section 7.1.1] *No sporicidal agents documented as used. Pharmacist compounds Cat 3 compounds such as Semaglutide and Tirzepatide.*	No
CLEANING AGENT RESIDUE REMOVAL IN PECs: In a PEC, sterile 70% IPA is applied after cleaning, disinfecting, or after one-step disinfectant cleaner or sporicidal agent application to remove residue. [USP 797 Section 7]. *Nothing documented*	No
PEC SANITIZATION WITH STERILE 70% IPA: Sterile 70% IPA is applied to the horizontal work surface, including removable trays, immediately before initiating compounding and at least every 30 minutes. If a compounding process takes more than 30 minutes, the work surface is disinfected immediately after the end of the compounding process. Sterile 70% IPA is allowed to dry. [USP 797 Section 7] *Does not include undertray and there is residue on the inside of the CACI glass.*	No
CLEANING SUPPLIES & TOOLS: All cleaning and disinfecting supplies (e.g., wipers, sponges, pads, and mop heads), except for tool handles and holders, are low lint. Supplies used inside PECs are sterile. [USP 797 Section 7.1.2]	Yes
REUSABLE CLEANING TOOLS: Reusable cleaning tools (e.g., mop frames) are made of cleanable materials and are cleaned and disinfected before and after each use. Reusable tools are dedicated for use in the classified areas or SCA and are not removed. Mops used in HD compounding areas, are dedicated for use only in those areas. [USP 797 Section 7.1.2] *No proper mops dedicated to SCA-not currently using a u line mop*	No
MATERIALS MOVEMENT INTO CLASSIFIED AREAS: Before any item is introduced into the clean side of anteroom(s), placed into pass-through chamber(s), or brought into the SCA, it is wiped with a sporicidal disinfectant, EPA-registered disinfectant, or sterile 70% IPA using low-lint wipers by personnel wearing gloves. Dwell time is followed. [USP 797 Section 8.1] *Not observed to be wiped prior to reintroduction into the CACI*	No

FACILITY COMPOUNDS CATEGORY 3

CATEGORY 3-WEEKLY SPORICIDAL CLEANING OF PECs: Weekly cleaning using a sporicidal agent is performed on all internal surfaces of PEC and equipment in PEC's. [USP 797 Section 7] *Nothing documented for weekly cleaning prior to compounding Semaglutide and Tirzepatide.*	No
CATEGORY 3-WEEKLY SPORICIDAL CLEANING OF SECs: Weekly cleaning using a sporicidal agent includes application on work surfaces outside the PEC, pass-through chambers, and floors. [USP 797 Section 7] *Not documented*	No
CATEGORY 3 -MONTHLY SEC SPORICIDAL DISINFECTION: A sporicidal disinfectant is applied to work surfaces, pass-through chambers, storage shelving and bins, equipment outside of PEC's, sink surfaces, floors, ceilings, walls, doors, and doors frames at least once monthly. [USP 797 Section 7] *Not documented*	No

P. COMPOUNDING CSPs FROM NONSTERILE COMPONENTS OR SUPPLIES – CATEGORY 2 & 3

PRESTERILIZATION ACTIVITY CONTAINMENT ENCLOSURES: Pre-sterilization procedures, such as weighing and mixing of nonsterile components, occur in ISO Class 8 or better environment (e.g., anteroom or buffer room) and are performed in single-use containment glove bags, CVEs, BSCs, or CACIs. [USP 797 Section 4.2.6] *Cat 3 compounds api not weighed in a cleanroom suite-weighed in uncertified unclassified hood.*	No
LOCATION OF STERILE & NONSTERILE PECs: PECs used for sterile and nonsterile compounding (e.g., pre-sterilization procedures) are placed in separate rooms unless the buffer room can maintain an ISO Class 7 classification during particulate generating activities. Co-located PECs are at least 1 meter apart and particle-generating activities are not performed during sterile compounding processes [USP 797 Section 4.2.1; USP 800 Section 5.3] *Cat 3 compounds api not weighed in a cleanroom suite-weighed in uncertified unclassified hood.*	No
COMPONENT SOPs: Written SOPs address the selection, receipt, evaluation, handling, storage, and documentation of all CSP components including ingredients and container closures. [USP 797 Section 9.3] *Not documenting receipt of components prior to use in compounding, no batch records to review.*	No
COMPONENT QUALITY & COA: APIs and components comply with the criteria in the USP-NF (if one exists for inactive components) and have a COA including specifications and test results showing the API or component meets expected quality. APIs and other components labeled "not for pharmaceutical use", "not for injectable use", "not for human use", or equivalent are not used in CSPs. [USP 7 Section 9.3.1] *API's do not state USP grade for Semaglutide, Tirzepatide, or Beta NAD- does not state USP*	No
API MANUFACTURERS: APIs are manufactured by an FDA-registered facility in the U.S. or comply with the laws and regulations of the applicable regulatory jurisdictions outside of the U.S. [USP 797 Section 9.3.1] *Not all COA's provide to inspector*	No

STERILE, DEPYROGENATED SUPPLIES: Supplies in direct contact with CSPs are sterile and depyrogenated. A COA or similar conformance documentation is reviewed. [USP 797 Section 9.3.1] *Beakers are not sterilized*	No
COMPONENT RECEIPT: Upon receipt, the external packaging of components is examined and components of unacceptable quality or showing deterioration are promptly labeled as rejected and segregated from active stock. [USP 797 Section 9.3.2] *Not documented as accepted or rejected-not examined*	No
COMPONENT EXPIRATION DATING: Upon receipt, APIs and components are inspected for a visible manufacturer expiration date. Components lacking expiration dates are assigned an expiration date no more than 1 year after receipt and both the date of receipt and facility assigned expiration date is clearly marked on the component packaging. [USP 797 Section 9.3.2]	N/A
COMPONENT EVALUATION BEFORE USE: All components are reinspected before use to ensure correct identify, appropriate quality, within expiry date, have been stored under appropriate conditions. [USP 797 Section 9.3.3] *Sterile vials not been marked with indication to be ready for use in compounding*	No

Q. STERILIZATION OF CSPs - CATEGORY 2 & 3

CSP Sterilization Overview	No
STERILIZATION METHOD(S) APPROPRIATENESS: Sterilization method(s) used do not degrade CSP physical and chemical stability (e.g., affecting its strength, purity, or quality) or packaging integrity. [USP 797 Section 10] *Pharmacist is not sterilizing period*	No
STERILITY ASSURANCE LEVEL (SAL) FOR TERMINAL STERILIZATION METHODS: Terminal sterilization method(s) (e.g., steam, dry heat, or irradiation) achieve a SAL or PNSU (probability of a nonsterile unit) of (0.000001) [USP 797 Section 10]	N/A
STERILIZATION OF INJECTABLES WITHIN 6 HOURS OF COMPLETION: Injectable CSPs containing nonsterile components or that come into contact with nonsterile devices (e.g., containers, tubing) during compounding are sterilized within 6 hours of completion. [USP 797 Section 10]	N/A
STERILIZATION SOPs include: 1) A description of terminal sterilization and depyrogenation process(es) used in the preparation of CSPs and/or compounding equipment, including the temperature, pressure (if applicable), duration, permissible load conditions for each cycle, and the use of biological indicators and endotoxin challenge vials (ECVs). 2) Personnel training and competency assessment on sterilization and depyrogenation methods and equipment used by the facility. 3) Schedule and method for establishing and verifying the effectiveness of methods selected. 4) Methods for maintaining and cleaning the sterilizing and depyrogenation equipment. [USP 797 Section 10]	N/A
CSP Sterilization by Filtration	No
STERILIZING FILTERS: Sterilizing filters used are sterile, depyrogenated, have a nominal pore size of 0.22 µm or smaller, and are appropriate for pharmaceutical use. Sterilizing filters are certified by the manufacturer to retain at least 10,000,000 microorganisms of a strain of Brevundimonas diminuta per square centimeter of upstream filter surface area. Filters are chemically and physically compatible with all ingredients in the CSP (e.g., water-miscible alcohols may damage filter integrity); chemically stable at the pressure and temperature conditions that will be used; and have enough capacity to filter the required volumes. [USP 797 Section 10.2] *No batch records indicating sterilization by filtration has been performed prior to releasing Semaglutide and Tirzepatide inj.*	No
BUBBLE POINT TESTING: Sterilizing filters are subjected to the manufacturers' recommended integrity testing, such as a post-use bubble point test. If multiple filters are required for the compounding process, each of the filters passes a filter-integrity test. [USP 797 Section 10.2] For failed BP testing, CSP is discarded or, after investigating, refiltered not more than one time. [USP 797 Section 10.2] *Never done or documented*	No
CSP PREFILTRATION: When CSPs are known to contain excessive particulate matter, prefiltration is performed using a filter of larger nominal pore size (e.g., 1.2 µm) or a separate filter of larger nominal pore size placed upstream of (i.e., prior to) the sterilizing filter. [USP 797 Section 10.2] *Not done*	No
CSP Sterilization by Steam	No
STEAM STERILIZATION CYCLES: Sterilization cycles allow for an exposure duration that includes sufficient time for the entire contents of the CSP to reach and remain at the sterilizing temperature during the duration of the sterilization period. Items are placed in the autoclave to allow steam to reach CSPs without entrapment of air. [USP 797 Section 10.3]	N/A
BIOLOGICAL INDICATOR USE: The effectiveness of steam sterilization is verified and documented with each sterilization run or load by using appropriate biological indicators (e.g., spores of Geobacillus stearothermophilus) and other confirmation methods. [USP 797 Section 10.3] *Instruments are not sterilized that come into contact with the compounds*	No
CSP PREFILTRATION: Immediately before filling containers that will be sterilized via steam, CSP solutions are passed through a filter with a nominal pore size of not larger than 1.2 µm for removal of particulate matter. [USP 797 Section 10.3]	N/A
AUTOCLAVE WATER SOURCE: The steam supplied in the autoclave is generated using water per the manufacturer's recommendation. [USP 797 Section 10.3] *No autoclave to steam sterilize rubber stoppers used in 2 ml compounded vials of Semaglutide*	No
CALIBRATED DATA RECORDER: A calibrated data recorder or chart is used to monitor each cycle and to examine for cycle irregularities (e.g., deviations in temperature or pressure). [USP 797 Section 10.3] *No temps documented, no validations*	No
CSP Sterilization by Dry Heat	No
DRY HEAT STERILIZATION CYCLES: Dry heat sterilization cycles allow for an exposure duration that includes sufficient time for the entire contents of CSPs and other items to reach and remain at the sterilizing temperature for the duration of the sterilization period. [USP 797 Section 10.4]	N/A
CSP PREFILTRATION: Immediately before filling ampules and vials that will be sterilized by dry heat, CSP solutions are passed through a filter with a nominal pore size of not larger than 1.2 µm for removal of particulate matter. [USP 797 Section 10.4]	N/A
CALIBRATED DATA RECORDER: The calibrated oven is equipped with temperature controls and a timer. A calibrated data recorder or chart is used to monitor each cycle and the data is reviewed to identify cycle irregularities (e.g., deviations in temperature or exposure time). [USP 797 Section 10.4]	N/A
BIOLOGICAL INDICATOR USE: The effectiveness of the dry heat sterilization method is verified and documented with each sterilization run or load using appropriate biological indicators (e.g., spores of Bacillus atrophaeus) and other confirmation methods (e.g., temperature-sensing devices). [USP 797 Section 10.4] *Not using BI's for any production*	No

R. DEPYROGENATION OF EQUIPMENT - CATEGORY 2 & 3

DEPYROGENATION SOPs include: 1) A description of terminal sterilization and depyrogenation process(es) used in the preparation of CSPs and/or compounding equipment, including the temperature, duration, permissible load conditions for each cycle, and the use of biological indicators and endotoxin challenge vials (ECVs). 2) Personnel training and competency assessment on sterilization and depyrogenation methods and equipment used by the facility. 3) Schedule and method for establishing and verifying the effectiveness of methods selected. 4) Methods for maintaining and cleaning the sterilizing and depyrogenation equipment. [USP 797 Section 10] *No procedure followed to depyrogenate glassware*	No
DEPYROGENATION CYCLE: Dry heat depyrogenation is used to render glassware, metal, and other thermostable containers and components pyrogen free. The exposure period includes sufficient time for items to reach the depyrogenation temperature; items remain at the depyrogenation temperature for the duration of the depyrogenation period. [USP 797 Section 10.1] *Incorrect cleanroom design for Cat 3 compounding*	No
DEPYROGENERATION VIA RINSING: Non-thermostable items are depyrogenated by multiple rinses with sterile, nonpyrogenic water (e.g., Sterile Water for Injection or Sterile Water for Irrigation) and then thoroughly drained or dried immediately before use in compounding. [USP 797 Section10.1] *SIPA used to rinse beakers and glassware not depyrogenated. No oven to validate*	No
ENDOTOXIN CHALLENGE VIAL (ECV) USE: The effectiveness of the dry heat depyrogenation cycle(s) is established initially and verified annually using ECVs to demonstrate the cycle achieves a greater than or equal to 3-log endotoxin reduction. The effectiveness of the depyrogenation cycle is re-established if there are changes to the depyrogenation cycle. Cycle verifications are documented. [USP 797 Section 10.1] *Not demonstrated, however is compounding Cat 3 injectables*	No

S. MASTER FORMULATION AND COMPOUNDING RECORDS – ALL CATEGORIES

MASTER FORMULATION RECORD (MFR): A MFR is created for all CSPs prepared from nonsterile ingredient(s) or CSPs prepared for more than one patient. [USP 797 Section 11.1] *Not provided or completed prior to production in June 2024*	No
MFR MODIFICATIONS: Any changes or alterations to an MFR are approved and documented per facility's SOPs. [USP 797 Section 11.1]	No
MFR DOCUMENTATION: An MFR includes at least the following: 1) Name, strength or activity, and dosage form of the CSP; 2) Identities, amounts of all ingredients, and, if applicable, relevant characteristics of components; 3) Type and size of container closure system(s); 4) Complete instructions for preparing the CSP including equipment, supplies, a description of the compounding steps, and any special precautions; 5) Physical description of the of the final CSP; 6) BUD and storage requirements; 6) Stability reference; 7) Quality control procedures; 8) other information as needed to describe the compounding process and ensure repeatability. [USP 797 Section 11.1 (Box 9)] *No MFRs however batch compounding Cat 3 compounds*	No
COMPOUNDING RECORD (CR): A CR is created for all Category 1, Category 2, and Category 3 CSPs. A CR is created for immediate-use CSPs prepared for more than one patient. [USP 797 Section 11.2] *None documented*	No
CR DOCUMENTATION: A CR includes at least the following: 1) Name, strength or activity, and dosage form of the CSP; 2) Date and time of preparation of the CSP; 3) Assigned internal identification number (e.g., prescription, order, or lot number); 4) A method to identify the individuals involved in the compounding process and individuals verifying the final CSP; 5) Name of each component; 6) Vendor, lot number, and expiration date for each component for CSPs prepared for more than one patient and for CSPs prepared from nonsterile ingredient(s); 7) Weight or volume of each component; 8) Strength or activity of each component; 9) Total quantity compounded; 10) Final yield; 11) Assigned BUD and storage requirements; 12) Results of QC procedures. And, if applicable, 13) MFR reference for the CSP; and 14) Calculations made to determine and verify quantities and/or concentrations of components. [USP 797 Section 11.2 (Box 10)] *No batch records provided for several Tirzepatide vials dispensed to patients*	No
STERILIZATION CYCLE DOCUMENTATION: The date, run, and load numbers of the steam or dry heat sterilizer used to sterilize a CSP are documented on the CR if applicable. [USP 797 Sections 10.3 & 10.4] *No runs documented, no batch records provided.*	No

T. RELEASE INSPECTION AND TESTING – ALL CATEGORIES

RELEASE TESTING PROCEDURES: All release testing procedures (e.g., visual inspections and testing) are included in facility documentation such as MFRs and SOPs. [USP 797 Section 12] *Missing in MFR for compounded injectables*	No
VISUAL INSPECTION: CSPs are visually inspected before release and dispensing to determine whether the 1) physical appearance of the CSP is as expected (e.g., free of inappropriate visible particulates or other foreign matter, discoloration, or other defects), 2) container closure integrity is intact (e.g., checking for leakage, cracks in the container, or improper seals), 3) CSP and its labeling match the prescription or medication order. [USP 797 Section 12.1] *Not documented at the conclusion of the batch prior to relase*	No
DELAYED DISPENSING VISUAL INSPECTION: When CSPs are not released or dispensed on the day of preparation, a visual inspection is conducted immediately before its release to ensure the CSP is free from any defects such as precipitation, cloudiness, or leakage, which could develop during storage. [USP 797 Section 12.1] *No quarantine area noted, no documentation provided*	No
CSP REJECTION & QUARANTINE: CSPs found to be of unacceptable quality (e.g., observed defects) are promptly rejected, clearly labeled as rejected, and segregated from active stock. [USP 797 Section 12.1] *Releasing without sterility and other study confirmations*	No
INVESTIGATION OF OOS RESULTS: Out-of-specifications results and defects indicating sterility or stability problems are investigated to determine the root cause and a corrective action plan is implemented and documented per facility SOPs. [USP 797 Section 12 & 12.1] *None noted, deficient CQI*	No

U. CSP HANDLING, STORAGE, PACKAGING, SHIPPING, & TRANSPORT – ALL CATEGORIES

STORAGE AREA TEMPERATURE MONITORING: Temperature in CSP & component storage areas is monitored at least once daily and recorded on a log on days when the facility is open or by a continuous temperature recording device; temperature data is readily retrievable. Monitoring equipment is calibrated or verified for accuracy as recommended by the manufacturer or every 12 months. [USP 797 Sections 9.3 & 19.1]	No
TEMPERATURE EXCURSIONS: When CSPs have been exposed to temperature excursions above or below storage temperature limits for the CSP, a Designated Person determines whether the CSP has retained its integrity or quality. CSPs are discarded if the impact of the excursion cannot be determined. [USP 797 19.1]	No
CSP PACKAGING: CSP packaging and shipping materials are selected to protect CSPs from damage, leakage, contamination, degradation, adsorption and prevent inadvertent exposure to transport personnel. [USP 797 Section 19.2]	Yes
SHIPPING & TRANSPORTING: Modes of transport are selected that are expected to deliver properly packaged CSPs in an undamaged, sterile, and stable condition. Special handing instructions are provided and/or affixed to the exterior of the container when applicable. [USP 797 Section 19.2] *Cold chain*	Yes

V. STERILE QUALITY PROGRAM, SOP's & DOCUMENTATION- ALL CATEGORIES

QA/QC PROGRAM & SOPs: A Quality Assurance (QA) and Quality Control (QC) program is documented in facility SOPs and formally establishes a system of 1) adherence to procedures, 2) prevention and detection of errors and other quality problems, 3) evaluation of complaints and adverse events, and 4) appropriate investigations and corrective actions. The QA/QC SOPs describe the roles, duties, and training of personnel responsible for each aspect of the QA program. [USP 797 Section 18] *No QA/QC person to document and measure outcomes*	No
INVESTIGATIONS & CAPAs: A designated person(s) follows up to ensure investigations are conducted and corrective actions are taken if problems, deviations, failures, or errors are identified or when complaints or adverse reactions are reported. A complete record of each reported complaint and adverse reaction is created and retained. Investigations and corrective actions are documented. [USP 797 Sections 17, 18.2, & 18.3] *No investigations for failure to conduct sterility testing or appropriately filter sterilize compounds prior to release*	No
ADR & COMPLAINT DOCUMENTATION: A complete record of each reported complaint and adverse reaction is created and retained per USP 797. [USP 797 Section 18.1] *Not documented*	No
RECALL PROCEDURES & SOP: If CSPs are dispensed or administered before the results of release testing are known, procedures are in place to immediately notify the prescriber of a failure of specifications with a potential to cause patients harm; determine the severity of the problem and urgency for implementation/completion of recall; identify patients (or other points of distribution) who have received affected CSP; recall any unused dispensed CSPs; quarantine remaining stock in the pharmacy; investigate if other lots are affected and recalled if needed; conduct investigation and document reason for the failure. [USP 797 Section 18] *There has been no recall initiated for products that were compounded as Category 3 injectable compounds such as Trizepatide and Semaglutide inj.*	No
RECALL REPORTING: Recalls are reported to the appropriate regulatory body as required by the laws and regulations of the applicable regulatory jurisdiction. [USP 797 Section 18.1] *No recalls for failure to sterilize compounds released to patients.*	No
ANNUAL QA/QC REVIEW: The overall QA/QC Program is reviewed at least once every 12 months by the Designated Person(s); the review is documented, and corrective actions are taken if needed. [USP 797 Section 18] *No documented*	No
ANNUAL SOP REVIEW: Facility sterile compounding SOPs are reviewed every 12 months by the Designated Person(s); the review is documented. Changes to SOP are made only by the Designated Person and documented. Acknowledgement of revisions to SOP's are communicated to all personnel. [USP 797 Section 17] *Not documented by Designated Person AH*	No
STERILE SOPs: Facility maintains SOPs covering all aspects of the sterile compounding process and other support activities. [USP 797 Section 17]	No
STERILE COMPLIANCE DOCUMENTATION: Facility has and maintains written or electronic documentation to demonstrate compliance with requirements in this chapter. [USP 797 Section 20] *No compliance for cleaning, training, sterility and stability assurance or container closure and AET testing or any testing compliance prior to releasing injectable compounds to patients or provide assurance to inspector for proper functioning equipment to be able to compound.*	No
DOCUMENTATION RETENTION: Documentation complies with all laws and regulations of the applicable regulatory jurisdiction. Records are legible and stored in a manner that prevents their deterioration and/or loss. All required documentation for a particular CSP is readily retrievable for at least 4 years after preparation. [USP 797 Section 20] *No batch records provided.*	No

W. HAZARDOUS DRUG HANDLING & COMPOUNDING – ALL CATEGORIES

DESIGNATED PERSON: The entity has a Designated Person who is qualified and trained to be responsible for implementing appropriate HD procedures, overseeing compliance with USP 800 requirements, ensuring environmental control of the storage and compounding areas, monitoring HD facility operations, testing, and acting on results. [USP 800 Section 4]	
HAZARD COMMUNICATION PROGRAM (HCP): Facility has SOPs to ensure effective training regarding proper labeling, transport, storage, and disposal of HDs and use of Safety Data Sheets. The HCP and HD SOPs include a written plan describing 1) how USP 800 requirements are implemented, 2) HD chemical container labeling with the identity of the material and appropriate hazard warnings, 3) readily accessible location of HD chemical SDSs known and accessible by all personnel, 4) HD risk training and information provided to all personnel with HD exposure risk before initial HD handling work assignment and whenever hazard changes, 5) personnel of reproductive capability written acknowledgement of understanding of HD handling risks. [USP 800 Section 8]	
ASSESSMENT OF RISK: All HD drugs follow the requirements of USP 800 unless an assessment of risk (AOR) is performed. If an assessment of risk approach is taken, the entity must document what alternative containment strategies and/or work practices are being employed for specific dosage forms to minimize occupational exposure. The AOR is reviewed at least every 12 months and minimally contains the type of HD, dosage form, risk of exposure, packaging, and manipulation. [USP 800 Section 2]	
LIST OF HAZARDOUS DRUGS: Facility maintains a list of HDs that includes any items on the current NIOSH that the entity handles. The list is reviewed every 12 months and whenever a new agent or dosage form is used. [USP 800 Section 2]	
CONTAINMENT REQUIREMENTS: All antineoplastic HDs requiring manipulation and HD active pharmaceutical ingredients (APIs) on the NIOSH list follow all the requirements of USP 800. [USP 800 Section 2, Box 1]	
HD HANDLING SOPs: SOPs are created and maintained for the safe handling of HDs used by the facility. SOPs are reviewed annually; review is documented, and any revisions are communicated to personnel handling HDs. [USP 800 Section 17]	
HD HANDLING AREAS, SIGNAGE, & ACCESS: Signage designating HD handling areas are prominently displayed and access to HD handling areas is restricted to authorized personnel. Designated areas are available for receipt, unpacking, and storage of HDs; and sterile HD compounding. [USP 800 Section 5]	
HD RECEIPT: There is a designated area for the receipt of antineoplastic HDs or API's that is neutral/normal or negative pressure relative to surrounding areas. HDs are not unpacked from external shipping containers in sterile compounding areas or in positive pressure areas. HDs are delivered immediately after unpacking to HD storage area. [USP 800 Section 5.1]	
HD RECEIVING SOPs: Facility SOPs for receiving HDs that include required PPE during HD receiving and handling, a tiered approach to assessing HD packaging and shipping containers for signs of damage or breakage (e.g., visible signs of leakage, sounds of broken glass), management of known or suspected damaged HD containers, and transport to HD storage location(s) for nondamaged containers. [USP 800 Section 10]	
HD STORAGE: HDs are stored to prevent spillage or breakage, off floors, and in areas appropriate for natural disasters. Antineoplastic HDs and HD API are stored separately from non-HDs to prevent contamination and personnel exposure. HD storage areas are externally ventilated and negative-pressure rooms with at least 12 ACPH. [USP 800 Section 5.2]	
HD REFRIGERATED STORAGE: Refrigerated antineoplastic HDs are stored in a dedicated refrigerator, in a negative pressure area with at least 12 ACPH. Pass through refrigerators are not used. [USP 800 Section 5.2]	
STERILE HDs COMPOUNDED IN A C-SCA: C-SCA maintains a minimum of 12 ACPH of HEPA- filtered air and has negative pressure to adjacent areas of -0.01" w.c. to -0.03" w.c. [USP 800, sections 5.3.2 Table 3]	
C-SEC DESIGN AND ENGINEERING CONTROLS: The C-SEC has fixed walls physically separated from other preparation areas, is externally ventilated , and has 30 ACPH. [USP 800 Section 5.3.2 Table 3]	

C-SEC DESIGN AND PRESSURE DIFFERENTIALS: The C-SEC has negative pressure to adjacent areas of -0.01" w.c. to -0.03" w.c. [USP 800 Sections 5.3.2 Table 3]	
C-SEC ACCESS VIA ANTE ROOM: The classified area used for entry into the negative pressure buffer room has fixed walls and maintains a minimum of 30 ACPH of HEPA-filtered air, positive pressure of +0.02" w.c. to all adjacent unclassified areas, and ISO7 or better classification. [USP 800 Section 5.3.2]	
C-SEC ACCESS VIA NON-HD BUFFER: A negative-pressure HD buffer entered exclusively through a non-HD buffer room contains a line of demarcation (LOD) within the negative-pressure buffer room for donning/doffing HD PPE and a method a transport of HDs, HD CSPs, and HD waste into and out of the HD buffer (e.g., pass-through chamber). Pass through chambers are included in semi-annual facility certification. [USP 800 Section 5.3.2]	
C-SEC SINK & SAFETY EQUIPMENT: A sink is available for hand washing and an eyewash station and/or other emergency safety precautions meeting applicable laws and regulations are readily available and located where operation does not interfere with ISO classifications. Sinks are located at least 1 meter from the entrance into the buffer room (or at least 1 meter from the C-PEC in a C-SCA). [USP 800 Sections 5.3 & 5.3.2]	
C-PEC LOCATION AND VENTING: All C-PECs used for sterile HD compounding (e.g., CACIs or BSCs), are located within a C-SEC or C-SCA, externally vented, and maintain an ISO 5 or better air quality. [USP 800 Section 5.3.2]	
C-PEC OPERATION & OUTAGES: C-PECs operate continuously if supplying some or all the negative pressure in the C- SEC or if used for sterile compounding. During power outages, repairs, or relocation, C-PEC use is suspended immediately. Once C-PEC power is restored, all PEC surfaces are decontaminated, cleaned, and disinfected, and compounding is not resumed until the manufacturer's specified recovery time has elapsed. [USP 800 Section 5.3]	
REQUIRED HD PPE: When compounding HDs, gowns, head, hair, shoe covers, and two pairs of chemotherapy gloves are donned per facility SOPs. For all other HD handling activities, including HD receipt, storage, transport, cleaning activities, spill control, and waste disposal, facility SOPs define the required PPE based on the OSP and AOR. Disposable PPE is not reused; reusable PPE is decontaminated and cleaned after each use. [USP 800 Section 7]	
GLOVES: Chemotherapy gloves are tested to ASTM standard D6978 (or its successor) and are powder free. Gloves are inspected for physical defects. Gloves are changed when torn, punctured, or contaminated. Personnel wash hands with soap and water after removing gloves. [USP 800 Section 7.1]	
GOWNS: HD gowns are disposable, resistant to permeability by HDs, close in back, are long sleeved, closed cuff, and seamless. Gowns are changed per manufacturer's permeation information; if no data is available, HD gowns are change every 2-3 hours or immediately after a spill or splash. Gowns are limited to HD handling areas and are donned over the sterile compounding frock. [USP 800 Section 7.2, USP 797 Section 3.3]	
SHOE COVERS: When compounding, a second pair of shoe covers is donned before entering the C-SEC and doffed when exiting the C-SEC. [USP 800 Section 7.3]	
EYE AND FACE PROTECTION: Appropriate eye (goggles) and face protection (face shield) are worn when there is a risk for spills or splashes or when working outside of a C-PEC. Surgical masks are not used when respiratory protection is required per SOP and/or AOR as protection from HD exposure. [USP 800 Section 7.4]	
PPE DISPOSAL: HD PPE is disposed of appropriately prior to exiting the C-SEC. Chemotherapy gloves and sleeve covers (if used during compounding) are carefully removed and discarded immediately into an appropriate waste container inside of the C-PEC or contained in a sealable bag for discarding outside of the C-PEC. [USP 800 Section 7.6]	
INITIAL HD TRAINING & COMPETENCY: Personnel who handle HDs are trained and demonstrate competency per their job function before independently handling HDs and when a new HD medication, process, SOP, or equipment is introduced. Training minimally includes an overview of the entity's HD list and their risks; review of HD SOPs; proper use of PPE, equipment, and devices; prevention of HD exposures and spills; HD exposure and spill response; use of a spill kit, PPE, and NIOSH-certified respirators; and HD disposal. Based on job duties, personnel receive additional HD training in HD acquisition and receipt, preparation, compounding, dispensing, labeling, storage, and transport. Training and competency assessments are documented. [USP 800 Sections 8, 9, 11.1, 16, & 17]	
ONGOING HD COMPETENCY ASSESSMENT: HD handling competencies are reassessed and documented at least every 12 months. [USP 800 Section 9]	
HD ATTESTATION: Personnel of reproductive capability have a written acknowledgement attesting to their understanding of HD handling risks. [USP 800 Section 8]	
BUDs OF STERILE HDs COMPOUNDED IN A C-SCA: BUDs and storage conditions are in accordance with USP 797 requirements for Category 1. HD CSPs compounded in a C-SCA are prepared from only sterile starting components. [USP 800 Section 5.3.2] CSTDs are used as a supplemental engineering control only. [USP 800 Section 5.3 and Table 3]	
BUDs OF STERILE HDs COMPOUNDED IN A C-SEC: BUDs and storage conditions in accordance with USP 797 requirements for Category 2, or Category 3 CSPs. [USP 800 Section 5.3.2]	
NONSTERILE-TO-STERILE HD COMPOUNDING: HD CSPs compounded from nonsterile starting components are compounded inside a sterile suite. [USP 800 Section 5.3.2]	
DEDICATED HD EQUIPMENT: Disposable or cleanable equipment for compounding (e.g., mortar and pestle, graduated cylinder, spatulas) is dedicated for use with HDs. [USP 800 Section 13]	
NON-HD COMPOUNDING IN A C-PEC: Non-HDs compounded in a HD C-PEC are placed in protective outer wrapping, labeled for PPE handling precautions, and treated as an HD. [USP 800 Section 5.3.2 and Table 3]	
D/D/C/D SOPs: Written procedures for decontamination, deactivation, cleaning, and disinfection are available and followed. Cleaning of sterile compounding areas also complies with USP 797 requirements. Procedures include agents used, dilutions (if used), frequency, and documentation requirements. [USP 800 Section 15]	
DEACTIVATION, DECONTAMINATION, CLEANING & DISINFECTION (D/D/C/D): All areas where HDs are handled (receiving, compounding, transport, administering, disposal) and all reusable equipment and devices are deactivated/decontaminated, cleaned, and then disinfected. [USP 800 Section 15]	
TRAINING OF D/D/C/D: Personnel are trained in deactivation/decontamination, cleaning, and disinfection to protect themselves and the environment from contamination. [USP 800 Section 15]	
PPE DONNED DURING D/D/C/D: Personnel wear appropriate PPE resistant to cleaning agents used, including 2 pairs of ASTM-tested chemotherapy gloves and impermeable disposable gowns. Eye protection and face shields are worn if splashing may occur. Respiratory protection is used if warranted. [USP 800 Section 15]	
D/D/C/D AGENTS USED: Agents selected are appropriate for the type of HD contamination(s), location, and surface materials. Sterile 70% IPA is used to remove residue left on sterile surfaces and compounding areas by decontaminating agents. [USP 800 Section 15 & 15.4]	
DECONTAMINATION DURING COMPOUNDING: C-PEC is decontaminated at least daily (when used), after as spill, before and after certification, voluntary interruption, or if ventilation tool is removed. The C-PEC worksurface is decontaminated between compounding of different HDs. [USP 800 Section 15.2]	
MONTHLY UNDERTRAY CLEANING: Area under the work tray of a C-PEC is deactivated, decontaminated, and cleaned at least monthly. [USP 800 Section 15.2]	
DISPOSAL OF D/D/C/D CLEANING SUPPLIES: Disposable cleaning supplies are discarded per EPA regulations and facility SOPs. [USP 800 Section 15]	

LABELING, PACKAGING, TRANSPORT SOP: Facility has SOP for the labeling, handling, packaging, and transport of HDs addressing the prevention of spills/exposures, training for exposure, and spill kit use. The SOP describes appropriate shipping containers and insulating materials for transport based on product specifications (e.g., required storage conditions), transport vendors, and mode of transport. [USP 800 Section 11 & 11.2]	
HD LABELING: HD CSPs are identified as hazardous and labeled with special handling precautions. Labeling process for compounded HD products does not introduce contaminated materials into non-HD areas. [USP 800 Sections 11.1 & 13]	
PACKAGING: Packaging materials and containers that maintain the physical integrity, stability, and sterility of HDs during transport. Packaging protects HDs from damage, leakage, contamination, and degradation, while protecting healthcare workers who transport HDs. [USP 800 Section 11.2]	
TRANSPORT: HDs that are transported are labeled, stored, and handled according to regulations, facility SOPs, and in containers that minimize risk of breakage or leakage. Pneumatic tubes are not used to transport liquid or antineoplastic HDs. [USP 800 Section 11.3]	
HD SPILL SOP: Facility has an SOP to prevent spills. The SOP directs the management and cleanup of suspected or known damage to or spills of HDs upon receipt, storage, handling, compounding, packaging, and transport. SOP addresses appropriate response based on factors such as the size, scope, and who is responsible for cleanup. SOP states the location and capacity of kits and immediate steps that should be taken to evaluate and address personnel exposure, secure spill area, and minimize exposure risk to other personnel. [USP 800 Section 16]	
SPILL KITS, & SINGAGE: Spill kits are readily available with appropriate supplies, PPE, and signs to restrict access to affected areas. restriction posted, and documentation of spills occur when needed. [USP 800 Section 16]	
SPILL CLEAN UP & DOCUMENTATION: Spills are contained and cleaned immediately only by qualified personnel with appropriate PPE. After cleanup is complete, spill circumstances and management are documented. Qualified personnel are available at all times while HDs are being handled. [USP 800 Section 16]	
DISPOSAL REGULATION COMPLIANCE: Disposal of HD waste, including unused HDs and trace-contaminated PPE and materials, is performed by trained and appropriately garbed personnel and complies with federal, state, and local regulations. [USP 800 Sections 11.4 & 17]	

X. LYOPHILIZATION

Sterile preparations prepared for lyophilization are maintained in ISO 5 unidirectional laminar flow air throughout sterilization, filling, and transport to the lyophilizer. [64B16-27.797(5) F.A.C.]	
A recorded smoke study is available and demonstrates that transport from the PEC to the lyophilizer is accomplished in ISO 5 laminar flow air at all times. [64B16-27.797(5) F.A.C.]	
The pharmacy has established and follows policies and procedures for the high-level disinfection of the lyophilizer chamber, piping, and all other areas of the unit which pose a potential risk for contamination of the product. [64B16-27.797(5) F.A.C.]	
The pharmacy validated the high-level disinfection procedure initially, and after changes to the cleaning process or agents. Documentation of studies is available for inspection. [64B16-27.797(5) F.A.C.]	
Validation studies for high level disinfection are performed with the 5-aerobic bacterial and fungal ATCC organisms referenced in USP<71> are conducted by an external vendor unless the firm has an internal laboratory capable of performing the studies. An internal laboratory is separate from the compounding and work areas of the pharmacy to prevent contamination in the pharmacy. [64B16-27.797(5) F.A.C.]	
Policies and procedures are established and followed for cleaning the lyophilizer prior to disinfection and include cleaning agents and schedules. Documentation of cleaning is maintained and available for inspection. [64B16-27.797(5) F.A.C.]	
Policies and procedures are established for the maintenance of the lyophilizer and at a minimum include the manufacturers recommendations. [64B16-27.797(5) F.A.C.]	
The maintenance schedule includes provisions for periodic testing of the chamber for leaks and all other recommended procedures described by the equipment manufacturer. Documentation of routine maintenance is available for inspection. [64B16-27.797(5) F.A.C.]	
SOPs and quality assurance program established to include validation of the filling process, container closure integrity, frequent monitoring of fill volumes, identification of over fills and underfills, assessment of personnel involved in compounding for lyophilization, equipment qualification, formula verification, and evaluation of finished product for conformance to specifications. [64B16-27.797(5) F.A.C.]	
The pharmacy has provisions for sterilizing, with filters, the inert gas or air used for backfilling during the vacuum release phase. These Sterilizing filters undergo the manufacturers recommended integrity test. [64B16-27.797(5) F.A.C.]	
Media fills are conducted every six months using the maximum batch size and demonstrate the filling, transport to the lyophilizer, loading and stoppering operations. Media is NOT frozen during the media fill operation. [64B16-27.797(5) F.A.C.]	
Personnel preparing sterile compounds for lyophilization wear sterile Personal Protective Equipment that covers all exposed skin. [64B16- 27.797(5) F.A.C.]	
Glove Fingertip Sampling is performed with every batch after fill and transport into the lyophilizer on all personnel compounding for lyophilization. The results are incorporated into the batch record. [64B16-27.797(5) F.A.C.]	
In-process acceptance criteria such as color, moisture limits and visual appearance are established for each lyophilized product. [64B16- 27.797(5) F.A.C.]	
A 100% visual examination of the finished product is conducted to determine that the product conforms to the established visual criteria and is incorporated into the batch record. [64B16-27.797(5) F.A.C.]	
Finished product testing is conducted on all batches. Procedures have been established for selecting test samples from the batch and are written and followed. Such procedures may include location of vials in the lyophilizer and positions in the fill line. [64B16-27.797(5) F.A.C.]	
Finished product testing includes sterility testing using a USP<71> method unless an alternative test method has been validated and shown to be equivalent or better. Diluents used to reconstitute the sample vials for testing are preservative free. [64B16-27.797(5) F.A.C.]	
Each batch of lyophilized product with a beyond use date that falls within the USP<797> guidelines and is not tested for sterility, has viable air and surface sampling that is collected in critical areas of ISO 5 locations as well as sampling of the gloves and sleeves of personnel documented in the batch record. [64B16-27.797(5) F.A.C.]	
Every lyophilized product has established endotoxin levels Each batch of lyophilized product is tested for endotoxin in accordance with USP<85> and confirmed to fall within the set limits and documented in the batch record. [64B16-27.797(5) F.A.C.]	
Potency, radiochemical purity, or applicable test to assure label claim is conducted on every batch and documented in the batch record. In lieu of potency testing, weight-based verification may occur based on formula verification. Potency testing shall be based on the USP monograph if one is available. [64B16-27.797(5) F.A.C.]	

Y. SPECIAL PARENTERAL ENTERAL & EXTENDED SCOPE

Technicians properly identified. [64B16-27.100 (2) F.A.C.]; [64B16-27.4001 F.A.C.]; [64B16-27.410 F.A.C.]; [64B16- 27.420 F.A.C.].	
Medication is properly labeled for dispensing to patient. [64B16-28.108(2) F.A.C.]	

Outdated medications removed from active stock. [64B16-28.110 F.A.C.]; [64B16-28.1191 F.A.C.]	
Continuous Quality Improvement Program described in the Pharmacy policy and procedure manual and quarterly summarization of Quality Related Events are available for inspection. [64B 16 27.300 F.A.C.]; [766.101 (1) (a)(l) F.S.]	
Pharmacy maintains patient profile with allergy information and medications dispensed. [64B16-27.800, F.A.C.]	
All controlled substance prescriptions (electronic, faxed, verbal and written) contain required information. [893.04(a)(b)(c) F.S.]; [21CFR1306.05]	
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.].	
Controlled substance inventory taken on a biennial basis and available for inspection. [893.07(1)(a), F.S.] [21CFR1304.11] [21CFR1304.04]	
DEA 222 forms properly completed or records of CSOS orders electronically completed, linked to the original order, archived and retrievable. [893.07(2) F.S.]; 21CFR 1305.13(e)]; [21CFR1305.22(g)]	
Controlled substance records and prescription information in computer system are retrievable and maintained for 4 years. [21CFR1304.04]; [465.022(12) (a) F.S.]; [21CFR1306.22]; [64B16-28.140 F.A.C.]	
Certified daily log or signed printout maintained. [21CFR1306.22(f)(3)]; [64B16-28.140(3)(d) F.A.C]	
Pharmacy is reporting to the PDMP within 24 hours of dispensing controlled substance. [893.055(4) (3)(a), F.S.]	
Invoices for medications purchased from a Florida licensed wholesaler/distributor are retrievable for inspection. [499.005 (14) F.S.]	
A special sterile products and parenteral/enteral compounding pharmacy provides telephone accessibility to its pharmacist(s) for its patients at all hours. [64B16-28.820(3)(b)]	
A special sterile products and parenteral/enteral compounding pharmacy provides special handling and packaging of compounded parenteral and enteral preparations when delivering from the pharmacy to the patient or institution as required to maintain stability of the preparations. [64B16-28.820(3)(b)]	

Remarks:

This is the 2nd inspection of the new business inspection for file #29867. Pharmacy is dispensing compounded products without sterility assurance. Was advised to not compound injectable weight loss medication until confirmation from the Board of Pharmacy. Inspection conducted with pharmacist Amy Hamilton. Present on 5196 Mariner Blvd was Stephanie Robinson, Office Manager and Chris Kasper with IT. Owners were not present and firm was informed of 465.017 Authority to inspect.

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.

Inspector Signature

CULLIPHER, MALA

Date:8/15/2024

Representative:

[redacted]

Date:8/15/2024