DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
60 Eighth Street NE Atlanta, GA 30309 (404)253-1161 Fax:(404)253-1202	5/12/2025-5/15/2025
	FEI NUMBER 3032314463

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Priyanka Rana , President and Chief Pharmacy Officer

FIRM NAME	STREET ADDRESS
Apothecary Pharma LLC	1913 Evans Rd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Cary, NC 27513-2041	Outsourcing Facility

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

Quality Control System

OBSERVATION 1

The responsibilities and procedures applicable to the quality control unit are not in writing and fully followed.

Specifically, the QCU failed to
- ensure all batch records are reviewed for completeness
- review Certification Report Control ID #4049-339748-64877 (dated 11/25/2024) for the ISO 7 filling cleanroom and Certification Report 5041-1698657R2 (dated 11/25/2024) for the ISO 5 laminar air flow work station before producing sterile drug products that were distributed to market in 2025
-finalize all draft procedures including: SOP1002 Responsibilities of Apothecary's Quality Unit, SOP1011 Corrective Action/ Preventative Action (CAPA), SOP1012 Batch Records, and SOP1014 Out-Of-Specification (OOS) Results
- follow SOP2004 Visual Inspection by shaking and inverting the vials too forcibly generating excessive air bubbles. SOP 2004 states to (b) (4) avoiding air bubble formation.

OBSERVATION 2

Protective apparel is not worn as necessary to protect drug products from contamination.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Justine Tomasso, FDA Center Employee Sarah M Gauna, FDA Center Employee Xiaohui Shen, FDA Center Employee	X Justine Tomasso FDA Center Employee Signed By: Justine C. Tomasso -S Date Signed: 05-15-2025 13:17:15	5/15/2025

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Specifically, on 5/12/2025, during production of Semaglutide Injection 2.5mg/mL Batch (b) (4) we observed

- Operators had exposed skin of forehead and cheeks
- SOP0003 Cleanroom Entry and Exit is not followed. For example, operators did not don shoe covers over facility clogs. Per the SOP the coverall should be donned prior to booties, however, we observed the booties donned before the coverall. An operator entered the gowning room with goggles on instead of donning goggles in the gowning room. An operator entered the gowning room with a mask instead of donning the mask in the gowning room. Also, the operators ignored the line of demarcation. We observed one operator gowned on the dirty side of the line of demarcation. We observed another operator wear the face mask upside down.

Facility and Buildings Control System

OBSERVATION 3

Aseptic processing areas are deficient regarding systems for maintaining any equipment used to control the aseptic conditions.

Specifically, on 5/12/2025, during production of Semaglutide Injection 2.5mg/mL Batch (b) (4) we observed the ISO 5 LFH appears to have rust on the outside wall, underneath the bench, and on top panel. Additionally, the top panel of the ISO 5 LFH appeared to be dented and damaged.

OBSERVATION 4

Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room and equipment to produce aseptic conditions.

Specifically, on 5/12/2025, during production of Semaglutide Injection 2.5mg/mL Batch (b) (4) we observed operator(s)

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- push down the trash into the bag with their gloved hand and then returned to the ISO 5 without disinfecting their gloves
- fail to consistently disinfect items, including the air particulate counter and bag of sterile wipes, before putting them into the ISO 5 hood.

Production Control System

OBSERVATION 5

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile did not include adequate validation of the aseptic and sterilization process.

Specifically, smoke studies have not been performed under dynamic conditions to support the production and release of (b) (4) batches of Tirzepatide 10mg/mL. Additionally, we observed the volume and/or location of the smoke in the 11/25/2024 smoke study video for the filling room and ISO 5 LFH appeared insufficient to visualize the airflow pattern.

OBSERVATION 6

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established, written and followed.

Specifically, on 5/12/2025, during production of Semaglutide Injection 2.5mg/mL Batch (b) (4)

a.) we observed operator(s)
- block first air by putting their gloved hands and wrists over opened vials during filling
- fail to move with slow and deliberate movements during filling
- rest their forearms on the ISO 5 bench during filling
- lean their heads and upper body into the hood exposing skin, from cheeks and forehead.

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	Justine Tomasso, FDA Center Employee Sarah M Gauna, FDA Center Employee Xiaohui Shen, FDA Center Employee	X Justine Tomasso FDA Center Employee Signed By: Justine C. Tomasso -S Date Signed: 05-15-2025 13:17:16	5/15/2025

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b.) vials behind the first row of vials were blocked from first air in the ISO 5 (b) (4) laminar flow hood.

OBSERVATION 7

Batch production and control records do not include in-process and laboratory control results for each batch of drug product produced.

Specifically, your visual inspection program for the implementation and documentation of in-process controls, tests, and examinations is inadequate. For example, the batch records for Tirzepatide 10 mg/mL

- Batch (b) (4) states that 12 vials were rejected out of (b) (4) that were inspected.
- Batch (b) (4) states that 11 vials were rejected out of (b) (4) that were inspected.
- Batch (b) (4) states that 13 vials were rejected out of (b) (4) that were inspected.

The batch records do not specify whether rejects were due to critical, major, or minor defects or whether the acceptance criteria for visual inspection defects were met. You did not document complete results of 100% visual inspection, including specification of identified rejects. You did not document results of Acceptance Quality Limit (AQL) inspection completed after 100% visual inspection.

503B

OBSERVATION 8

Your outsourcing facility has not submitted a report to FDA identifying a product compounded during the previous six months as required by section 503B(b)(2)(A) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

Specifically, your outsourcing facility failed to submit an initial product report to the FDA upon

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registration as a 503B outsourcing facility.

X Sarah M Gauna
FDA Center Employee
Signed By: 2004033743
Date Signed: 05-15-2025 13:17:47

X Xiaohui Shen
FDA Center Employee
Signed By: Xiaohui S. Shen -S
Date Signed: 05-15-2025 13:18:45

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE

Justine Tomasso, FDA Center Employee
Sarah M Gauna, FDA Center Employee
Xiaohui Shen, FDA Center Employee

X Justine Tomasso
FDA Center Employee
Signed By: Justine C. Tomasso -S
Date Signed: 05-15-2025
13:17:15

DATE ISSUED
5/15/2025

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."