DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

| DISTRICT ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| 1201 Main Street, Suite 7200<br>Dallas, TX 75202<br>(214)253-5200 Fax:(214)253-5314<br>ORAPHARM2_RESPONSES@fda.hhs.gov | 9/24/2024-10/4/2024*<br>FEI NUMBER<br>3021758709 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Jules Dsouza, Director of Quality - 503A

| FIRM NAME | STREET ADDRESS |
|---|---|
| Empower Clinic Services, LLC dba Empower Pharmacy | 7601 N Sam Houston Pkwy W Ste 100 |
| CITY, STATE, ZIP CODE, COUNTRY<br>Houston, TX 77064-3595 | TYPE ESTABLISHMENT INSPECTED<br>Producer of Sterile and Non-sterile drug products |

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:**

## OBSERVATION 1

Hazardous drugs were produced without providing adequate containment, segregation, and/or cleaning of work surfaces, utensils, and/or personnel to prevent cross-contamination.

Specifically, you have not demonstrated to ensure hazardous drugs do not contaminate non-hazardous drugs compounded within your cleanroom environment. Currently, the (b) (4) filling line in the ISO-5 room, which consists of a (b) (4) design under (b) (4) pressure, is used for both hazardous and non-hazardous drug production. These drug types can be processed one after another, where on some occasions, the processing of both non-hazardous and hazardous drugs occur on the same day. This is also the case for your (b) (4) filled vials that utilize the (b) (4) ISO-5 laminar flow hoods located in Formulation Room (b) (4) to perform these activities. You rely on your cleaning validation to support this practice; however, this validation does not consist of containment studies that demonstrate you can effectively prevent cross contamination between these drug types.

## OBSERVATION 2

Production areas have difficult to clean or contain porous, particle generating, or visibly dirty equipment or surfaces.

Specifically, on 9/25/2024, we observed the following inside your firm's ISO-5 classified cleanroom, where human drug products are aseptically filled:

1. What appears to be rust on the outlets in the ISO-5 classified cleanroom and adjacent to your

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| | Demario L Walls, Investigator<br>Saundrea A Munroe, Investigator | X Demario L Walls Investigator Signed By: Demario L Walls -S Date Signed: 10-04-2024 14:33:15 | 10/4/2024 |

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firm's ISO-5 classified (b) (4) filling line.

2. What appears to be rust above the wheel of the cart located inside the ISO-5 cleanroom adjacent from the ISO-5 classified (b) (4) filling line.

3. What appears to be chipped metal particles on the outlets in the ISO5 classified cleanroom.

4. Multiple dents and chips observed on the walls next and adjacent to the ISO-5 (b) (4) filling line located in the ISO-5 classified cleanroom.

5. A loose gasket hanging above the opening of the (b) (4) inside the ISO-5 classified cleanroom where exposed (b) (4) vials are loaded.

6. Caulking above the opening of your firm's (b) (4) located in the ISO-5 classified cleanroom where the (b) (4) stainless steel meets the wall appears to be not smooth and not easily cleanable.

7. Gaps in the ISO-5 classified cleanroom wall where it meets the floor under the HVAC return vent adjacent from the (b) (4) and ISO-5 classified (b) (4) fill line.

8. A wipe hanging from the vial collection tray of you ISO-5 classified (b) (4) fill line.

Observations were made during the start/duration of aseptic filling operation of Gonadorelin 1mg/ml, lot 203759, BUD 03/24/2025. According to your sterile compounding manager, the status of the ISO-5 classified cleanroom and ISO-5 classified (b) (4) filling line on 09/25/2024 is clean.

**OBSERVATION 3**
Lack of routine certification of the ISO 5 area.

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Specifically,

1. The certifications performed in October 2023 and April 2024 for your ISO-5 room used for (b) (4) filling and (b) (4) of sterile vials does not include an evaluation of particulate counts (non-viable analysis) for eight (8) of the (b) (4) HEPA filters intended to provide ISO-5 class air quality. These eight (8) HEPAs are located directly over the filling line. Additionally, your routine environmental monitoring does not include the performance of air viable and non-viable within this filling space.

2. Throughout operations on 09/25/2024 for the filling of Gonadorelin 1mg/ml, lot 203759, BUD 03/24/2025, we observed the door within the ISO 7 room leading into the ISO-5 room opened at least 10 times to either communicate with operators or to retrieve supplies. The firm has not demonstrated through either room certification, smoke studies, environmental monitoring, or media fills this practice does not compromise the quality of first pass air intended for maintaining drug sterility.

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**OBSERVATION 4**

Failure to appropriately and regularly clean and disinfect or sterilize equipment located in the ISO 5 area.

Specifically,

1) For the (b) (4) filling line located in your ISO-5 room, you do not have scientific rationale to support not sterilizing all product contact surfaces such as the stopper sorting bowl, supply hopper and insertion station that come into direct contact with sterile vials. Currently, the referenced surfaces are decontaminated by chemical disinfectants. These items comprise of the container closure systems used for parenteral drug products purported to be sterile.

2. During cleaning of your ISO-5 classified room and ISO-5 classified (b) (4) filling line,

your firm failed to meet the established contact (dwell) time of (b) (4) for your sporicidal agent.(b) (4) On 09/27/2024, we observed the (b) (4) applied to surfaces in the ISO-5 classified room and ISO-5 classified (b) (4) filling line dry after approximately 3 minutes without being reapplied by the operator to meet the established contact (dwell) time.

3. You failed to perform an adequate line clearance of the (b) (4) and ISO 5 classified (b) (4) filling line. On 09/25/2024 during aseptic filling operations of Gonadorelin 1mg/ml, lot 203759, BUD 03/24/2025, we observe your operator recover an amber glass vial during the aseptic filling process. The glass vials in use for the aseptically filled product was clear. According to your Sterile Manager on 09/25/2024, the status of the ISO-5 classified (b) (4) filling line is clean to include but not limited to line clearance of the (b) (4) and ISO 5 classified (b) (4) filling line.

**OBSERVATION 5**

Failure to conduct media fills that closely simulate aseptic production operations under the worst-case, most-challenging, and stressful conditions.

Specifically, for your (b) (4) operations, you do not have scientific rationale to support compounding a maximum batch size of (b) (4) vials. The largest batch size most recently produced by your facility was (b) (4) vials on 09/23/2024 for Tirzepatide/Niacinamide (2.5 mL) 8/2mg/ml. Your most recent media fill performed 05/02/2024 approved 05/21/2024 challenged a maximum batch size of (b) (4) vials. The most recent media fill for (b) (4) vials was approved 12/21/2022 challenged a maximum batch size of (b) (4) vials. Additionally, your media fills are not designed to qualify operators as suitable for performing these operations since this is determined by your personnel media fills evaluating (b) (4) vialing operations and not (b) (4) operations. (b) (4) vialing operations was last performed in your organization 05/2022.

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**OBSERVATION 6**
Inadequate routine environmental monitoring in the ISO 5 area.

Specifically, you do not have scientific rationale to support your action limit/specification for surface sampling of your ISO-5 designated areas as greater than or equal to (b) (4) colony forming units (CFU)s as opposed to less than one (1) colony forming unit. For example, you recovered too numerous to count (TNTC) CFUs from surface sampling of the (b) (4) (b) (4) internally identified as VSS40 inside the ISO-5 classified cleanroom during the aseptic filling of Semaglutide/Cyanocobalmin (2.5ml) 5/0.5mg/ml, lot#199411 BUD: 04/09/2025. After identifiying the organism as *Paenibacillus lautus*, a spore former, your firm's quality unit proceeded to approved the entire batch on the premise that this is not (b) (4) product.

**OBSERVATION 7**
Smoke studies were not and were inadequately performed under dynamic conditions.

Specifically, you failed to perform adequate smoke studies of your ISO-5 classified room including but not limited to your ISO-5 classified (b) (4) filling line, where finished drug products are aseptically filled, to assess whether proper particle control dynamics have been achieved throughout the critical area. This was evidence by the airflow patterns during aseptic interventions and providing mitigation in circumstances where air turbulence/eddy currents and stagnant air were depicted. Your smoke studies conducted April 2024 of your firm's ISO-5 classified (b) (4) -Formulation (b) (4) and ISO-5 classified (b) (4) -Formulation (b) (4) failed to demonstrate unidirectional airflow in your aseptic operations. Examples of deficiencies reference above include but not limited to the items tabulated below:

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| Classified Area | Time stamp | Status | Date |
|---|---|---|---|
| ISO-5 (b) (4) Hazardous | 1:17 – 1:22 | Dynamic | 4/25/2024 |
| ISO-5 (b) (4) (Non-hazardous) | 0:42 – 0:52 | Dynamic | 4/25/2024 |
| ISO-5 classified (b) (4) filling line | 0:08 – 0:22 | Dynamic | 4/25/2024 |

**OBSERVATION 8**

Use of ingredients not intended for pharmaceutical use in non-sterile drug production.

Specifically, you used non-pharmaceutical grade Azelaic Acid, Lot (b) (4) expiration date 09/15/2026, as an ingredient in the production of non-sterile drug products including but not limited to: Anti-Aging Ultra, Lot 203734, BUD 12/22/2024. The Azelaic Acid, Lot (b) (4) expiration date 09/15/2026, used to produce Anti-Aging Ultra, Lot 203734, BUD 12/22/2024, is labeled as cosmetic grade. Your firm release a quantity of (b)(4) units in interstate commerce.

***DATES OF INSPECTION**

9/24/2024(Tue), 9/25/2024(Wed), 9/26/2024(Thu), 9/27/2024(Fri), 9/30/2024(Mon), 10/01/2024(Tue), 10/02/2024(Wed), 10/03/2024(Thu), 10/04/2024(Fri)

X Saundrea A Munroe
Investigator
Signed By: Saundrea A. Munroe -S
Date Signed: 10-04-2024 14:33:52

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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."