DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Main Street, Suite 7200 Dallas, TX 75202 (214)253-5200 Fax:(214)253-5314	11/3/2025-11/14/2025* FEI NUMBER 3021758709

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Pejmon J. Abrarpour, COO

FIRM NAME	STREET ADDRESS
Empower Clinic Services, LLC dba Empower Pharmacy	7601 N Sam Houston Pkwy W Ste 100
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Houston, TX 77064-3595	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

Microbial contamination was present in the ISO (b)(4) area.

Specifically, during a review of selected non-conformance reports, NC-002307 documented on August 21, 2024, at approximately 0925, a viable air sample collected from Location (b)(4) within ISO Class (b)(4) Filling Room 1267 recovered one (1) colony-forming unit (CFU) during routine (b)(4) environmental monitoring (EM) activities (exceed action limit of (b)(4) for ISO (b)(4) environments). Testosterone Cypionate in GSO Injection, 200 mg/mL (5 mL fill volume), Lot #202364, BUD 5/28/2025, Qty. (b) (4) vials was being filled using the (b) (4) Filler. Your firm failed to adequately control microbial contamination within your firm's ISO (b)(4) rooms. Your firm's investigation documented the microbial was introduced by a technician introducing the contamination by hand or body positioning during setup in the ISO (b)(4) environment: or from an operator being in close proximity to the sampling site while performing an aseptic intervention. The batch was further processed, accepted by quality, and dispensed for patient specific prescriptions.

OBSERVATION 2

Failure to appropriately and regularly clean and disinfect or sterilize equipment located in the ISO (b)(4) area.

Specifically,

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	Camerson E Moore, Investigator Oluwasefunm Agbanigo, Investigator	X Camerson E Moore Investigator Signed By: Camerson E. Moore - S Date Signed: 11-14-2025 14:51:25	11/14/2025

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A. During observation of the filling setup for the finished sterile drug, L-Carnitine (30mL) 500 mg/ml, Lot # 221071, BUD 1/2/2026, Qty. (b) (4) units, in ISO (b)(4) Formulation Room (b)(4) (Non-sterile Compounding Suite (b)(4)), a technician failed to disinfect (b)(4) scissors with (b) (4) after removing from ISO (b)(4) BSC, using them within the ISO (b)(4) Cleanroom, then returning them to the ISO (b)(4) BSC.

B. Sterile compounding technician was observed failing to disinfect sterile gloves after performing task within ISO (b)(4) Cleanroom prior to returning to the ISO (b)(4) BSC, while setting up L-Carnitine (30mL),500 mg/ml, Lot # 221071, BUD 1/2/2026, Qty. (b) (4) in ISO (b)(4) Formulation Room (b)(4) (Non-sterile Compounding Suite (b)(4)).

C. During observation of the filling setup for the finished sterile drug, L-Carnitine (30mL), Qty. (b) (4) units, Lot # 221071 in ISO (b)(4) Formulation Room (b)(4) (Non-sterile Compounding Suite (b)(4)), an iPad contained within a plastic protective case was found with a cloth string attached, which is hard to clean and disinfect. Quality Director reported iPad and case is not included as part of EM sampling and was observed not being disinfected during any of the 4-day sterile aseptic processing observations. A similar iPad contained within a plastic protective case was found with a cloth string attached is also within the ISO (b)(4) Filling Cleanroom.

D. Technicians within ISO (b)(4) Cleanroom failed to disinfect (b)(4) pen used by two different technicians for documenting setup activities prior to and after use. Firm management reported, the pen is not part of the items required to be disinfected within the ISO (b)(4) Filling Cleanroom per the firm's quality director. Discussions were held with the firm's management regarding the pen being a microbial contamination transfer point.

This is a repeat Observation.

OBSERVATION 3

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Personnel were observed conducting aseptic manipulations where the movement of "first air" in the ISO (b)(4) area is blocked or disrupted.

Specifically, during observation of the firm's manual aseptic filling and stoppering within ISO (b)(4) Formulation Room (b)(4) (Non-hazardous drug formulation and filling) and ISO (b)(4) Formulation Room (b)(4) (Hazardous drug formulation and filling) within (b)(4) air flow ISO (b)(4) BSCs, technicians were observed disrupting "first air" during filling and capping open vials by holding the hand that is not in use with an open palm up potentially disrupting unidirectional air flow. Similar hand/palm orientation technique was observed in the firm's April 2025 recorded smoke studies, E4996-MF-7.mp4, E4996-MF-6.mp4, and E4689-MF-7.mp4.

OBSERVATION 4

Personnel were observed moving quickly in a critical area or in an area immediately adjacent to a critical area likely causing disruption of unidirectional airflow.

Specifically, during observations of the (b) (4) Filler production equipment setup, sterile batch filling/capping, and cleaning of the sterile drug product, Tirzepatide/ Niacinamide (4 mL) 17 / 2 mg/mL, Lot # 221077, BUD 2/1/2026, Qty. (b) (4) vials, technicians within the ISO (b)(4) Filling Cleanroom while performing wipe down interventions of the doors and sidewalls used a rapid wipe down method (rapid back and forth strokes) potentially disrupting unidirectional flow.

OBSERVATION 5

Smoke studies were inadequately performed under dynamic conditions.

Specifically, your firm's April 2025 ISO (b)(4) cleanroom smoke studies failed to include the intervention involving the (b) (4) Filler equipment setup, sterile filling/capping, and cleaning disinfection method used for wiping down unit doors and sidewalls during production of sterile drug products used a rapid wipe down method (rapid back and forth strokes) potentially disrupting

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unidirectional flow within the ISO (b)(4) Cleanroom during dynamic conditions. **This is a repeat Observation.**

OBSERVATION 6

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

Specifically, your firm's media fills failed to reflect actual production sizes based on vial fill/size. For example, during review of the firm's report, Summary Report - (b)(4) ml (b)(4) Media Fill Report and Protocol, A-REP-SCP-0003 dated 30-May-2025 reported filling of (b)(4) vials verse the maximum of (b)(4) vials with a fill volume of (b)(4) mL. Documented within the procedure, A-SOP-SCP-0011, Aseptic Fill - Process Verifications, the (b) mL vial is used for fill volumes ranging from (b)(4) mL - (b)(4) mL with a Theoretical Batch Size of (b)(4) vials. A review of firm's production records since the previous FDA inspection, found Tirzepatide /Niacinamide Injection 8/2 mg/mL, Lot 218493 Compounded 9/17/2025, Expiry 6/14/2026 reported a Theoretical Batch Size of (b)(4) vials with an actual released quantity (b)(4) vials with a fill volume of (b)(4) mL. Tirzepatide /Niacinamide Injection 17/2 mg/mL also has a fill volume of (b)(4) mL, which has a Theoretical Batch Size of (b)(4) vials. **This is a repeat Observation.**

***DATES OF INSPECTION**

11/03/2025(Mon), 11/04/2025(Tue), 11/05/2025(Wed), 11/07/2025(Fri), 11/10/2025(Mon), 11/11/2025(Tue), 11/12/2025(Wed), 11/13/2025(Thu), 11/14/2025(Fri)

X Oluwasefunm Agbanigo
Investigator
Signed By: Oluwasefunmi Agbanigo -S
Date Signed: 11-14-2025 14:53:21

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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."