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 ORAPHARM2_RESPONSES@fda.hhs.gov	10/16/2023-12/1/2023* FEI NUMBER 3021758709

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Pejmon Jonathan 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 Houston, TX 77064-3595	TYPE ESTABLISHMENT INSPECTED 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

Personnel were observed conducting aseptic manipulations where the movement of "first air" in the ISO 5 area is blocked or disrupted.

Specifically, on 11/13/2023, during a review of selected (b) (4) aseptically sterile lots that were produced within your firm's Formulation Room (b) (4) designated ISO 5 LAFUs (Asset IDs E4252 & E4689), the following poor aseptic techniques were observed (b) (4) :

A. During the aseptic production of Lipo (M/C) 30ml, processed on 10/31/2023, Lot 186017, BUD 04/24/2024, we observed the following deficiencies within your firm's ISO 5 LAFU (b) (4) Asset ID E4252):
   1. Sterile compounding technician was observed reaching over open finished drug filled vials while filling empty vials.
   2. Your firm's sterile compounding technician was observed dumping aluminum caps from (b) (4) bag overtop rubber stoppered vials and placing the caps on top of the stoppered vials while the (b) (4) sterile compounding technician filled empty sterile vials.

B. During the aseptic production of Lipo (M/C) 30ml, processed on 10/31/2023, Lot 186017, BUD 04/24/2024, we observed the following deficiencies within your firm's Formulation Room (b) (4) LAFU (b) (4) (Asset ID E4689):
   1. Your firm's sterile compounding technician was observed obstructing first air by placing a large open bag of (b) (4) rubber stoppers and metal caps in front of an un-stoppered tray of filled sterile vials.

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	Camerson E Moore, Investigator Demario L Walls, Investigator	X Camerson E Moore Investigator Signed By: Camerson E. Moore - S Date Signed: 12-01-2023 16:38:28	12/1/2023

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2. Your firm's sterile compounding technician was observed obstructing first air by placing an open bag of sterile rubber stoppers and aluminum caps in front of a tray of open sterile vials.

C. During the aseptic production of Bi-Amino Injection (30ml) 100/100 ml, Lot 187369, BUD 04/28/2024, we observed the following deficiencies within your firm's ISO 5 LAFU (b) (4) Asset ID E4252):
   1. Your firm's sterile compounding technician was observed reaching over open exposed finished sterile drug vials while (b) (4) aseptically filling empty sterile vials.
   2. During aseptic filling of sterile vials by your firm's sterile compounding technician, we observed large open bags of stoppers, aluminum caps in front the tray of open filled sterile drug vials, and a hanging bottle of (b) (4) disrupting airflow and first air during aseptic filling.
   3. Compounding technician observed un-stoppered tray of vials filled with finished sterile drug product first air being blocked by an open large bag of (b) (4) rubber stoppers and metal caps within ISO 5 LAFU.

OBSERVATION 2

Personnel infrequently changed and sanitized gloves to prevent contamination.

Specifically,

A. On 10/23/2023, during observation of your firm's automated vial filling operation within your firm's ISO 5 Cleanroom, for the drug product, NAD+ (Nicotinamide Adenine Dinucleotide) (LYO) 500mg Injectable, Lot 186001, BUD 10/15/2024 within the firm's ISO 5 Filling Room, we observed the firm's sterile compounding technician enter, perform a designated task within the (b) (4) filling machine, and restart the ISO 5 (b) (4) filling machine without disinfecting their gloves prior to returning to stacking the vials into the (b) (4) containers. Additionally, other technicians were observed entering the ISO 5 Classified production area,

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touching the entry door and proceeded to perform tasks within the room without disinfecting their gloves.

B. Your firm's sterile compounding technician failed to disinfect gloves after performing an activity on the (b) (4) table within the ISO 7 area prior to returning to the ISO 5 LAFU(b)(4) (Asset ID E4252) to add sterile rubber stoppers and metal caps overtop of finished sterile drug filled vials during the aseptic production LIPO (M/C) 30 ml, Lot 186017 processed on 10/31/2023, BUD 04/27/2024.

C. Your firm's sterile compounding technician was observed using there sterile gloves to push down trash inside garbage bin after unwrapping rubber stoppers and metal caps from (b) (4) bag within ISO 5 LAFU(b)(4) (Asset ID E4252). Your firm's sterile compounding technician failed to change sterile gloves before returning to aseptic filling operations. This action was observed twice during the aseptic production of LIPO (M/C) 30ml, Lot 186017, BUD 04/27/2024.

OBSERVATION 3

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

Specifically,

A. During a walk-though of your firm's warehouse for the storage of APIs and drug components, we found the following API/drug component, Edetate Disodium Dihydrate (EDTA) USP, Lot (b) (4) Expiry 3/24/2026, QC Approval 8/11/23, with a printed affixed label bearing the text, "Not for Use As Drug/API, or Drug Product". The product was received through your firm's unapproved supplier. The API manufacturer does not have an active registration with the FDA and is listed under Import Alert 66-79. The importer/distributor was also found not to have an active registration. Your firm used the "Not for Use as Drug/API or Drug Product" to compound the following sterile drug product:

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1. Lot 167270, Expiry 11/30/2023 (API Lot (b) (4), Retest Date 10/4/2024)
    1. Request Rx (b) (7)(C), (b) (6)
    2. Request Rx (b) (7)(C), (b) (6)
2. Lot 168911, Expiry 11/30/2023 (API Lot (b) (4), Retest Date 10/4/2024)
    1. Request Rx (b) (7)(C), (b) (6)
    2. Request Rx (b) (7)(C), (b) (6)
3. Lot 173691, Expiry 7/6/2024 (API Lot (b) (4), Retest Date 10/4/2024)
    1. Request Rx (b) (7)(C), (b) (6)
    2. Request Rx (b) (7)(C), (b) (6)

B. During a review of your firm's sterile drug production logs, the following finished sterile drug products were selected in support of your firm's use of the non-pharmaceutical grade components:

1. Edetate Disodium Preservative Free (30 mL) 150 mg/mL Injectable, Lot 185526, Expiry 10/4/2024, Qty. (b) (4) vials, using the API, EDTA Disodium Salt Dihydrate, (b) (4) CAS No. (b) (4) (Received 1/11/2022). API Lot (b) (4) was used to compound the finish drug product. API Lot (b) (4), CAS No (b) (4) Kg (Received 8/9/2023) of the same product was found in the firm's warehouse labeled in part, "Not For Use As Drug/API, or Drug Product".

2. LIPO C10 ML 15.50.50.5 MG/ML, Lot 179320, BUD 2/14/2024, dispensed with Rx (b) (7)(C), (b) (6) was found to contain EDTA, Lot (b) (4), Expiry 10/4/2024.

3. Nicotinamide Adenine Dinucleotide (LYO) 1000 MG Injectable, Lot 177180 BUD May 22, 2024, Rx (b) (7)(C), (b) (6) Logged Formula Worksheet documents the use of (b) (4) of NAD+ (Excelar reagent (ER) is equal to analytical reagent (AR) grade which is of pure quality for synthesis and preparation at research standards.

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4. Rx (b) (6), (b) (7)(C), NAD+ (NICOTINAMIDE ADENINE DINUCLEOTIDE) (15 ML) 300 MG/ML Nasal Spray, Lot 182759, BUD 10/2/2023 was compounded using API lots: Lot (b) (4), Expiry 11/10/24; Product Level - ER (Excelar Reagent) Grade; and Lot (b) (4) PO(b) (4) Expiry 22 May 2024; Product Level - ER (Excelar Reagent) Grade.

OBSERVATION 4

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

Specifically, your firm's (b) (4) management reported it has no data to ensure clean/deactivation reagents and methods used within the ISO 5 Cleanroom for the (b) (4) filling/ stoppering/ capping equipment is adequate to prevent cross contamination of hazardous and non-hazardous sterile finished drug products. Your firm's quality manager reported all sterile drug products undergo sterility, endotoxin, and potency testing only. No other laboratory testing is performed to ensure cleaning effectiveness and deactivation of hazardous APIs and or excipients in the prevention of cross contamination.

OBSERVATION 5

Inadequate routine environmental monitoring in the ISO 5 area and classified areas.

Specifically, during a review of your firm's environmental sampling results for your firm's ISO 5 classified areas and equipment, we found your firm's frequency for performing EM surface and viable air sampling is inadequate for ensuring adequacy for aseptic processing. For example, your firm performs EM surface and variable air sampling in your ISO 5 Classified Cleanroom and ISO 5 LAFUs where your firm conducts aseptic manipulations, the (b) (4) vial filling, stoppering, and capping (b) (4). Your firm's COO reported your firm performs the (b) (4) to sterilize the non-sterile drug product within the ISO 5 (b) (4). Your firm's management was

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unable to provide justification for the difference in frequency for EM sampling within the ISO 5 Classified areas and equipment. Your firm's management reported the firm follows the written procedure, Aseptic Environmental Sampling Plan SOP, A-SOP-QUA-0006, which documents EM sampling frequencies.

OBSERVATION 6

Inadequate post-use (b) (4) testing on (b) (4) used to sterilize drug products.

Specifically, during a review of your firm's non-conformances, we found your firm initiated a total of 4 Non-conformance reports for (b) (4) failures for (b) (4) used during the (b) (4) process. Your firm's reports documented only 1 out of the (b) (lots underwent a (b) (4) process, the remaining (b) (lots were released based on the (b) (4) which occurred in your firm's Formulation Room(s). For example, your firm quality unit reviewed, approved, and released finished drug products (b) (4) within your firm's inadequately EM sampled ISO 5 (b) (4) in Formulation Rooms (b) (4) Your firm's management reported all sterile drug products undergo a total of (b) (4) . The initial occurs after formulation within Formulation Rooms (b) (4) The (b) (4) occurs prior to undergoing the filling, stoppering, and filling process steps. Initiates non-conformances documenting only undergoing (b) (4) that occurred within Formulation Room (b) (4) include:

A. NC-000004 dated 1/3/2022, LIPO-C 10ML Injectable, Lot 117845 BUD June 28, 2022, Qty. (b) (4) released.
B. NC-000008 dated 1/17/2022, LIPO-B Injection 30ML Injectable, Lot 119134 BUD January 13, 2023, Qty. (b) (4) released.
C. NC-000009 dated 1/20/2022, Taurine Injection 50mg.mL, Lot 119650 BUD January 19, 2023, Qty. (b) (4) released.

OBSERVATION 7

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Biological indicators were not used to verify the adequacy of the sterilization cycle.

Specifically, your firm fail to use biological indicators to ensure your firm's glassware is endotoxin free by undergoing an adequate (b) (4). Your firm's senior engineer reported biological indicators were only used during the cycle validation and temperature probe use for temperature monitoring and recording of processing temperatures. He continued in stating there is no defined revalidation process for the cycle and or temperature probe using biological indicators.

OBSERVATION 8

Compounding with components, containers or other materials that have not been verified to assure that they do not contribute endotoxin contamination that may be objectionable given the product's intended use.

Specifically, your firm management reported your firm assigns (b) (4) expiry date to all (b) (4) glassware used in the production of sterile drug products. Your firm's management failed to provide laboratory records/data in support of your firm's assigned expiry ensuring no endotoxins are present on the glassware used in drug production.

***DATES OF INSPECTION**

10/16/2023(Mon), 10/17/2023(Tue), 10/18/2023(Wed), 10/19/2023(Thu), 10/20/2023(Fri), 10/23/2023(Mon), 10/24/2023(Tue), 10/25/2023(Wed), 10/26/2023(Thu), 10/27/2023(Fri), 10/30/2023(Mon), 10/31/2023(Tue), 11/01/2023(Wed), 11/07/2023(Tue), 11/13/2023(Mon), 11/21/2023(Tue), 11/29/2023(Wed), 11/30/2023(Thu), 12/01/2023(Fri)

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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."