DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612-2445 (949)608-2900 Fax:(949)608-4417 ORAPHARM2_RESPONSES@fda.hhs.gov	8/1/2024-8/28/2024* FEI NUMBER 3011887629

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Donald M. Mordas, Vice President of Operations

FIRM NAME	STREET ADDRESS
Empower Pharmacy	5980 W Sam Houston Pkwy N Ste 300
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Houston, TX 77041-5254	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:

OBSERVATION 1

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

Specifically,

A. Your firm released a batch of a sterile product even though positive microbial growth was detected during environmental monitoring (EM) within the ISO 5 production area. During the aseptic filling of Pyridoxine HCL, Lot (b) (4), Compounding Date 4/18/2024, BUD 4/18/2025, Batch Size: (b) (4) EM identified 1 CFU of Bacillus altitudinis/pumilus/safensis on a surface contact plate inside the ISO 5 LAFH, Equipment ID: E2150, however, the batch was released and distributed to customers.

B. The sterile inner layer of bags containing vials was routinely opened in the ISO 7 filling room and introduced into the ISO 5 LAFH without being disinfected. On 8/1/2024, during the production of Glycine 50 mg/ml, Lot# (b) (4), BUD: 7/30/2025, Batch Size: (b) (4) vials, it was observed that the (b) (4) operator cut open the outer layer of a vial bag and introduced the sterile inner bag into the ISO 5 LAFH, Equipment ID: E2150 without disinfection. Subsequently, the (b) (4) operator opened the inner layer bag containing the vials inside the hood prior to filling. The same practice was observed in the production of Testosterone Cypionate 200 mg/ml, Lot# (b) (4) on 7/15/2024, as seen in the production camera footage.

C. No EM monitoring of surface contact samples for (b) (4) used to place stoppers to open filled vials during aseptic processing has been performed. (b) (4) are typically used in the production

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	Dogbeda F Mackenzie, Investigator Taichun Qin, Investigator X Dogbeda F Mackenzie Investigator Signed By: Dogbeda F. Mackenzie -S Date Signed: 08-28-2024 15:14:26	8/28/2024

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of a batch containing (b) (4) vials. The firm conducts in-house sterilization of (b) (4) and has established a (b) (4) holding time. During the production of Glycine, Lot# (b) (4), it was observed the production operator used (b) (4) to place stoppers on vials during aseptic processing.

D. The smoke study failed to demonstrate the impact of the 6-inch horizontal gaps below the back wall of the ISO 5 LAFHs on unidirectional airflow. The smoke study dated 6/26/2023 shows airflow exiting the ISO 5 LAFH, Equipment ID: E2150, through gaps below the two side walls. However, no smoke study was conducted to show that airflow could exit through the gaps in the back wall, which would prevent airflow from the ISO 7 cleanroom from entering the ISO 5 LAFH. This LAFH is used for the aseptic filling of sterile drug products. Also, the smoke study failed to demonstrate the impact of a bar hole on the side wall of the ISO 5 LAFH, Equipment ID: E 2150. No smoke study was conducted to show that the bar hole could prevent airflow from the ISO 7 cleanroom from entering the ISO 5 environment.

E. A full batch was released despite a reported deviation in non-viable particle monitoring in the ISO 5 areas. During the filling operation for Ascorbic Acid Preserved 500 mg/ml Injection (30 mL), Lot# (b) (4), BUD: 5/25/2025, Batch Size: (b) (4) vials on 6/17/2024, the (b) (4) counter (E2142) recorded a Total Particulate Count (TPC) that exceeded the action level during a (b) (4). No definite root cause was identified; however, the batch, including vials filled during that (b) (4), was released.

F. Your firm does not perform proper aseptic techniques while performing sterile operations. It was observed on 7/30/2024, during the setup of drug product Glycine 50mg/mL Injection Lot (b) (4), BUD: 30 JUL 2025), your technician was observed picking up a pair of scissors off the ISO - 7 floor, moved behind the ISO - 5 hood (Equipment ID: E2150) to wipe the scissors then placed the scissors back into ISO - 5 hood (Equipment ID: E2150). This operator proceeded to operate in the ISO-5 hood with the same pair of gloves. The pair of scissors that was incorrectly introduced in the ISO- hood was then used to open a bag of sterile stoppers that were used to

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stopper this lot.

OBSERVATION 2

There is a failure to thoroughly review any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

Specifically,

A. Investigation of complaints on lack of efficacy was inadequate. Your firm has received approximately 20 complaints for lack of efficacy of compounded drug products since August, 2022. The investigation of each complaint did not identify any deficiencies in production, and no returned samples were received; However, your firm did not test any retention samples for complaints related to lack of efficacy as part of your investigation process. For example, your firm received complaints for lack of efficacy for Testosterone 200 mg Pellet, Lot # (b) (4) & Lot# (b) (4) dated 5/16/2023 per COM-0000001217, Testosterone 200 mg Pellet, Lot # (b) (4) dated 5/22/2023 per COM-0000001233 and Ketamine HCl Preserved 100mg/mL Injection (10mL), Lot# (b) (4) dated 10/24/2022 per CPOM-0000000382. The retention samples have not been tested for these complaints.

B. Investigation of EM OOS during aseptic batch processing was inadequate. On 5/4/2023, during the filling operations of Lipo-B/Methionine/Choline Chloride/Cyanocobalamin 25/50/1 mg/ml, Lot (b) (4), BUD: 10/30/2023, Batch Size: (b) (4) vials, personal monitoring of operator (b) (7)(C), identified 1 CFU of fungi. According to the investigation report, the most likely root cause was improper gowning and aseptic technique, leading to the disqualification of the operator from aseptic production. However, the investigation was inadequate as it lacked information on any batches the operator produced before the EM results were available.

C. Your firm opened the following NCs to investigate environmental monitoring excursions:

NC #	Sample date	Impact

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NC - 000673	16 AUG 2023	routine EM sampling of Gowning room
NC - 000698	24 AUG 2023	routine EM sampling of Filling suite
NC - 000700	25 AUG 2023	Cyanocobalamin lot (b) (4)
NC - 000701	25 AUG 2023	Cyanocobalamin lot (b) (4)
NC - 000709	29 AUG 2023	Cyanocobalamin lot (b) (4)
NC - 000710	29 AUG 2023	Cyanocobalamin lot (b) (4)
NC - 000711	28 AUG 2023	Magnesium Chloride Lot (b) (4)
NC - 000712	31 AUG 2023	Ascorbic Acid Preservative Free (PF) lot (b) (4)
NC - 000713	28 AUG 2023	Biotin lot (b) (4)
NC - 000724	07 SEP 2023	Ascorbic Acid Preserved lot (b) (4)
NC - 000727	07 Sep 2023	routine EM sampling of (b) (4) room
NC - 000728	31 Aug 2023	routine EM sampling of Filling suite
NC - 000732	12 Sep 2023	routine EM sampling of formulation room
NC - 000733	8 Sep - 14 Sep 2023	Biotin lot (b) (4)

During review of these investigations your firm failed to extend the investigation to other batches manufactured outside 24 Aug 2023 and 19 Sep 2023. For example, your firm did not include sterile drug product Glutathione 200mg/mL, Lot (b) (4), BUD: 18 Nov 2023, however this lot was manufactured on 16 Aug 2023. *Pseudomonas luteola* was identified in a routine EM sample that was collected on 16 Aug 2023 (same day this lot was aseptically filled) from the gowning room.

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OBSERVATION 3

Laboratory controls do not include the establishment of scientifically sound and appropriate specifications and test procedures designed to assure that drug products conform to appropriate standards of identity, strength, quality and purity.

Specifically,

On 8/1/2024, during the walkthrough of the microbiology laboratory, it was observed that all EM (b) (4) plates were placed in (b) (4) bag for incubation without any visible gaps. For example, the EM plates for zinc sulfate 10 MG/ML ZINC, lot # (b) (4) were placed in (b) (4) bag for incubation. Currently, all EM samples were placed in (b) (4) for microbial growth testing. Your growth promotion testing was conducted in a contract laboratory. There is no documented evidence or study demonstrating the impact of this practice on bacterial and fungal growth.

OBSERVATION 4

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

Specifically,

A. During the visual inspection of Ketamine HCL Preserved 100 mg/ml, Lot (b) (4) BUD:1/27/2025, Batch Size: (b) (4) vials on 8/1/2024, it was observed that visual inspectors did not (b) (4) the vials, as required by the Visual Inspection Procedure for Visual Inspection, Document Number: B-SOP-VIL-0003. The same practice was observed during the production of Glutathione Preservative-Free 200 mg/mL, Lot#(b) (4), BUD: 1/27/2025, Batch Size: (b) (4) vials on 8/2/2024.

B. During the visual inspection of Ketamine HCL Preserved 100 mg/mL, Lot# (b) (4) it was observed that the inspector (b) (4) the vials in a manner that caused bubbles to form, potentially interfering with the inspection. However, Section 6.3.6.2 of the Visual Inspection procedure , Document Number: B-SOP-VIL-0003 specifies: "(b) (4)

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(b) (4)
".

OBSERVATION 5

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

Specifically,

A. Your firm does not adequately maintain your ISO-5 hoods used to produce sterile drug products. On 8/12/2024, discolored stains were observed on the HEPA filter inside your ISO - 5 hood (Equipment (b) (4)). Additionally, discolored stains were observed in (b) (4) ISO – 5 hoods (Equipment ID: (b) (4)) and on the legs on the ISO - 5 hood (Equipment ID: (b) (4) .

B. On 08/12/2024, scratches were observed inside ISO - 5 hoods (Equipment IDs: (b) (4) The scratches do not appear to be smooth and cleanable for aseptic operations.

OBSERVATION 6

Adverse reactions were not reported to FDA using form FDA 3500A within 15 calendar days of initial receipt of information.

Specifically,

Your outsourcing facility has not submitted an adverse event report to FDA in accordance with the content and format requirements established through guidance or regulation under 21 CFR 310.305 as required by section 503B(b)(5). Your firm received a serious adverse event on July 29, 2022, concerning a patient who experienced hypersensitivity reactions following an intravenous (IV) infusion of ascorbic acid, methylcobalamin, and bacteriostatic water. This adverse event was reported to FDA on September 2, 2022 (FAERS #21290234).

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OBSERVATION 7

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically,

A. Personnel monitoring performed do not accurately represent the environment in which sterile drug product are filled. Your procedure B-SOP-QC-0002, Personnel Monitoring Program, Revision 001, Effective date: 2-Jan-2024, Section 6.2.1 instructs that personnel monitoring (b) (4) .

i. Aseptic operators working in (b) (4) ISO – 5 hoods (Equipment ID: (b) (4)) were observed on 7/31/2024 sanitizing their gloves prior to performing personnel monitoring. Your Operators failed to (b) (4) aseptic filling of sterile drug product Lipo-B/Methionine/Choline Chloride/Cyanocobalamin 25/50/1 mg/mL Injection Solution Lot (b) (4), BUD: 27 Jan 2025, as required by your procedure.

ii. Aseptic operators working in ISO – 5 hood (Equipment ID: E2151) were observed on 7/31/2024 sanitizing their gloves prior to performing personnel monitoring. Your Operators failed to (b) (4) aseptic filling of sterile drug product Testosterone Cypionate 200mg/mL Lot (b) (4), BUD: 10 Jul 2025, as required by your procedure.

iii. Aseptic operators working in (b) (4) ISO – 5 hoods (Equipment ID: (b) (4)) were observed on 7/31/2024 sanitizing their gloves prior to performing personnel monitoring. Your Operators failed (b) (4) aseptic filling of sterile drug product Glutathione Preservative Free 200 mg/mL Lot (b) (4), BUD: 27 Jan 2025. The personnel monitoring of the aseptic operator who performed aseptic filling in ISO – 5 hood (Equipment ID: (b) (4)) was performed by a supervisor.
Additionally, this operator was observed (b) (4) media plate, rather than (b) (4) to capture the gloved hands utilized during aseptic production. Section

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B. Your procedure B-SOP-QC-0009, Performing Personnel Monitoring, Revision 001, Effective date: 2-Jan-2024, Section 6.4.1.5 states Personnel (b) (4) . Your employees failed to perform PM according to your procedure and they were not corrected by (b) (7)(C) operator.

i. On 08/06/2024, your firm's aseptic operator, who was performing personnel monitoring sampling, failed to employ proper fingertip plating techniques during PM after conducting aseptic filling of your sterile drug product Testosterone 200mg/mL (Lot (b) (4)), BUD: 5 AUG 2025. The aseptic operator was observed (b) (4) media plate, (b) (4) to capture the gloved hands utilized during aseptic production.

ii. Aseptic operator working in ISO – 5 hood (Equipment ID: E2151) was observed on 7/31/2024 (b) (4) media plate, (b) (4) to capture the gloved hands utilized during aseptic production. Your Operators failed to perform PM according to your procedure after concluding aseptic filling of sterile drug product Glutathione Preservative Free 200 mg/mL (30 ML) Lot (b) (4) BUD: 27 Jan 2025.

OBSERVATION 8

The container of your outsourcing facility's drug products does not include information required by section 503B(a)(10)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

Specifically,

1. The containers of your outsourcing facility's drug products do not include information required by section 503B(a)(10)(B). Specifically, your containers do not include the following information:

a) Information to facilitate adverse event reporting: www.fda.gov/medwatch and 1–800–FDA–1088.

Examples of your container labels that do not contain this information:

☐ Glycine Injectable Solution 50 mg/mL (30 mL)

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b)Directions for use, including, as appropriate, dosage and administration.

Examples of your container labels that do not contain this information:

☐Glycine Injectable Solution 50 mg/mL (30 mL)

OBSERVATION 9

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

Specifically,

A. The validation of disinfectant efficacy was inadequate. Your firm conducted a disinfectant efficacy study of (b) (4) Formula in 2017, which only covered materials such as (b) (4) However, this study did not include surfaces like those of bags containing vials or supplies (e.g., (b) (4) (b) (4) Formula is used to disinfect surfaces of supplies when transferring them from (b) (4) area.

B. Your firm failed to perform a cleaning validation for the cleaning of the following equipment used in compounding your sterile pellet drug products Testosterone and Estradiol:

Equipment	Asset ID
(b) (4) Tableting Machine	E4318
(b) (4) Milling Machine	E1057
(b) (4) Tablet Sorter/Sampler	E1117
(b) (4) Filling and Sealing Machine	E1821
(b) (4) Blender	E1119

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Metal Detector /Tablet Deduster	E1044
Sieves	N/A

***DATES OF INSPECTION**

8/01/2024(Thu), 8/02/2024(Fri), 8/05/2024(Mon), 8/06/2024(Tue), 8/07/2024(Wed), 8/08/2024(Thu), 8/09/2024(Fri), 8/12/2024(Mon), 8/13/2024(Tue), 8/14/2024(Wed), 8/15/2024(Thu), 8/16/2024(Fri), 8/27/2024(Tue), 8/28/2024(Wed)

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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."