DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
404 BNA Dr., Bldg. 200, Ste. 500 Nashville, TN 37217-2597 (615)366-7801 Fax:(615)366-7802 ORAPHARM2_RESPONSES@fda.hhs.gov	10/3/2022-10/13/2022* FEI NUMBER 3010241801

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Jonathan A. Sims, Owner/Pharmacist-in-Charge	
FIRM NAME Pharmacy Plus, Inc. dba Vital Care Compounder	STREET ADDRESS 115 S 40th Ave
CITY, STATE, ZIP CODE, COUNTRY Hattiesburg, MS 39402-6600	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

You did not make adequate product evaluation and take remedial action where actionable microbial contamination was found to be present in the ISO 5 classified aseptic processing area during aseptic production.

Specifically, on 3/29/22 your firm's certification company detected an out-of-specification, (b) (4), for active air (fungus organisms identified: *Cladosporium spp, Epicoccum nigrum, Penicillum commune, etc.)* within your firm's ISO-5 (b) (4) laminar airflow hood ((b) (4)). From 8/4/21 (previous certification that detected no growth), through 3/29/22, your firm produced and dispensed approximately (b) (4) lots. The six (6) lot numbers listed below are still on the market within expiration:

- Cyclosporin Ophthalmic 2% Oil ((b) (4)), 3,000mL, lot #58114, BUD:11/25/22
- Medroxyprogesterone Acetate 300mg/mL Suspension, 1,000mL, lot #55786, BUD:12/31/22
- Tacrolimus Ophthalmic 0.02% Suspension ((b) (4)), 2,400mL, lot #55228, BUD:12/17/22
- Papaverine/Phentolamine Injection 150mg/5mg Vial Solution, 500mL, lot #55092, BUD:10/22/22
- Methylcobalamin PF 1mL Injection Solution 5,000MCG/mL, 500mL, lot#57997, BUD:2/25/23
- Triamcinolone Acetonide Injection 6mg/mL Suspension, 1,200mL, lot #58232, BUD: 3/8/23

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	Jared P Stevens, Investigator Martrice A Packer, Investigator Jessica P Mcalister, Investigator	X Jared P Stevens Investigator Signed By: Jared P. Stevens -S Date Signed: 10-13-2022 09:28:16	10/13/2022

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OBSERVATION 2

The cycle parameters ((b) (4)) used for (b) (4) sterilization of product intended to be sterile were not lethal to heat-resistant microorganisms.

Specifically, biological indicators (BIs) were not used to verify the adequacy of your firm's sterilization cycles by (b) (4) for your suspension drug products (e.g., Triamcinolone) and by (b) (4) for your (b) (4) drug products (e.g., Cyclosporin).

OBSERVATION 3

The final containers/closures used for drug product intended to be sterile were not sterilized and (b) (4) .

Specifically, your firm conducted a (b) (4) study on 9/30/22 for the (b) (4) These vials were not used in production but were intended to demonstrate the effectiveness of the cycle time which is used to (b) (4) sterilize empty (b) (4) vials. On 10/4/22, day 5 of (b) (of (b) (4) the four biological indicators used failed. Your firm's cycle time is potentially insufficient in achieving sterilization of empty (b) (4) vials.

In addition, your firm assigns a 6-month BUD after sterilization (b) (4) for un-used (left over from a batch) purchased sterile vials (b) (4) . Your firm has no assurance that these critical product contact surfaces maintain their sterility for this duration.

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OBSERVATION 4

The ISO 5 classified aseptic processing areas had difficult to clean, particle-generating and visibly dirty equipment or surface.

Specifically, on 10/3/22, the following deficiencies were observed in your firm's ISO-5 (b) (4) pertaining to inadequate cleaning and sanitization and potential particle generating supplies.

a. Rust-like stains were observed on the stainless-steel within your firm's (b) (4).
b. The sleeves within the (b) (4) contained (b) (4) nuts and gaskets with grooves which are difficult to clean as they are not disassembled. In addition, according to your firm's operator, the interior portion of the sleeves within your ISO-5 (b) (4) is not cleaned and sanitized and (b) (6) places (b) (6) (b) (4) hands inside of them to access the unit.
c. A household non-sterile trash bag was observed to be secured with an elastic rubber band on the right side of the working surface within your (b) (4) which cannot be adequately cleaned and sanitized and can introduce microbial and particulate contamination. The trash bag contained used supplies from the last lot of Mitomycin Injection, 0.375mg/mL, lot #66536 produced on 9/27/22.

OBSERVATION 5

Disinfecting agents and cleaning pads and cleaning wipes used in the ISO 5 classified aseptic processing areas were not sterile.

Specifically, on 10/4/22, prior to aseptic operations of finished drug product, DMSO with Lidocaine 50%/0.5%, lot #66829, Use by: 10/5/22 (QTY: 1 vial) (Bladder Irrigation) your firm's operator was

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observed cleaning the ISO 5 (b) (4) laminar airflow hood with a non-sterile cleaning pad. In addition, on 10/4/22, during the (b) (4) cleaning, your firm's facilities manager was observed cleaning the interior surfaces of the ISO-5 hoods with non-sterile wipes.

OBSERVATION 6

Personnel used a non-sterile tool on and manually contacted the inner surface of the container or closure.

Specifically, on 10/4/22, during aseptic operations of finished drug product, DMSO with Lidocaine 50%/0.5%, lot #66829, Use by: 10/5/22 (QTY: 1 vial) (Bladder Irrigation) your firm's operator was observed (b) (4) the finished product vial with the (b) (4) bag. Your operator stated for larger batch sizes she uses her (b) (4) hand.

OBSERVATION 7

Personnel did not disinfect and change gloves frequently enough to prevent contamination.

Specifically, on 10/4/22, during aseptic operations of finished drug product, DMSO with Lidocaine 50%/0.5%, lot #66829, Use by: 10/5/22 (QTY: 1 Vial) (Bladder Irrigation) your firm's operator was observed spraying (b) (6) (b) (4) hands with (b) (4) within the ISO-7 Cleanroom then wiped (b) (6) hands with a wipe exposed to lower quality air that was left open on a cart within the ISO 7 Cleanroom. The operator then proceeded to produce the drug product aseptically within the ISO 5 (b) (4) laminar airflow hood without first disinfecting (b) (6) gloves.

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OBSERVATION 8

You produced hazardous drugs without providing adequate segregation, cleaning of work surfaces and cleaning of utensils to prevent cross-contamination.

Specifically, according to your firm's Director of Operations, your firm conducts weighing of these hazardous bulk drug substances (mitomycin, cyclosporin and testosterone) within your non-sterile (b) (4) hood which is also used for the weighing/mixing of non-hazardous bulk drug substances without cleaning of the work surfaces and equipment with a deactivating agent (e.g., oxidizing agent).

OBSERVATION 9

Media fills were not performed that closely simulate aseptic production operations incorporating, as appropriate, worst-case activities and conditions that provide a challenge to aseptic operations.

Your firms, "High Risk Media Fill ((b) (4))", dated 3/4/22, 3/16/22, 8/22/22 and 8/30/22 are inadequate as they fail to incorporate the largest batch sizes for each operator, that would simulate various aseptic production operations (e.g., (b) (4)) as well as include different container closure systems ((b) (4)) that potentially challenge your aseptic operations. In addition, your firm (b) (4) sterilized a portion of the media fill vials which fails to evaluate the operator's aseptic technique. Lastly, your firm failed to (b) (4) all media fill vials.

OBSERVATION 10

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ISO-5 classified areas were not adequately certified under dynamic conditions.

Specifically, unidirectional airflow was not verified under operational conditions within your firm's ISO-5 (b) (4) laminar airflow (b) (4) (designated for (b) (4)). During the smoke study video labeled August 2022, the air is observed moving (b) (4). The smoke study fails to incorporate all aseptic operations, simulated manipulations, and supplies (e.g., sterile IV bags (b) (4) or larger, transfer tubing, etc.), used in routine production that can potentially disrupt unidirectional airflow within the ISO-5 unit.

***DATES OF INSPECTION**

10/03/2022(Mon), 10/04/2022(Tue), 10/05/2022(Wed), 10/06/2022(Thu), 10/13/2022(Thu)

X Martrice A Packer
Investigator
Signed By: Martrice A. Packer -S
Date Signed: 10-13-2022 09:28:55

X Jessica P Mcalister
Investigator
Signed By: Jessica L. Mcalister -S
Date Signed: 10-13-2022 09:30:10

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EMPLOYEE(S) SIGNATURE
Jared P Stevens, Investigator
Martrice A Packer, Investigator
Jessica P Mcalister, Investigator

X Jared P Stevens
Investigator
Signed By: Jared P. Stevens -S
Date Signed: 10-13-2022
09:28:16

DATE ISSUED
10/13/2022

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."