DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderley Place, Suite 200 Maitland, FL 32751 (407)475-4700 Fax:(407)475-4768 ORAPHARM2_RESPONSES@fda.hhs.gov	6/6/2022-6/17/2022* FEI NUMBER 3010621916

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Andrew M. Vukadinovich, Director of Operations

FIRM NAME	STREET ADDRESS
Drug Depot, LLC., dba APS Pharmacy	34911 Us Highway 19 N Ste 600
CITY, STATE, ZIP CODE, COUNTRY Palm Harbor, FL 34684-1921	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

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

Specifically, on 06/10/22, we identified two (2) HEPA filters (Hood (b)(4) and Hood (b)(4)) containing brown stains. These laminar flow hoods are used to perform aseptic operations for drug products purported to be sterile. Per the Compounding Supervisor, the brown stains are suspected to be product.

OBSERVATION 2

Personnel conducted aseptic manipulations in an area that blocked the movement of first pass air around an open unit, either before or after it was filled with sterile product.

Specifically,

A. On 06/06/22, during production activities of Testosterone Cypionate/Anastrozole (b) (4) Oil (10mL) 200mg/0.5mg/mL Injectable Lot: 774910 BUD: 12/03/2022, we observed the placement of bagged (b) (4) and forceps leaning against the side interior wall of the ISO5 environment blocking the exhaust air within the sterile zone in BSC (b)(4). This was also depicted on the smoke study ((b) (4)) which revealed turbulent airflow as air circulated around the materials.

B. On 06/09/22, we observed the (b) (4) of (b)(4) vials of Semorelin 15mg Injectable Lot: 775617 BUD: 11/10/2022 in your Non-Hazardous ISO-5 Zone. During filling activities within

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Saundrea A Munroe, Investigator Jessica M Simpson, Investigator Martrice A Packer, Investigator	X Saundrea A Munroe Investigator Signed By: Saundrea A. Munroe - S Date Signed: 06-17-2022 11:06:00	6/17/2022

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the ISO5 laminar flow hood (b) (4), we observed the operator reaching directly over open vials of drug product (both during filling and (b) (4) activities) which could introduce contaminants from donned garments.

OBSERVATION 3

Personnel moved rapidly in the vicinity of open sterile units and instruments, which disrupted the airflow and increased the risk of bringing lesser quality air into the ISO 5 classified aseptic processing area.

Specifically, on 06/06/22, we observed the production of Testosterone Cypionate/Anastrozole (b) (4) Oil (10mL) 200mg/0.5mg/mL Injectable Lot: 774910 BUD: 12/03/2022. During compounding activities in BSC (b) (4) we observed the technician making rapid movements.

OBSERVATION 4

Your firm failed to perform adequate smoke studies under dynamic conditions to demonstrate unidirectional airflow within the ISO 5 area.

Specifically, smoke study ((b) (4)) for LFH (b) (4) and its associated ISO5 Zone used for (b) (4) of non-hazardous drug products was reviewed and found to depict areas indicating poor airflow. There is concern that air velocity directly over the (b) (4) is not effectively reaching the product because it begins to settle at the top of the (b) (4). Therefore, your products intended to be sterile are produced in an environment that may not provide adequate protection against the risk of contamination.

OBSERVATION 5

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	Saundrea A Munroe, Investigator Jessica M Simpson, Investigator Martrice A Packer, Investigator	X Saundrea A Munroe Investigator Signed By: Saundrea A. Munroe - S Date Signed: 06-17-2022 11:06:00	6/17/2022

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Your firm failed to perform adequate personnel monitoring.

Specially, on 06/09/22, after (b) (4) of Semorelin 15mg Injectable Lot: 775617 BUD: 11/10/2022, we observed (b) (4) monitoring of the technician that performed the compounding activities. (b) (4) plating was found inadequate as the technician lightly touched (b) (4) onto the plate instead of firmly pressing and rolling (b) (4) onto the agar.

***DATES OF INSPECTION**
6/06/2022(Mon), 6/07/2022(Tue), 6/08/2022(Wed), 6/09/2022(Thu), 6/10/2022(Fri), 6/13/2022(Mon), 6/14/2022(Tue), 6/17/2022(Fri)

X Jessica M Simpson
Investigator
Signed By: Jessica M. Simpson -S
Date Signed: 06-17-2022 11:06:26

X Martrice A Packer
Investigator
Signed By: Martrice A. Packer -S
Date Signed: 06-17-2022 11:07:15

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EMPLOYEE(S) SIGNATURE
Saundrea A Munroe, Investigator
Jessica M Simpson, Investigator
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Investigator
Signed By: Saundrea A. Munroe -S
Date Signed: 06-17-2022 11:06:00

DATE ISSUED
6/17/2022

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."