

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER 555 Winderley Place, Suite 200 Maitland, FL 32751 407-475-4700 ORAPharm2_responses@fda.hhs.gov Industry Information: www.fda.gov/oc/industry		DATE(S) OF INSPECTION 09/27/2021-10/05/2021
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Prince L. Hinson, Rph., Owner & Pharmacist in Charge		FEI NUMBER 3007426960
FIRM NAME Westlab Pharmacy Inc. dba Westlab Pharmacy	STREET ADDRESS 4410 W. Newberry Rd.	
CITY, STATE, ZIP CODE, COUNTRY Gainesville, FL 32607-2290	TYPE ESTABLISHMENT INSPECTED Producer of Sterile & 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 (I) (WE) OBSERVED:

OBSERVATION 1

Vermin was observed in your production area.

Specifically, on 9/27/21, a large dead insect that was identified by your firm's personnel as a wasp was observed within the ceiling light fixture directly above the ISO-5 laminar airflow hood within your firm's ISO-7 Cleanroom. Additionally, a few similar large insects were also observed within the ceiling light fixtures within your ISO-8 Anteroom where sterile gowning is conducted.

OBSERVATION 2

Non-microbial contamination was observed in your production area.

Specifically,

- A. From 9/27-9/29/21, brown stains were observed in the middle of your firm's HEPA filter within the ISO-5 laminar airflow hood.
- B. During the walk thru of your firm's non-sterile suite, the (b) (4), Model (b) (4), Serial (b) (4) was observed to contain a circular opening on the right side that was covered with clear tape which cannot be cleaned and sanitized. Your firm's Pharmacy Technician stated (b) (6) replaces the tape (b) (4). On 9/27/21, your firm produced (b) (4) drug products which include, but are not limited to, Progesterone 200mg capsules, lot #09272021@76, BUD:3/2/22 dispensed under RX (b) (4) on 9/28/21.
- C. During the walk-thru of your firm's non-sterile suite, a fire sprinkler located in the ceiling between your (b) (4), designated hazardous (b) (4) containment hoods contained an accumulation of dust.

OBSERVATION 3-

Environmental monitoring was not performed in your aseptic processing areas.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE <i>Jessica P. McAlister</i>	EMPLOYEE(S) NAME AND TITLE (Print or Type) Jessica P. McAlister, Pharmacy Compounding National Expert	DATE ISSUED 10/5/21
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Specifically, environmental monitoring (viable/non-viable, surface and personnel monitoring) was not conducted during or directly after sterile compounding operations.

OBSERVATION 4

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.

Specifically, on 9/2/21 your firm produced (b) (4) of Oculostasis Ophthalmic eye drops, lot #09022021@30, BUD: 10/17/21 which incorporated the dispensing of sterile product within an opened sterile dropper container. Instead, your media fills simulate a closed system ((b) (4)) utilizing syringes and sealed sterile vials which fails to incorporate worst-case simulations that pose a challenge to aseptic technique.

OBSERVATION 5


Personnel were observed conducting aseptic manipulations or placing equipment/supplies in an area that blocked the movement of first pass air around an open unit, whether before or after it is filled with sterile product.

Specifically, on 9/29/21, your firm's Pharmacy Technician was observed in the ISO-5 laminar airflow hood blocking the movement of first pass air around the (b) (4) of the sterile vial containing Trimix 30mg/2mg/20mcg/mL 5mL injectable, lot #09292021@40, BUD: 11/13/21 dispensed under Rx #(b) (4). In addition, (b) (6) was observed to conduct aseptic manipulations close to the horizontal HEPA filter which creates turbulent airflow as also depicted in your firm's recent smoke study.

OBSERVATION 6

Hazardous drugs were produced without providing adequate cleaning of work surfaces, utensils, and/or personnel to prevent cross-contamination.

Specifically, on 9/27/21, your firm produced (b) (4) drug products which include, but are not limited to, Progesterone 200mg (qty:90) Capsules, lot #09272021@76, BUD:3/2/22 dispensed under R (b) (4) and Testosterone 250mg (qty: 60) Troches, lot #09272021@54, BUD: 10/27/21 dispensed under (b) (4) within the (b) (4).

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Serial (b) (4) and failed to use a deactivating agent to clean the hood in between batches of hazardous drug products.

OBSERVATION 7

Non-pharmaceutical (b) (4) (not meeting specifications of (b) (4)) was used as a component within non-sterile drug production.

Specifically, your firm is utilizing the (b) (4) to produce non-sterile drug products. Your firm's Pharmacy Technician stated that your firm does not conduct testing (chemistry or microbiology), to ensure the non-pharmaceutical (b) (4) meets USP specifications.

OBSERVATION 8

A water source is present in the cleanroom where the ISO 5 area is located.

Specifically, your firm has a fire sprinkler located in the ceiling directly above the ISO-5 laminar airflow hood where sterile production is performed.

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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."