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	8/6/2018-8/15/2018* FEI NUMBER 3007426960

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Prince L. Hinson, Owner and Pharmacist-In-Charge

FIRM NAME	STREET ADDRESS
Westlab Pharmacy, Inc. dba Westlab Pharmacy	4410 W Newberry Rd, Ste A5
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Gainesville, FL 32607-2290	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 I OBSERVED:

OBSERVATION 1

The ISO 5 classified aseptic processing area was located within a non-classified room (segregated production area).

Specifically, your firm's ISO 5 (b) (4), which is used to produce mitomycin and cyclosporine drug products, is located in a non-classified room. The following Lots were produced in the (b) (4) between 05/14/18-08/14/18:

1. Mitomycin Opth 0.02%, Lot 06152018@13
2. Cyclosporin Aqueous 0.5% solution, Lot 06132018@43
3. Cyclosporin Aqueous 1% solution, Lot 06252018@45
4. Cyclosporin Aqueous 1% solution, Lot 07262018@7

OBSERVATION 2

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

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	Jennifer L Huntington, Investigator	X Jennifer L Huntington Investigator Signed By: Jennifer L. Huntington Date Signed: 08-15-2018 07:33:28	8/15/2018

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Specifically, on 08/06/18, during a medial fill, I observed the ISO 5 Laminar Airflow Workstation (LAFW) was cleaned using non-sterile wipes prior to the media fill. The non-sterile wipes were maintained in the ISO 7 clean room during production.

In addition, your firm utilizes the following non-sterile products to clean the ISO5 LAFW and the ISO 5 (b) (4):

1. (b) (4)
2.
3.

OBSERVATION 3
You used a non-pharmaceutical grade component in the formulation of a drug product.

Specifically, your firm used non-pharmaceutical grade (b) (4) in the production of Alprostadil 500mcg/mL injectable, Lots 03182018@42 and 07252018@17.

In addition, your firm produced non-sterile products using non-pharmaceutical grade ingredients. Examples include, but are not limited to:

1. Vancomycin/Water 250mg/mL solution, Lot 07022018@53
2. Tetracaine HCL 0.5% Spray, Lot 07022018@17
3. Amikacin/Dexamethasone Otic 1/0.1% solution, Lot 07022018@76
4. Estradiol/Estriol/Prog/Test (Raspberry) 0.4/0.6/50/1 MG Troche, Lot 07022018@3
5. Estradiol/Estriol 0.6/1.4MG Trits, Lot 07022018@1

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OBSERVATION 4

Personnel engaged in aseptic processing were observed with exposed hands.

Specifically, an operator was observed donning sterile gloves inside the ISO 5 LAFW prior to the media fill on 08/06/18.

OBSERVATION 5

The ISO 5 classified aseptic processing areas had difficult to clean equipment or surface.

Specifically, on 08/08/18, I observed uncovered, exposed light fixtures inside the ISO 5 LAFW during the production of Dexamethasone 24mg/mL injectable, Lot 08082018@30 and EDTA Opth 1.5% solution, Lot 08082018@31.

OBSERVATION 6

Written procedures are lacking which describe in sufficient detail the identification, sampling, testing, approval and rejection of components, drug product containers and closures.

Specifically, your firm's procedure, SOP 6.010, Product Procurement, Receipt and Inspection, Version 1, Effective 12/20/12, lack's written procedures for the sampling, identity testing, and approval or rejection of components, containers, and closures used in the production of non-sterile drug products. In addition, your firm does not perform identity testing on the active ingredients used in the production of non-sterile drug products. Examples include, but are not limited to:

1. Acetylcysteine, USP, Lot (b) (4)

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2. Aminocaproic Acid EP, Lot (b) (4)

3. Progesterone USP Micronized Powder, Lot (b) (4)

OBSERVATION 7

Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the final specifications and identity and strength of each active ingredient prior to release.

Specifically, your firm has failed to perform testing for identity and strength for non-sterile finished drug products. Examples include, but are not limited to:

1. Progesterone 200mg G.R. CAPS, Lot 07252018@3

2. Acetylcystine Oral 20% Na, Lot 07182018@8

3. Aminocaproic Acid 250mg/mL solution, Lot 07112018@45

OBSERVATION 8

Drug products do not bear an expiration date determined by appropriate stability data to assure they meet applicable standards of identity, strength, quality and purity at the time of use.

Specifically, your firm has failed to perform stability testing for its non-sterile drug products. Examples include, but are not limited to:

1. The beyond use date (BUD) for Aminocaproic Acid 250mg/mL solution, Lot 07112018@45 is 180 days.

2. The BUD for Acetylcystine Oral 20% Na, Lot 07182018@8 is 60 days.

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3. The BUD for Progesterone 200mg G.R Caps. Lot 07252018@3 is 180 days.

OBSERVATION 9

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 01/05/17 your firm documented an actionable number of CFUs (colony forming units) in the ISO 5 LAFW (laminar airflow workbench). Upon retest on 01/10/17, an actionable number of CFUs were documented. A negative surface sample was not detected until 01/24/17. A total of (b) (4) lots were produce from 01/05/17-01/24/17 in the ISO 5 LAFW with no product evaluation performed.

*DATES OF INSPECTION

8/06/2018(Mon), 8/07/2018(Tue), 8/08/2018(Wed), 8/09/2018(Thu), 8/10/2018(Fri), 8/13/2018(Mon), 8/14/2018(Tue), 8/15/2018(Wed)

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