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	5/6/2019-5/16/2019* FEI NUMBER 3010241801

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Ronald D. Edwards, Owner

FIRM NAME	STREET ADDRESS
Pharmacy Plus, Inc. dba Vital Care Compounder	115 S 40th Ave
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Hattiesburg, MS 39402-6600	Producer of Sterile and Non-sterile Drugs

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

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

Specifically,

a) You only conduct environmental monitoring including personnel monitoring every (b) (4) .
b) You do not monitor the pressure in the classified rooms. Since the end of December 2018, you have not monitored and documented the pressure.

This is a repeat observation.

OBSERVATION 2

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

Specifically,

a) You do not have cleaning records prior to January 2019 and they do not include documentation of contact times for the cleaning agents you use. This includes documentation to show you conducted triple cleaning after you had growth in the ISO 7 rooms on March 28, 2017, September 13, 2017 and March 26, 2018.
b) You use a product called (b) (4) that is not labeled as sterile to clean the ISO 5 (b) (4) and laminar flow hood.
c) You use non-sterile wipes and mop covers to clean the classified area including inside the (b) (4) and laminar flow hood.

This is a repeat observation.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Claire M Minden, Investigator	X Claire M Minden Investigator Signed By: Claire M. Minden -S Date Signed: 05-16-2019 09:26:40	5/16/2019

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OBSERVATION 3

Clothing of personnel engaged in the manufacturing, processing, packing and holding of drug products is not appropriate for the duties they perform.

Specifically, the gown, mask, hairnet and booties used in the classified area is not sterile.

This is a repeat observation.

OBSERVATION 4

Buildings used in the manufacture, processing, packing, or holding of a drug product do not have the suitable size to facilitate cleaning, maintenance, and proper operations.

Specifically,

a) The anteroom (ISO 7) is crowded with several carts, cabinets and the (b) (4) that make operations difficult.
b) Rust is on floor in the anteroom.
c) You do not have written procedures for handling spills or cleaning for hazardous drugs or blood derived components.
d) Scales used to weigh powders in the hoods for non-sterile products have dirt and rust stains.
e) Spatulas used for non-sterile products are worn, stained and have nicks.

OBSERVATION 5

The written stability program for drug products does not include meaningful and specific test methods.

Specifically, you do not conduct sterility testing beyond the initial production date on finished products where you apply extended beyond use dates up to (b) (4) years. In addition, the data you use to support your extended beyond

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use dates is several years old and do not reflect any changes made in the process or to suppliers of components or bulk drug substances.

OBSERVATION 6

Each batch of drug product required to be free of objectionable microorganisms is not tested through appropriate laboratory testing.

Specifically, you only perform potency testing of your non-sterile products.

OBSERVATION 7

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

Specifically,

c) Your media fill does not mimic actual operations to include the quantities, different size vials/containers and multiple manipulations.

d) You have no records to qualify the (b) (4) you use for (b) (4) sterilization.

This is a repeat observation.

OBSERVATION 8

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

Specifically,

a) You do not test each lot/batch of sterile drug product for potency for each active ingredient prior to release for distribution.

b) You use (b) (4) that does not meet the definition of purified water in your non-sterile products.

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OBSERVATION 9

Records are not kept for the maintenance, sanitizing and inspection of equipment.

Specifically,

d) You have no records to document the proper (b) (4) for (b) (4) sterilization were used.
e) You do not conduct (b) (4) testing and I observed (b) (4) being thrown away prior to being tested.

This is a repeat observation.

OBSERVATION 10

There are no written procedures for production and process controls designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess.

Specifically,

a) The Formula Worksheets do not include instructions for mixing times or number of times the ointment mill should be used.
b) I observed no final check to verify the correct ingredients and amounts were added during this inspection.

*DATES OF INSPECTION

5/06/2019(Mon), 5/07/2019(Tue), 5/08/2019(Wed), 5/09/2019(Thu), 5/10/2019(Fri), 5/16/2019(Thu)

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