DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
6000 Metro Drive, Suite 101 Baltimore, MD 21215 (410)779-5455 Fax:(410)779-5707	4/11/2016-4/18/2016*
	FEI NUMBER 3008723337

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Christopher K. Currin , RPh., Co-Owner

FIRM NAME	STREET ADDRESS
RX South DBA RX3 Compounding Pharmacy LLC	12230 Iron Bridge Rd., Suite C
CITY, STATE, ZIP CODE, COUNTRY Chester, VA 23831-1534	TYPE ESTABLISHMENT INSPECTED Producer of 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

Aseptic processing areas are deficient regarding systems for maintaining any equipment used to control the aseptic conditions.

Specifically,

On 11Apr16, during aseptic processing of Phenylephrine HCL Injectable, lot 04112016@2, and IC Rescue Solution lot t04082016@13, brown stains were observed on the surface of the HEPA filter located in the ISO 5 classified Laminar flow hood (b) (4)
On 13Apr16, rusty conditions were observed on the metal support structure beneath (b) (4) ISO 5 Laminar flow (b) (4) in the IV room.

OBSERVATION 2

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

Specifically,

Cleaning records dated between 01Jan16 and 31Mar16 do not demonstrate use of sporicidal disinfectant in the ISO 5 Laminar flow hoods in the IV room, or in the ISO 7 areas. The only product used to disinfect the ISO 5 hoods, is sterile (b) (4) .

OBSERVATION 3

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Stacie A Woods, Generic Drug User Fee Amendments (GDUFA) Linda F Murphy, Investigator Haijing Hu, FDA Center Employee or Employee of Other Federal Agencies	4/18/2016 X Stacie A Woods Stacie A Woods Generic Drug User Fee Amendments (GDUFA) Signed by: Stacie A. Woods -S	4/18/2016

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Procedures designed to prevent microbiological contamination of drug products purporting to be sterile do not include adequate validation of the sterilization process.

Specifically,

A. Your firm did not validate the sterilization (b) (4) to demonstrate the process was adequate for (b) (4) of 100% glycerin injectable. (b) (4) validation records did not show sterilization was achieved with (b) (4); however, glycerine 100% injectable, lot numbers t03242016@31 and t03282016@33 were sterilized on 29Mar16 and 04Apr16, respectively and dispensed.

B. Your firm did not adequately validate the depyrogenation process to demonstrate the process was adequate for depyrogenating the in-process glassware. Your validation report did not include the (b) (4) in the validation process.

C. Your firm did not perform media fills to simulate the most challenging production conditions. (b) (4) (b) (4) media fill records dated between 17Jun15 and 05Jan16 showed that you performed media fills with (b) (4) however, prostaglandin 500 mcg/ml lot 02042016@40 (b) (4)), lot 12142015@41 (b) (4)), and lot 10262015@17 (120 ml), exceeded the (b) (4) media fill volume.

OBSERVATION 4

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

Specifically,

A. Environmental monitoring for viable and non-viable particulates is not performed each day sterile drug products are produced. For example,
   1) Your firm performs (b) (4) .

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2) Your firm's personnel monitoring (fingertips (b) (4) are monitored (b) (4) (b) (4)
3) Viable and nonviable air monitoring is (b) (4)

B. Records were not available to demonstrate Magnehelic gauges used to measure pressure differentials between the following areas were calibrated:
1) Between the (b) (4),
2) Between the (b) (4)
3) Between the (b) (4)
In addition, the pressure differential between the (b) (4) is not documented.

OBSERVATION 5

There is no written testing program designed to assess the stability characteristics of drug products.

For example,

A. Sterility, endotoxin, and potency were not tested throughout the six (6) months shelf life for Testosterone Cypionate (Sesame) 200mg/ml injectable, lot number t01062016@18 and Methylcobalamin 25mg/ml (PF) injection solution, lot number 02182016@23.

B. Sterility and endotoxin were not tested throughout the six (6) months shelf life for Prostaglandin (UD) 500mcg/ml injectable, lot number 02042016@40.

C. Sterility method suitability was not assessed for Testosterone Cypionate (Sesame) 200mg/ml injectable.

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OBSERVATION 6

Protective apparel is not worn as necessary to protect drug products from contamination.

Specifically,

During aseptic processing of Phenylephrine HCL Injectable, lot 04112016@2, and IC Rescue Solution lot t04082016@13 on 11Apr16, a technician was observed with exposed skin around the eyes and eyebrows.

***DATES OF INSPECTION**

4/11/2016(Mon),4/12/2016(Tue),4/13/2016(Wed),4/14/2016(Thu),4/15/2016(Fri),4/18/2016(Mon)

4/18/2016

X Linda F Murphy

Linda F Murphy
Investigator
Signed by: Linda F. Murphy -S

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