DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
4040 North Central Expressway, Suite 300 Dallas, TX 75204 (214)253-5200 Fax:(214)253-5314	7/23/2019-8/6/2019* FEI NUMBER 3010177428

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Gary D. Daley, President

FIRM NAME	STREET ADDRESS
Randol Mill Pharmacy	1014 N Fielder Rd
CITY, STATE, ZIP CODE, COUNTRY Arlington, TX 76012-3149	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 I OBSERVED:

OBSERVATION 1

Personnel engaged in aseptic processing were observed with exposed hair.

Specifically, during my observations of you firm's aseptic practices in compounding sterile drug product, Progesterone Cottonseed Oil 100 mg/ml injectable, 8mL vial, Lot 07232019@12, Expiry 8/22/2019, I observed your firm pharmacy technician's face with eyebrows exposed in the ISO 5 LAF hood.

OBSERVATION 2

Non-sterilized equipment was used in sterile drug production.

Specifically, while observing your firm's pharmacy technician lot preparation and aseptically process the drug product, Progesterone in Cottonseed Oil, 100 mg/mL Injectable, 8 mL vial, Lot 07232019@12, Expiry 8/22/2019, Qty. (b) (4) vials, the following aseptic processing equipment and materials were not sterilized and adequately disinfected prior to use in the ISO 5 LAF hood:

A. During set-up preparations for aseptically processing the drug product, Progesterone in Cottonseed Oil, 100 mg/mL Injectable, 8 mL vial, Lot 07232019@12, I observed your firm's pharmacy technician fail to disinfect 2 out of the (b) (4) syringes when transferred from the ISO7 to the ISO 5 LAF hood. Additionally, the technician failed to re-sanitize her hands after leaving and reentering the ISO 5 aseptic processing area a minimum of 6 times.

B. I observed your pharmacy technician use an unsterilized (b) (4) and metal cap crimper within your firm's the ISO 5 LAF hood. The (b) (4) is used to (b) (4)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Camerson E Moore, Investigator	X Camerson E Moore Investigator Signed By: Camerson E. Moore -S Date Signed: 08-06-2019 11:10:21	8/6/2019

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(b) (4)
(b) (4) Both are stored within the ISO 7 Cleanroom underneath a stainless-steel table on top of a plastic container. They wiped with (b) (4) sterile (b) (4) prior to use.

C. During a review of your firm's cleaning supplies, I found your firm uses (b) (4) (b) (4) Solution, as your firm's sporicidal agent for daily use within your firm's cleanroom. Your firm failed to ensure the adequacy of this reagent within your firm aseptic processing area.

OBSERVATION 3

Your facility design allowed the influx of poor quality air into a higher classified area.

Specifically, your firm's cleanroom is inadequately designed such that it allows the influx of poor-quality air into the ISO 7 classified area. For example,

A. Your firm uses a portable A/C Unit as feed air into the ISO 7 Cleanroom HEPA, which is also is the location of your ISO 5 LAF. Your firm has no maintenance records for the portable A/C. Your firm failed to assess the air quality supplied by the A/C unit.

B. Your firm has a wall mounted HEPA filter in both the ISO 8 Anteroom and ISO 7 Cleanroom also contains your firm's ISO 5 LAF hood. Your firm failed to assess these areas for adequate airflow in the prevention of possible dead zones which may contribute to the contamination of sterile drug products.

C. During my walkthrough of your firm's aseptic processing area, I observed airflow vents between your ISO 7 Cleanroom to ISO 8 Anteroom and ISO 8 Anteroom to Non-classified area was obstructed. Your firm failed to ensure the airflow vents were unobstructed.

OBSERVATION 4

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You produced hazardous drugs without providing adequate cleaning of work surfaces and cleaning of utensils to prevent cross-contamination.

Specifically, during a review your firm's 2018 - 2018 Sterile Compounding Log Book, I found your firm aseptically processed the sterile drug product, Testosterone Cyp, 250MG/ML, 10 mL Vial, Lot # 01232018@3, Expiry 07/22/2018. Your firm fail to use a deactivating agent on work surfaces after the production of hazardous drug product to prevent cross-contamination.

OBSERVATION 5

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established and written.

Specifically, your firm failed to adequately design procedures to prevent microbiological contamination of sterile drug products. For example:

A. Your firm failed to perform a (b) (4) test when using the (b) (4) (b) (4) to (b) (4) For example, your firm aseptically processed the drug product, Methlcobalin W/PSV 1000 MCG/ML Injectable, Lot # 07012019@1, BUD 12/28/2019, Qty. (b) (4) using (b) (4) Your firm's compounding specialist reported no (b) (4) test was performed on the (b) (4). The (b) (4) was submitted to the firm's contract testing laboratory for sterility testing.

B. Your firm's media fill challenge is inadequate. Your firm's media fill does not represent your firm's worse-case and most complex high-risk manipulation. Your firm uses "(b) (4) (b) (4) Kit", which requires your firm's technician to aseptically proces (b) (4) vials. Your firm's compounding specialist reported your firm will aseptically manipulate up to (b) (4) vials in one lot.

C. Your firm fail to perform and maintain records of smoke studies for your firm's ISO 5 LAF hood, under dynamic conditions, in order to ensure unidirectional airflow in the prevention of

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microbiological contamination during aseptic drug processing.

OBSERVATION 6

Time limits are not established when appropriate for the completion of each production phase to assure the quality of the drug product.

Specifically, your firm failed to establish hold time specifications for the drug product, Testosterone Cyp, 250MG/ML, 10 mL Vial, Lot # 01232018@3, Expiry 07/22/2018. Your firm's pharmacy technician reported, during production, the drug product was held in the non-sterile state over night in the ISO 5 LAF unit. Your firm's compounding specialist reported your firm failed to establish hold time specifications for this drug product.

OBSERVATION 7

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

Specifically, your firm failed to establish a written stability program for your firm's manufactured drug products to ensure product quality.

*DATES OF INSPECTION

7/23/2019(Tue), 7/24/2019(Wed), 7/25/2019(Thu), 7/26/2019(Fri), 8/06/2019(Tue)

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