

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

DISTRICT ADDRESS AND PHONE NUMBER 4040 North Central Expressway, Suite 300 Dallas, TX 75204 (214)253-5200 Fax: (214)253-5314	DATE(S) OF INSPECTION 2/25/2019-3/18/2019*
	FEI NUMBER 3012937475

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED  
Henry Shiu, PharmD, Pharmacist-In-Charge & Owner

FIRM NAME Front Door Pharmacy, LLC dba Pure Pharmacy	STREET ADDRESS 8973 Interchange Dr
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CITY, STATE, ZIP CODE, COUNTRY Houston, TX 77054-2513	TYPE ESTABLISHMENT INSPECTED Producer of Sterile & Non-sterile Drug Products
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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 skin.

Specifically, on 3/6/2019, your pharmacist was observed with exposed skin while compounding the sterile drug, P-105 Lot # 030719@1 BUD 9/7/19, Qty. (b)(4) vials @ 10ml (b)(4) vials sent to contract laboratory for testing and (b)(4) vials dispensed - Rx (b)(6) dated 3/13/2019 & Rx (b)(6) dated 3/14/2019). Your pharmacist sterile gloves failed to extend over the sleeves of the gown worn.

**OBSERVATION 2**

Media fills were not performed that closely simulate aseptic production operations incorporating, as appropriate, worst-case activities and conditions that prove a challenge to aseptic operations.

Specifically, your media fill program fails to simulate aseptic production operations for the worst-case activities and conditions within your firm's aseptic processing operations. For example, your firm's media fill aseptically simulates manipulating (b)(4) vials. However, the pharmacy maximum compound compound batch size is (b)(4) vials for the compounded sterile drug, P-105.

**OBSERVATION 3**

<b>SEE REVERSE OF THIS PAGE</b>	EMPLOYEE(S) SIGNATURE Cameron E Moore, Investigator	Cameron E Moore Investigator Signed By: Cameron E. Moore-S Date Signed 03-18-2019 13:45:13 X	DATE ISSUED 3/18/2019



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

Specifically, your firm pharmacist was observed using an unlabeled bottle non-sterile (b) (4) to disinfect the ISO 5 Hood aseptic processing surfaces. Unlabeled bottles of non-sterile (b) (4) were found in the pharmacy's ISO 8 Anteroom, ISO 7 Cleanroom (b) (4)

**OBSERVATION 6**

The use of sporicidal agents in the cleanrooms and ISO 5 classified aseptic processing area was inadequate.

Specifically, your firm failed to validate the use of (b) (4), surface disinfectant decontaminant cleaner, as a sporicidal agent used in your firm's clean room and aseptic processing area.

**OBSERVATION 7**

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

Specifically, your firm air returns are adjacent to your HEPA filters in the ceiling of the ISO 8 Anteroom and ISO 7 Cleanroom (b) (4) used in the production of sterile drugs. Your firm fail to provide records and/or documents (smoke study) in support of adequate air circulation in the prevention of an influx of poor quality air into a higher classified area.

**OBSERVATION 8**

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Laboratory test equipment used in the preparation and testing of collected samples are inadequate.

Specifically, your firm uses a (b) (4) Model (b) (4) for the incubation of (b) (4) collected media-fills. The unit fail to have adequate temperature and relate humidity controls to perform and control these environmental conditions.

**OBSERVATION 9**

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

Specifically, your firm produces the non-sterile hazardous drug, Testosterone Cream 100 mg/mL without adequate segregation, deactivation, and adequate cleaning program to prevent cross-contamination. All non-sterile compounded drugs are compounded in the same designated drug production area without adequate cleaning requirements.

**OBSERVATION 10**

ISO-5 classified areas were not certified under dynamic conditions. Specifically, unidirectional airflow was not verified under operational conditions.

Specifically, your firm's clean room re-certification tests dated (b) (4) (b) (4) were documented as being performed in dynamic conditions. On 2/27/2019, the pharmacy contract clean room certifier was asked if he recertifies the clean room while pharmacy is performing media fills and/or compounding actual sterile drug products. He reported no, he simulates motion in the clean room compounding area and documents as being in a dynamic state. Pharmacist

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reported no medial fills and/or drug compounding occurred during any of the clean room re-certifications.

**OBSERVATION 11**

The ISO-classified areas have difficult to clean, particle-generating, or visibly dirty equipment or surfaces.

Specifically, during a walk-through on 2/25/2019, foreign particulate matter was observed in ISO 7 production area on top of (b) (4) which was not in service, adjacent to the ISO 5 Hood.

**\*DATES OF INSPECTION**

2/25/2019(Mon), 2/26/2019(Tue), 2/27/2019(Wed), 2/28/2019(Thu), 3/01/2019(Fri), 3/06/2019(Wed), 3/18/2019(Mon)

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