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	6/3/2025-6/13/2025* FEI NUMBER 3014480778

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
David Rabbani, CEO/President

FIRM NAME	STREET ADDRESS
Pharmcore Inc. dba Hallandale Pharmacy	2666 Sw 36th St
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Fort Lauderdale, FL 33312-5005	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

Materials were exposed to lower than ISO 5 quality air.

Specifically,

During observation of sterile compounding activities on 6/3/2025 and 6/4/2025, it was observed that sterile (b) (4) wipes, which were opened and stored in the ISO-7 cleanroom environment, were introduced and used within the ISO-5 hood during sterile compounding processes. This practice potentially compromises the sterility of the ISO-5 environment and the products being compounded.

For example:

1. On 6/3/2025: a) During production of Testosterone Cypionate/Anastrozole (Grape Seed Oil) 10mL Vial 200Mg/0.5mg/mL (lot 421645):

   - At approximately 11:33 AM, a sterile compounding technician used an (b) (4) wipe from the ISO-7 area to clean spilled drug product within the ISO-5 space.
   - Empty opened vials were present in the ISO-5 area when the wipe was introduced.

   b) During production of Testosterone Cypionate/Propionate (Grape Seed Oil) 5mL Vial 180mg/20mg/mL (lot 421621):

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Logan T Williams, Investigator X Logan T Williams Investigator Signed By: 2002955055 Date Signed: 06-13-2025 13:16:16	6/13/2025

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David Rabbani, CEO/President	
FIRM NAME Pharmcore Inc. dba Hallandale Pharmacy	STREET ADDRESS 2666 Sw 36th St
CITY, STATE, ZIP CODE, COUNTRY Fort Lauderdale, FL 33312-5005	TYPE ESTABLISHMENT INSPECTED Producer of Sterile and Non-Sterile Drug Products

☐At approximately 11:32 AM, a sterile compounding technician used an (b) (4) wipe from the ISO-7 area within the ISO-5 space.

☐Empty opened vials were present in the ISO-5 area when the wipe was introduced.

2.On 6/4/2025, during production of NAD+ 100mg/mL 10mL Vial (lot 422171):

☐A sterile compounding technician used (b) (4) wipes from the ISO-7 area to clean the working area after finishing filling a vial tray within the ISO-5 hood.

☐A new package of vials was introduced and opened to continue filling in the ISO-5 area where the (b) (4) wipe was utilized.

OBSERVATION 2

Smoke studies were inadequately performed under dynamic conditions.

Specifically,

Your firm's smoke studies do not include a full set up and simulation of processing within the ISO-5 space. Your firm utilizes equipment within the ISO-5 space such as filling needle stands and pumps/tubing that are not present in your firm's smoke studies. Your firm's current smoke studies were performed to show the transfer of vial bins between ISO-5 hoods and into the (b) (4) According to your firm's Quality Director, this is the worst case challenge that compounding technicians could face. Routine production has not been simulated to determine if smoke airflow is impacted for current processes and equipment in the ISO-5 area. In addition, turbulent air was observed during review of the most recent smoke study performed on 2/1/2025.

***DATES OF INSPECTION**

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6/03/2025(Tue), 6/04/2025(Wed), 6/05/2025(Thu), 6/06/2025(Fri), 6/09/2025(Mon), 6/10/2025(Tue), 6/11/2025(Wed), 6/12/2025(Thu), 6/13/2025(Fri)

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE

Logan T Williams, Investigator

X Logan T Williams
Investigator
Signed By: 2002955055
Date Signed: 06-13-2025
13:16:16

DATE ISSUED

6/13/2025

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."