DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderley Place, Suite 200 Maitland, FL 32751 (407)475-4700 Fax:(407)475-4768 Email: ORAPharm2_responses@fda.hhs.gov Industry Information: www.fda.gov/oc/industry	7/2/2018-7/13/2018* FEI NUMBER 3014480778

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Mr. David G. Rabbani, Owner and President

FIRM NAME	STREET ADDRESS
Pharmcore Inc. dba Hallandale Pharmacy	1109 E Hallandale Beach Blvd
CITY, STATE AND ZIP CODE	**TYPE OF ESTABLISHMENT INSPECTED**
Hallandale Beach, FL 33009-4431	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) (WE) OBSERVED:

OBSERVATION 1

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

Specifically,

1. Visible signs of debris and residue build-up were observed in the following ISO 5 areas located in the Sterile Suite:

a. Underneath the "grate" (return air slots) located on the edge of the (b) (4) (b) (4) Class II BSC (ISO 5 Hood), located in the hazardous area;

b. Underneath the "grate" (return air slots) located on the edge of the (b) (4) Class II BSC (ISO 5 Hood), located in the non-hazardous area;

c. On the back side of the work surface area of the (b) (4) Class II BSC (ISO 5 Hood), in the non-hazardous area.

2. Visible discoloration that appears to be rust was observed in the following classified areas of the Sterile Suite:

a. On the front, bottom portion of the (b) (4) Class II BSC (ISO 5 Hood) located in the non-hazardous area;

b. On the bottom support beam of the stainless-steel prepping table, located in the ISO 7 area approximately (b) (4) (b) (4) from the (b) (4) (b) (4) Class II BSC (ISO 5 Hood), in the hazardous area;

c. Along the outside of the (b) (4) Class II BSC (ISO 5 Hood) located in the non-hazardous area.

d. On the underside of the stainless-steel prepping table, located in the ISO 7 area approximately (b) (4) from the (b) (4) Class II BSC (ISO 5 Hood), in the non-hazardous area;

e. On the floor of the ISO 7 area, located in the non-hazardous area of the Sterile Suite.

3. Visible signs of debris and residue build-up were observed in the following ISO 7 areas located in the Sterile Suite:

a. On the HEPA filters located on the ceilings in the non-hazardous area (ISO 7);

b. On the top of the sliding door that separated the non-hazardous area (ISO 7) from the Anteroom (ISO 7);

c. On the top of the sliding door that separated the non-hazardous area (ISO 7) from the hazardous area (ISO 7).

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4. Dedicated mop heads used for (b) (4) cleaning of the floors and (b) (4) cleaning of the walls appear to be particle generating/shedding and have visible signs of fraying.

OBSERVATION 2
Your firm continued producing sterile drug products within your facility without establishing adequate controls to prevent contamination of the production environment.

Specifically,
1. Your firm cut 3 (three) holes in the ISO 7 vinyl walls of your Sterile Suite, which is surrounded by non-classified areas, potentially compromising the sterility assurance of your Sterile Suite.

2. Your firm's management stated the air pressures, Biological Safety Cabinets (BSC) (ISO 5), lights, and A/C are turned off in the Sterile Suite during (b) (4) cleanings and should be manually turned back on after cleaning. On 07/02/2018, we observed the air pressure and the BSC Hoods (ISO 5) remained shut off after cleaning was completed for approximately (b) (4) During this (b) (4) time period, the vinyl walls of your firm's modular sterile suite enclosure system appeared to become concave. However, the documentation provided by your firm did not demonstrate that the controls in place prevented the influx of contamination from the surrounding non-classified areas into the Sterile Suite production environment during this (b) (4) time period. Aseptic drug production occurred in the Sterile Suite following this cleaning. According to your firm's distribution log, (b) (4) prescriptions for sterile drug products were produced in this Sterile Suite from 02/01/2018 – 07/02/2018, resulting in the shipment of (b) (4) units of drug product.

3. We observed 3 unsealed holes in the (b) (4) Class II BSC (ISO 5 Hood), located in the non-hazardous area of the Sterile Suite.

4. We observed 3 large "patched" areas in your sterile suite:
a. We observed a patched area, approximately 36.5" width x 44" length, where an (b) (4) was removed, located in the non-hazardous Sterile Suite Area (ISO 7).
b. We observed a patched area, approximately 33.5" width x 41" length, where an (b) (4) was removed, located in the non-hazardous Sterile Suite Area (ISO 7).

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c. We observed a patched area, approximately 32" width x 36" length, where a (b) (4) was removed, located in the hazardous Sterile Suite Area (ISO 7).

5. We observed what appears to be a cylinder foam tube, located within the ISO 7 non-hazardous Sterile Suite. According to your firm's owner, this cylinder foam tube was placed to fill a gap between the (b) (4) (b) (4) and the vinyl wall in order to help stabilize the air pressure.

6. We observed what appear to be dead insects in your firm's fluorescent light fixture, located in the Non-Sterile Suite (ISO 8), where drug components are mixed prior to undergoing aseptic processing in the Sterile Suite (ISO 7). For example, on 07/02/2018, your firm's owner stated MIC Formula #2, Lot #MICF2C41, was weighed and mixed in the Non-Sterile Suite (ISO 8) prior to entering the Sterile Suite (ISO 5 and ISO 7) areas on 07/03/2018.

7. The (b) (4) is used (b) (4) prior to aseptic processing in your firm's sterile suite. According to the manufacturer's recommendations, the nozzle should be cleaned on a (b) (4) basis. However, according to your firm's Quality Assurance Assistant, your firm has not cleaned the (b) (4) in at least over a year. In addition, your firm does not have any written procedures or documented logs related to the cleaning of this equipment.

OBSERVATION 3
The system for monitoring and maintaining environmental conditions in the aseptic processing areas was deficient.

Specifically,
1. On 06/11/2018, your firm used an outside contractor to conduct viable air samples. On 06/26/2018, the contractor notified your firm received an out-of-compliance air sample resulting in a non-sporulating colony for fungal growth in your firm's Hazardous Room (ISO 7), located in your Sterile Suite. Your firm continued aseptic operations after receiving this notification for the following lots, including but are not limited to:
a. Human Chorionic Gonadotropin Lyophilized 6000IU Vial: Lot Numbers: HCG60128; HCG60129; HCG60130; HCG60131; HCG60132; HCG60133
b. Human Chorionic Gonadotropin Lyophilized 5000IU Vial: Lot Numbers: HCG50333; HCG50334; HCG50335; HCG50336; HCG50337
c. Testosterone Cypionate (Sesame Oil) 5ML Vial Injectable 200MG/ML: Lot Numbers: TCY2S-121;

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TCY2S-122; TCY2S-123; TCY2S-124; TCY2S-125; TCY2S-126; TCY2S-127
d. Testosterone Cypionate (Grapeseed Oil) 5ML Vial Injectable 200 MG/ML: Lot Numbers: TC20G165; TC20G166; TC20G167; TC20G168; TC20G169; TC20G170; TC20G171; TC20G172; TC20G173
e. Sermorelin Lyophilized 9MG Vial: Lot Number: SER9-78

2. On 07/05/2018, during the in-house sampling for surface and personnel batch environmental monitoring we observed the following:
a. The aseptic technician did not roll the contact plate against the workbench surface to ensure full plate contact.
b. The aseptic technician lightly touched their fingertips on the (b) (4) plates instead of rolling of fingertips on the media to ensure full plate contact.
c. The plates used for sampling were not prelabeled prior to sampling. After sampling had been conducted, the aseptic technician could not recall the location of where the sampled plates taken. We observed them erase the sample location and re-write on the same plate.
Formula #3 30ml Vial Injectable 25mg/50mg/50mg/0.51mg/0.009ml, lot #MCY0593 was produced on this date.

OBSERVATION 4
Equipment, materials, and/or supplies are not disinfected prior to entering the aseptic processing areas.

Specifically,
1. Personnel were observed touching equipment or other surfaces located outside of the ISO 5 area with gloved hands and then proceeding with aseptic processing without changing or sanitizing gloves. On 07/03/2018, we observed your pharmacy's aseptic technician gathering drug components and supplies, located outside the ISO 5 area, without changing or sanitizing their gloved hands 11 times during the aseptic drug processing of Methionine, Inositol, and Choline Chloride (MIC Formula #2), Lot #MICF2C41.

2. Equipment, materials, and/or supplies are not disinfected prior to entering the aseptic processing areas. According to your firm's Quality Assurance Assistant, materials are not disinfected during transfer from a dirty area to a cleaner area, which are utilized for sterile drug production. For example, materials transported from a non-classified area to the Anteroom (ISO 7) and from the Anteroom (ISO 7) into the non-hazardous room (ISO 7), are not disinfected.

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OBSERVATION 5
ISO-5 classified areas were not certified under dynamic conditions.

Specifically,
1. Your firm has not performed smoke studies under dynamic conditions in the ISO 5 areas (biological safety cabinets and (b) (4) area) located in your Sterile Suite Room since June 2016.

*DATES OF INSPECTION
07/02/2018 (Mon), 07/03/2018 (Tue), 07/05/2018 (Thu), 07/06/2018 (Fri), 07/09/2018 (Mon), 07/10/2018 (Tue), 07/11/2018 (Wed), 07/13/2018 (Fri)

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