

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER

6000 Metro Drive, Suite 101
Baltimore, MD 21215
(410) 779-5455 Fax: (410) 779-5707

DATE(S) OF INSPECTION

3/2/2016-3/23/2016*

FEI NUMBER

3004514280

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Mr. Simeon Georgiou, Owner/Pharmacist

FIRM NAME

Professional Arts Pharmacy

STREET ADDRESS

2015 Lord Baltimore Dr

CITY, STATE, ZIP CODE, COUNTRY

Baltimore, MD 21244-2558

TYPE ESTABLISHMENT INSPECTED

Compounding Pharmacy

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 air supply that is filtered through high-efficiency particulate air filters under positive pressure.

Specifically,

(b) (4) HEPA filters are located in the "Clean Room" (ISO 6) in the ceiling above the laminar flow hoods. There are no HEPA filters in the "Gowning Room" (ISO 6). In addition, the air feeding the (b) (4) [REDACTED] The firm does not do environmental monitoring (b) (4) [REDACTED]

OBSERVATION 2

Clothing of personnel engaged in the processing of drug products is not appropriate for the duties they perform.

Specifically,

A) On 03/03/2016 we observed a technician (b) (7)(C), (b) (6) [REDACTED] gowning up prior to entering and cleaning the floors in the "Clean Room" which includes (b) (4) [REDACTED] laminar flow hoods (ISO 5) used to produce sterile drug preparations, the adjacent "Gowning Room", and the adjacent "Entry Room" (non-classified). The "Entry Room" contains materials used for sterile preparations. We observed the following deficiencies with the firm's gowning practices:

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[Signature]

Dyanita Harouaka, LSO
Anne Abarten, CO

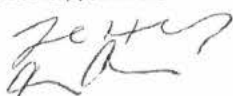
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1. The technician (b) (6), (b) (7)(C) wore only non-sterile gloves and non-sterile shoe covers, and non-sterile face mask prior to entering and cleaning the floors in the "Clean Room" and "Gowning Room". The same shoe covers and gloves worn in the "Entry Room" were also worn in the "Gowning Room" and "Clean Room".
 2. The technician's arms, face, neck, and hair were exposed within the "Clean" and "Gowning" rooms. We observed direct contact of the technician's arms/skin with the plastic curtains used to provide physical separation between the "Clean Room" and "Gowning Room", and between the "Gowning Room" and the "Entry Room".
 3. The technician (b) (6), (b) (7)(C) put on a non-sterile hair net and a non-sterile gown using the same pair of non-sterile gloves that were worn to clean the floors in the "Clean", "Gowning", and "Entry" rooms. The same pair of non-sterile gloves was used after cleaning and before donning the hairnet and gown.
- B) I (DH) observed the processing of sterile, injectable Glycine (60 mg/ml) on 03/08/2016 pursuant to Rx# (b) (6), (b) (7)(C)
1. The pharmacy technician (b) (6), (b) (7)(C) was wearing non-sterile gown, hairnet, face mask, and shoe covers in the "Clean Room". The technician's face/skin above the mask was exposed.
 2. Technician (b) (6), (b) (7)(C) (b) (4) to the "Gowning Room" and removed the sterile gloves followed by the gown, hairnet, and face mask. The gloves and face mask were discarded, but the gown and hairnet were kept in the "Gowning Room" for reuse. The technician was wearing street clothes with arms exposed.
 3. Technician (b) (6), (b) (7)(C) (b) (4) from the "Gowning Room" to the "Entry Room" by passing front facing through the plastic curtains which came into contact with the technician's exposed arms and street clothes.
 4. The Technician (b) (6), (b) (7)(C) re-entered the "Gowning Room" front facing and donned a new non-sterile face mask followed by the previously worn hairnet and gown prior to re-entering the "Clean Room" front facing through the plastic curtain.

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	Djamila Harouaka, CSO Anne Aberdeen, CO	

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OBSERVATION 3

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

Specifically,

- A) The firm does not monitor the differential pressures between the classified and unclassified areas ("Clean Room", "Gowning Room" and "Entry Room").
- B) Smoke studies are not performed under dynamic conditions.
- C) The firm does not perform environmental monitoring of the plastic curtains used to separate the classified and unclassified rooms ("Clean Room", "Gowning Room" and "Entry Room").
- D) The firm uses non-sterile (b) (4) and non-depyrogenated (b) (4) to produce sterile drug products.
- E) The firm does not have a standardized procedure for (b) (4) the (b) (4). On 02/25/2016 (b) (4) failure occurred for Prednisolone 50mg/ml injectable (Batch No. A5699). Pharmacist (b) (6), (b) (7)(C) told us the sterilization failed because the (b) (4) and that they repeated the sterilization (b) (4). Furthermore, there is no written record of any investigation.
- F) There is no qualification, no calibration or preventive maintenance of the (b) (4) (b) (4).

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OBSERVATION 4

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

Specifically,

- A) On 03/03/16 I (DH) observed the technician (b) (6), (b) (7)(C) cleaning the laminar flow hood. I observed the following deficiencies:
1. The technician (b) (6), (b) (7)(C) alternated between cleaning of the interior and exterior surfaces of the hood using the same non-sterile wipe (b) (4)
 2. As the cleaning progressed, no additional (b) (4) was added to the wipe. By the completion of the cleaning the surfaces did not appear to be wetted. The working surface of the laminar flow hood is the last surface to be cleaned.
 3. Each hood contained a (b) (4). The top of the (b) (4) was also wiped using the same (b) (4) wipe. The (b) (4) were not moved to wipe the counter underneath.
 4. The top of the horizontal shield of the hood was not cleaned. It was used to place a (b) (4) (b) (4) (b) (4).
 5. The firm has not established contact times for the cleaning and disinfecting of surfaces.
 6. The firm uses non-sterile (b) (4) wipes to clean the laminar flow hoods.
 7. The work area of the laminar flow hoods (b) (4) are constructed of formica.
- B) I (DH) observed a white residue and a yellow residue on the stainless steel back of the laminar flow hood (P1). I (DH) observed what appeared to be rust along the left hand side of laminar flow hood (P1).

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OBSERVATION 5

Test procedures relative to appropriate laboratory testing for sterility are not written and followed.

Specifically,

- A) The owner (SG) stated they started doing sterility testing on December 2015 and that those samples are (b) (4). As per the firm's sterility testing log, they have sent out (b) (4) samples from (b) (4) sterile product prescriptions dispensed from (b) (4). Products sent out for sterility testing are: (b) (4).

- B) The firm produces sterile drugs and (b) (4). At the time of dispensing a label is added indicating: "only good for ___ days in refrigerator and 45 days in the freezer". For example we observed the following products in the freezer:

(b) (4)

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OBSERVATION 6

Component testing is deficient in that each component is not tested for conformity with all appropriate written specifications for purity, strength, and quality.

Specifically,

The firm used (b) (4) (non-pharmaceutical grade) for the preparation of prescribed sterile eyes drops. In addition, the main ingredient concentration in (b) (4) Batch records indicated that the concentration was not adjusted to conform to specifications.

***DATES OF INSPECTION**

3/02/2016(Wed), 3/03/2016(Thu), 3/07/2016(Mon), 3/08/2016(Tue), 3/18/2016(Fri), 3/23/2016(Wed)

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