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 Industry Information: www.fda.gov/oc/industry	03/03/2015 - 03/13/2015* FEI NUMBER 3001576820

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Deril J. Lees, President/CEO

FIRM NAME	STREET ADDRESS
The Apothecary Shoppe, LLC	6136 E 51st St.
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Tulsa, OK, OK 74135-7704	Producer of 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 WE OBSERVED:

OBSERVATION 1

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

Specifically, the general gowning attire for personnel working in the ISO 5/ISO 7 classified areas consists of the following: scrubs donned in the facility, two disposable lab coats (one worn from the sterile prep area (ISO 8 ante room) and the second worn over the first lab coat when entering the ISO 7 Cleanroom); a single hair net; a surgical face mask with ties; and dedicated shoes worn in ISO 8 and ISO 7 areas. All are non-sterile. The operators also use a single pair of non-sterile gloves donned in the sterile prep area and then don a single pair of sterile gloves under the ISO 5 hood. The general gowning requirements leave exposed skin around the eyes, forehead and neck of the person preparing the drug product. On 3/9/15, we watched the preparation of lot #03092015@22 of Hydromorphone 20mg/mL PF IT 20mg/mL Injectable, lot #03092015@8 of Morphine Sulfate 30mg/mL (PF) Injectable and lot #03092015@33 of Tri-Mix 18/1mg/40mcg/mL Injectable in Hood (b) (4)

OBSERVATION 2

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically,

a) Your firm does not perform environmental monitoring of the ISO 5 area every day that your firm is preparing sterile drug products. SOP 3.020 Environmental Monitoring of the Clean Room Facility, version 1.0 effective 10/10/14, states "microbial surface sampling in the class 100-100,000 work area will be performed (b) (4) . (b) (4) testing will be done with (b) (4) ". In addition, your firm does not document the media type and lot number used to perform the environmental monitoring.

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b) Viable air monitoring of the ISO 7 cleanroom and the ISO 8 ante room (sterile prep room) is only performed every (b) (4) during certification of the rooms. Your firm does not perform viable air monitoring in the ISO 5 laminar flow hoods.

c) Your firm is not monitoring each operator working in the ISO 5 area and ISO 7 clean room (b) (4) . Your firm is currently sampling the fingertips of operators once every (b) (4) .

OBSERVATION 3

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile do not include validation of the sterilization process.

Specifically,

a) Your firm has not validated the sterilization process for any of the drug products you prepare. Your firm prepares various drug products from bulk non-sterile active pharmaceutical ingredients (API) and excipients that are then either (b) (4) . The drug products that (b) (4) include Triamcinolone Acetonide 40mg/mL Injectable, Testosterone Cypionate 200mg/mL Injectable and Estradiol/Testosterone 12.5/125mg pellet. Your firm has no documentation of the qualification of the (b) (4) for the drug products were developed. SOP 8.020 (b) (4) , version 1.0 effective 10/10/14, requires that (b) (4) . Your firm is not (b) (4) as required by your procedure.

b) Media fills performed by your firm with each of the operators that work in the ISO 5 area do not closely simulate actual production conditions or cover worst case or most challenging conditions. In routine production, your firm fills various size vials (2mL-30mL vials) as well as syringes, and batch sizes can be in excess of (b) (4) units. The media fill your firm performs has the operator filling (b) (4) .

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OBSERVATION 4

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

Specifically,

a) Your firm uses non-sterile wipes to disinfect the (b) (4) ISO 5 laminar flow hoods where drug products are prepared.

b) Your firm uses (b) (4) brand (b) (4) to clean the floors and walls of the ISO 7 cleanroom where the ISO 5 laminar flow hoods are located. Your firm has no documentation or data to demonstrate that these mop heads are made for use in a cleanroom and are sterile and non-shedding.

c) Your firm uses an (b) (4) solution for cleaning/disinfecting the floors and walls in the ISO 7 cleanroom. Your firm does not have documentation to demonstrate that the product is effective in cleaning/disinfecting the room and no documentation to show the product is stable for the (b) (4) it is used after preparation.

d) Your firm does not use a sporicidal disinfectant in the ISO 5 laminar flow hoods and ISO 7 cleanroom where drug products are prepared.

OBSERVATION 5

Aseptic processing areas are deficient regarding air supply that is filtered through high-efficiency particulate air filters under positive pressure.

Specifically,

a) The documentation from your 3rd party vendor for the certification of the (b) (4) ISO 5 laminar flow hoods, the ISO 7 cleanroom and the ISO 8 ante room (sterile prep room) is deficient in that the last report, dated 9/11/14, does not include the following:

i) Testing of the HEPA filter in the ISO 7 cleanroom.

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ii) Measurement of pressure in the cleanroom or ante room.
iii) Measurement of the pressure differential between the cleanroom and the ante room and between the ante room and the general pharmacy area (unclassified area).
iv) Measurement of the particle size to verify that the rooms and laminar flow hoods meet the requirements of an ISO 5, 7 or 8 area as stated in the report.

b) There is no documentation of the actual pressure differential measurement between the ISO 7 cleanroom and the ISO 8 ante room (sterile prep room) and between the ISO 8 ante room (sterile prep room) and the unclassified general pharmacy during operations. The documentation of the daily check of the pressure differential only documents "pass" or "fail" for the reading.

c) On 3/9/15, I observed the pressure gauge measuring the pressure differential between the ISO 8 ante room (sterile prep room) and the unclassified general pharmacy was at zero (0). When the door from the ante room to the general pharmacy was opened on 3/9/15, I observed the needle on the pressure gauge fall below zero (0). Several products were made in the rooms on 3/9/15, including lot #03092015@22 of Hydromorphone 20mg/mL PF IT 20mg/mL Injectable, lot #03092015@8 of Morphine Sulfate 30mg/mL (PF) Injectable and lot #03092015@33 of Tri-Mix 18/1mg/40mcg/mL Injectable.

OBSERVATION 6

Written procedures are not established for the cleaning and maintenance of equipment, including utensils, used in the manufacture, processing, packing or holding of a drug product.

Specifically, your firm cleans glass beakers and other utensils such as spatulas and scoops used to process drug products prior to sterilization, by (b) (4) with (b) (4) brand household dish detergent and then in a (b) (4) using (b) (4) brand (b) (4). The water supplied to the (b) (4) is (b) (4) and (b) (4). The equipment is then (b) (4). Your firm has not validated this cleaning process to demonstrate that it is adequate and that no residue or cross contamination of drug substances or cleaning products occurs.

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OBSERVATION 7

Each batch of drug product purporting to be sterile and pyrogen-free is not laboratory tested to determine conformance to such requirements.

Specifically, your firm does not conduct routine sterility or endotoxin testing for all injectable drug products produced. Your current procedure is to test lots (b) (4) [redacted].

OBSERVATION 8

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

Specifically, your firm does not have a written stability testing program to determine Beyond Use Dates (BUD) placed on all your drug products. For example,

a) Your firm has no documentation to justify the following BUDs placed on these injectable drug products prepared by your firm.

i. BUD of 180 days on Methylcobalamin 5000mcg/mL Injectable. This product is preservative free and not labeled as a single dose vial.
ii. BUD of 60 days on the Chorionic Gonadotropin (HCG) 1000U/mL Injectable
iii. BUD of 180 days on Triamcinolone Acetonide 40mg/mL Injectable

b) Your firm provided documentation of four (4) months of potency testing over time of Tri-Mix 30/2mg/20mcg/mL Injectable. However, there is no documentation of sterility or endotoxin testing performed for this product as part of this study. Your firm places a 180-day BUD on this product.

OBSERVATION 9

Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the final specifications and identity and strength of each active ingredient prior to release.

Specifically, your firm does not conduct routine testing for potency for all drug products produced by your firm.

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OBSERVATION 10

Routine calibration of electronic equipment is not performed according to a written program designed to assure proper performance.

Specifically,

a) Your firm does not calibrate temperature measuring devices used to monitor the following:

i) (b) (4) used to depyrogenate glass beakers used in the preparation of drug products
ii) The (b) (4) used to (b) (4) drug products
iii) "Freezer (b) (4) used to store finished sterile drug products
iv) "Supply (b) (4) Refrigerator" used to store refrigerated active pharmaceutical ingredients (API) and finished sterile drug products
v) "Supply (b) (4) Refrigerator" used to store media used for environmental monitoring
vi) Incubators (b) (4) used to incubate environmental monitoring samples, personnel monitoring samples and media fill vials

b)Your firm does not calibrate the pressure gauges used to monitor the measurement of the pressure differential between the ISO 7 cleanroom and the ISO 8 ante room and between the ISO 8 ante room and the unclassified general pharmacy.

c) Your firm does not use certified standard weights to calibrate the (b) (4) Balance in the sterile prep room (ante room). This balance is used to weigh API's and excipients used in the preparation of sterile drug products.

*** DATES OF INSPECTION:**
03/03/2015(Tue), 03/04/2015(Wed), 03/05/2015(Thu), 03/09/2015(Mon), 03/10/2015(Tue), 03/11/2015(Wed), 03/13/2015(Fri)

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