**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<br>Dallas, TX 75204<br>(214) 253-5200 Fax:(214) 253-5314<br>Industry Information: www.fda.gov/oc/industry | 07/29/2015 - 08/05/2015<br>FEI NUMBER<br>3011677351 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

**TO:** Abdul Hameed, Owner

| FIRM NAME | STREET ADDRESS |
|---|---|
| American Specialty Pharmacy | 10 Medical Pkwy Ste 105 |
| CITY, STATE, ZIP CODE, COUNTRY | TYPE ESTABLISHMENT INSPECTED |
| Dallas, TX 75234-7838 | Producer of 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 WE OBSERVED:**

## OBSERVATION 1

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

Specifically,

A. Media fill study was only performed for (b) (4) employee ((b) (6)) since the firm was established in January 2015 ((b) (6) is (b) (6), (b) (4) ). Furthermore, there is no media fill qualification done on any other employee in the firm. The following employees currently perform preparations: (b) (6), (b) (4) technician ((b) (6)), (b) (6), (b) (4) technician ((b) (6)), and one full time Pharmacist in Charge (PIC). Review of the prescriptions prepared from the last three months shows that all technicians (including the PIC and the (b) (6) pharmacy) have been preparing products.

B. SOP 9.110, date 04-13-09, titled "Sterile Compounding Process Validation (Media Fills)" states in section 6.0 that (b) (4) .

C. Media fill documentation provided by the firm for (b) (6) is incomplete. It does not capture the information required as per SOP 9.110, date 04-13-09, titled "Sterile Compounding Process Validation (Media Fills)" section 9.4 in the form "Environmental Monitoring (Media Fills):

(b) (4)

In addition, negative and positive controls results are not recorded.

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## OBSERVATION 2

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

Specifically,

A. The firm performed monitoring (viable, non-viable and surface) of ISO 5 only (b) (4) ((b) (4) and Laminar Flow) but no additional monitoring has been performed since the facility was established in January 2015. The third party testing report for initial qualification of the clean rooms ISO 5 and ISO 7 shows two out of compliance results (OOC) for location (b) (4) IV Room (4 CFU/$m^3$ ) and location (b) (4) Chemo Room (2 CFU/$m^3$). As per PIC results were obtained (b) (4). Retest results (b) (4) reported as no growth. However, there is no investigation report for the OOC.

B. SOP 3.030, date 04-13-09, titled "Environmental Monitoring of the Clean Room Facility" requires the following performance frequency monitoring in which the firm did not conduct:

| Sample Type | (b) (4) (b) (4) | Frequency required as per SOP | Reference SOP Step | Performed |
|---|---|---|---|---|
| (b) (4) | (b) (4) (b) (4) | (b) (4) | 6.4 | No |
| (b) (4) | (b) (4) (b) (4) | | 6.4 | No |
| (b) (4) | (b) (4) | | 6.1 | No |
| (b) (4) (b) (4) | (b) (4) (b) (4) | | 6.2 | No |

## OBSERVATION 3

Protective apparel is not worn as necessary to protect drug products from contamination.

Specifically,

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A. On 07/29/15, we observed the following deficiencies with the preparation of prescription # (b) (6) for Etoposide 80mg/250mL NS ((b) (4) ) in the Chemo Room (b) (4) ISO 5 hood.
   i. SOP 1.060, date 04-11-06, titled "General Aseptic Techniques" section 9.1.1 states "(b) (4) (b) (4) ". We observed that components brought into the ISO 5 were directly collected from a non-controlled area (outside anteroom ISO 7) directly into the ISO 5 without disinfecting or wiping with sterile (b) (4) or sterile disinfectant solution.
   ii. The technician ((b) (6)) used non-sterile absorbent pads ((b) (4) ) to lay down on the ISO 5 (b) (4) surface. These pads are stored loose without packaging in the ISO 7 area.
   iii. Sterile (b) (4) wipes used to clean (b) (4) were opened in the ISO 7 room and not in the ISO 5 (b) (4).
   iv. SOP 1.060, date 04-11-06, titled "General Aseptic Techniques" requires the following when working in an aseptic area, as stated in section 9.3.5 (b) (4) We observed the technician ((b) (6)) moved (b) (6) hands in and out of the ISO 5 (b) (4) multiple times without re-spraying gloves with sterile (b) (4) (b) (4) during sterile product preparation.

B. On 07/29/15, we observed the technician wore non-sterile protective apparel (facemask, shoe covers, hair covers, and disposable lab coat) except for gloves (double gloves used) while preparing Etoposide 80mg/250mL NS in the ISO 5 (b) (4) hood. Additionally, there was no sterile protective eye goggles wore during processing and cleaning. We observed facial skin and cheeks exposed. SOP 1.060, date 04-11-06, titled "General Aseptic Techniques" requires the following when working in an aseptic area, as stated in section 9.3.1 "Wearing appropriate clean room apparel for the level of sterile compounding to be performed".

## OBSERVATION 4

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

Specifically,

A. The firm does not specify contact time for cleaning agents used ((b) (4) ).

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B. We observed that the technician ((b) (6)) used expired cleaning agents (b) (4) and (b) (4) during the production of Etoposide 80mg/250mL NS. In addition, there is no written requirement to record date of opening for each container.

C. The firm does not have any written procedure to specify cleaning after each product preparation. SOP 3.020, date 04/13/09, titled "Cleaning and Maintenance of the Clean Room Facility" does not specify cleaning after each product preparation.

## OBSERVATION 5

The in-process control procedures were deficient in that they did not include an examination of the clarity of solutions.

Specifically, the firm does not have any written procedure requiring 100% visual inspection and does not perform and record 100% visual checks prior to distribution.

## OBSERVATION 6

Container closure systems do not provide adequate protection against foreseeable external factors in storage and use that can cause deterioration or contamination of the drug product.

Specifically, final prepared products that are light sensitive do not have the proper container or protection from light before use for the following light sensitive products: D5NS 500ml, Ondansetron 15mg/50mL NS, Dextrose 5%/NACL 0.90% 500mL, and Leicovorin Calc. 400mg/250ml 1/2NS.

## OBSERVATION 7

Written records are not made of investigations into unexplained discrepancies.

Specifically,

A. The firm does not have written procedures to investigate deviations, conduct root cause investigations and corrective actions.

B. No investigation was performed for an incident of water damage on the outer of the anteroom sink wall. As per PIC this event occurred approximately by the (b) (4)
   i. The firm stated they repaired the damage and repeated an environmental monitoring exercise, but the investigation is not documented.

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ii. There are no records showing if any processing activities were being performed during the damage.

## OBSERVATION 8

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

Specifically, calibration of incubator ((b) (4) Incubator; used for environmental monitoring media incubation and media fill incubation), thermometer (id: none available used to monitor incubator temperature) and the anteroom pressure gauge ((b) (4) used to monitor pressurization of the ISO 7 rooms) are not performed. In addition, there is no verification of incubator temperature.

## OBSERVATION 9

Employees are not given training in the particular operations they perform as part of their function.

Specifically, there is no in house training program in place to assure that personnel have the necessary skills in the operations which they perform, for example proper hand hygiene, garbing practices, personnel aseptic techniques, cleaning.

## OBSERVATION 10

Separate or defined areas to prevent contamination or mix-ups are deficient regarding operations related to aseptic processing of drug products.

Specifically, there is no procedure in place to document movement of personnel from/to Chemo Room (b) (4) and IV Room Laminar Flow, to prevent cross contamination into ISO 5 areas. Also there is not an entry log of each room.

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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 judgement, 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."