

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER 4040 North Central Expressway, Suite 300 Dallas, TX 75204 (214)253-5200 Fax: (214)253-5314	DATE(S) OF INSPECTION 8/14/2018-8/23/2018*
	FEI NUMBER 3012174424

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Jacqueline E. Esqueda, Pharmacist in Charge

FIRM NAME American Specialty Pharmacy	STREET ADDRESS 2414 Babcock Rd Ste 106
CITY, STATE, ZIP CODE, COUNTRY San Antonio, TX 78229-4870	TYPE ESTABLISHMENT INSPECTED 503B Outsourcing Facility

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**

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile did not include adequate validation of the aseptic and sterilization process.

Specifically,

1. Your firm has not conducted a (b) (4) study to validate the usage of (b) (4) (b) (4) which are less stringent and lower than manufacturer recommendations of (b) (4). None of your batch records indicate a specification for the (b) (4) test in sterile drug production. Examples include, but are not limited to:
 - a. Zinc batch 08162018@1 result (b) (4) using (b) (4)
 - b. Ascorbic acid batch 08092018@2 result (b) (4) using (b) (4)
 - c. Dexpantenol batch 07302018@2 result (b) (4) using (b) (4)
 - d. Glutathione batch 07302018@1 result (b) (4) using (b) (4)
 - e. Methylcobalamin batch 07182018@1 result (b) (4) using (b) (4)
 - f. Ascorbic acid batch 07092018@2 result (b) (4) using (b) (4)
 - g. Zinc batch 06182018@1 result (b) (4) using (b) (4)
 - h. Glutathione batch 06112018@1 result (b) (4) using (b) (4)
 - i. Testosterone batch 03132018@1 result (b) (4) using (b) (4)
2. Your firm has not conducted media fills under the most challenging conditions such as failing to

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simulate your largest batch size and failing to simulate your most difficult sterile processing methods; your aseptic operators have not been qualified on all media fills prior to performing aseptic operations.

- Your firm's smoke studies do not adequately mimic each critical step of your most challenging conditions of sterile drug processing. For example, dynamic smoke studies were not completed showing the stoppering of vials within your ISO 5 LAFW, did not mimic actual aseptic filling operations, and did not show that the ISO 5 filtered air adequately flows within your process.
- You firm has not conducted validation of the (b) (4) used to sterilize equipment used in the production and monitoring of your sterile drug products including goggles and air sampling equipment (b) (4)
- Your firm has not conducted validation of the (b) (4) used to depyrogenate your glassware used in sterile drug production.

OBSERVATION 2

Written records are not always made of investigations into unexplained discrepancies and the failure of a batch or any of its components to meet specifications.

Specifically,

- Your firm conducted recertification of your HEPA Laminar AirFlow Workbench ID (b) (4) (b) (4) Serial Number (b) (4) on November 8, 2017, and discovered seven leaks within the filter, some indicated as unrepairable. Your firm did not conduct an investigation into potential impact on production of sterile drug products since the last passing certification in May, 2017 and did not conduct an investigation into the potential production days with deficient air supply.
- You did not make adequate product evaluation and take remedial action where actionable microbial contamination on each hand of the technician was found to be present in the ISO 5 classified aseptic processing area during aseptic production of B-Complex B1/B2/B3/B5/B6

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Injectable batch 11272017@1 on 11/27/2017. Your firm released the batch for distribution on 12/15/2017. Your SOP 1.004 "Environmental Monitoring of the Cleanroom Facility" indicate ISO 5 action levels for samples as follows:

- a. Viable air >(b) (4)
- b. Surface >(b) (4)
- c. Gloved >(b) (4)

However, any contamination in the ISO 5 areas need to be investigated.

- 3. During visual inspection of your Taurine Injection 50mg/mL - Lot08022018@1, your firm found 2 fibers inside the final sterile product and failed to investigate. The lot was released for distribution 08/09/18.

OBSERVATION 3

Equipment and utensils are not cleaned, maintained and sanitized at appropriate intervals to prevent contamination that would alter the safety, identity, strength, quality or purity of the drug product.

Specifically,

Your firm has not conducted sterility hold time studies to confirm the indefinite hold times for in-house sterilized goggles and air sampling equipment, in-house depyrogenated glassware, and your "(b) (4)" which are cleaned/sanitized in an unclassified environment and stored uncovered in your ISO 7 area for (b) (4) Injection sterile drug production. In addition, your firm has not validated the maximum amount of sterilization cycles that your in-house sterilized goggles can undergo before breakdown. You firm also does not have procedures for the cleaning and storage of the above mentioned "(b) (4)" used in sterile drug production.

OBSERVATION 4

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Laboratory records do not include a statement of each method used in the testing of a sample and the location of data that establish that the methods used in the testing of the sample meet proper standards of accuracy and reliability as applied to the product tested.

Specifically,

Your firm failed to ensure that potency testing for Taurine 50mg/mL Lot08012018@1 met compendium standards. Your batch records indicate that your contract lab has not conducted product specific method validation.

OBSERVATION 5

There are no written procedures for production and process controls designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess.

Specifically,

Your master batch production records and your batch records for sterile drug production do not include procedures on required minimum mixing time for your Ascorbic Acid Injection and do not include instructions on extended holding and storage of intermediate steps.

OBSERVATION 6

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

Specifically,

Your firm is unable to provide documentation of positive pressure monitoring in the clean room during sterile drug production for the time period prior to March, 2018.

***DATES OF INSPECTION**

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8/14/2018(Tue), 8/15/2018(Wed), 8/16/2018(Thu), 8/17/2018(Fri), 8/20/2018(Mon), 8/21/2018(Tue), 8/22/2018(Wed), 8/23/2018(Thu)

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