

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

DISTRICT OFFICE ADDRESS AND PHONE NUMBER FDA Florida District 555 Winderley Place, Suite 200 Maitland, FL, 32751 (407) 475-4708 Fax: (407) 475-4770 Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 06/14,15,16, 21 / 2016
	FEI NUMBER 3011761363

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED
TO: Andrew Assad, PharmD, CPh, Managing Partner and Pharmacist in Charge

FIRM NAME Synergy Pharmacy Services	STREET ADDRESS 31201 US HWY 19 N, Suite 2
CITY, STATE AND ZIP CODE Palm Harbor, FL, 34684	TYPE OF ESTABLISHMENT INSPECTED 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 (I) (WE) OBSERVED:

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

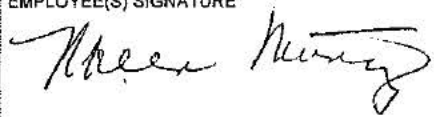
A. The media fills performed on site and used to qualify technicians in aseptic operations to be conducted in the ISO 5 areas do not simulate current process for sterile drug products, include the most challenging conditions encountered during preparation, or follow requirements established in Policy # RV-IV-18, Media Fill Testing. Deficiencies noted include:

a. The current Media Fill Testing process executed on site describes the preparation of (b) (4) that is (b) (4) which are incubated at (b) (4). However, the current process described on site for filling syringes of Glutathione Sterile Inhalation solution entails the (b) (4).

b. No growth promotion tests are conducted in media filled vials after the completion of the incubation period to ensure the media would support growth of organisms.

c. No documented evidence was available during the inspection to support the use of a (b) (4) for incubation purposes, even though the written policy requires incubation at (b) (4).

d. There is no documentation available for the media fill exercise performed at your firm. No documentation was available including instructions for the media preparation, length of time and steps conducted, and type of samples collected, inspected and analyzed. The only document available were test results for the media fill you said that was conducted.

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B. Lab coats used in the ISO 7 area identified as "single use" but are re-used, and are received in large and non-sealed bags, that would indicate that the units are not sterile. Sterile coveralls were not observed in the ante-room for use and are not required for use while operations are conducted in the ISO 5 area, which is located inside the ISO7 room.

C. There is no documentation that fingertip sampling was performed at the completion of the media fill exercise or at the completion of production batches. There is also no procedure that requires this sampling at the end of production.

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


A. There is no continuous or at least periodical monitoring of air pressure differentials during operations in the ISO 5 and ISO 7 Areas, as pressure readings/ relative humidity /temperature is documented (b) (4) (b) (4).

B. There is no viable and non viable monitoring performed during production in the ISO 5 area and it is not required. In addition, no surface monitoring is being conducted on the curtain between the ISO 5 and 7 areas and is not required. Acceptance criteria is not justified since your policy states that (b) (4) (b) (4) " would (b) (4) , which include (b) (4) (b) (4) .

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

A. Policy RX-IV-13, Laminar Air Flow Hoods, does not define acceptance criteria for certification of ISO 5 area (laminar flow work bench) and ISO 7 clean rooms or require a review of certification package provided by contractor to ensure acceptable results are obtained or require documentation of conditions reported as "static" and "dynamic".

B. Airflow pattern studies (smoke studies) (b) (4) conducted in

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(b) (4) was found inadequate in that:

- The video observed during this inspection did not show the smoke flow pattern in the ISO 5 area.
- The video depicted operations of (b) (4) which is not the current operation described on site for the aseptic fill of Glutathione Sterile Inhalation solution (b) (4).
- Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the areas and equipment to produce aseptic conditions. Specifically,
 - The suitability, efficacy, and limitations of sporocidal and disinfecting agents and procedures have not been assessed and approved to ensure potential contaminants are adequately removed from surfaces in the ISO5 and ISO7 classified areas when used as defined in established policy RX-IV-30, Cleaning and Disinfection of the Sterile Compounding Area. Cleaning and disinfecting agents reported for use by policy include (b) (4). However, agents used and documented in the cleaning form "Cleaning and Disinfection Log", reported (b) (4) only.
 - In addition, Policy RX-IV-30 does not include complete instructions on how to execute cleaning activities, minimum contact time, and does not describe steps conducted to clean items such as carts, chair, or storage bins maintained in the cleanrooms, or rotation schedule.
- There are no written standards or specifications, methods of testing, methods of cleaning, methods of sterilization, and methods of processing to remove pyrogenic properties. Specifically,
 - Your firm's depyrogenation (b) (4) has not been validated to define (b) (4) used for glassware and instruments used in the filling operation of sterile drug product Glutathione Inhalation Solution. In addition, no documentation was available to ensure the (b) (4) was qualified upon receipt or at any frequency thereafter.

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b. Instruments that are depyrogenated (b)(4) are not identified in a way that would allow a trace back to the depyrogenation (b)(4).

6. The responsibilities and procedures applicable to the quality control unit are not in writing.

Specifically, results of visual product inspection on product Glutathione Sterile Inhalation Solution are not documented.

7. 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 prepared and distributed sterile inhalation solutions (Glutathione Sterile Inhalation Solution) in the last three months without testing to determine conformance with potency.

K. Muniz
6/21/16

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