DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
158-15 Liberty Avenue Jamaica, New York 11433-1034 718-340-7000 Industry Information: www.fda.gov/oc/industry	06/10, 11, 12, 22/15
	FEI NUMBER 3010223213

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Thomas D'Angelo, Pharmacist/Co-Owner

FIRM NAME	STREET ADDRESS
Americare Compounding, LLC	319 Nassau Blvd.
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Garden City South, New York 11530	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:

OBSERVATION 1

Aseptic processing areas are deficient regarding systems for maintaining any equipment used to control the aseptic conditions.

a). Smoke studies were not performed under dynamic/operational conditions to verify that operators, processing equipment or activities of the ISO 7 (b) (4) clean room (aka Buffer Room) do not alter or impede the unidirectionality of air from the HEPA filters to the ISO 5 zone where drug products are aseptically processed. Similarly, smoke studies were not performed under dynamic/operational conditions for the ISO 7 (b) (4) clean room (b) (4) and the ISO 5 (b) (4) within that room.

b). During the processing of Dexamethasone 0.05% Ophthalmic Solution on 6/12/15 in the (b) (4) clean room, I observed the following: On the ISO 5 work table where open containers of sterile solutions and sterile equipment were being manipulated, there was clutter before/during/afterwards which included a bottle of (b) (4) and pliers.

OBSERVATION 2

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

a). No media fills/process simulations have been performed.

b). The sterile (b) (4) prepared for Alprostadil (b) (4) from non-sterile ingredients is assigned a shelf life of (b) (4) days. No hold time study has been conducted to support the stability/sterility over the time period that this sterile (b) (4) is prepared (b) (4).

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	James A. Liubicich	James A. Liubicich Investigator	06/22/2015

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OBSERVATION 3

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

Sterile drugs lots produced are not tested for sterility and/or endotoxins prior to distribution nor afterwards.

OBSERVATION 4

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

a). The operator's forehead, face, and neck were not fully covered allowing exposed facial skin and hair over the critical ISO 5 laminar flow areas where Dexamethasone 0.05% Ophthalmic Solution on 6/12/15 was being processed.

b). Sterile drug products are aseptically manipulated by the clean room operator who was observed wearing non-sterile eyeglasses, non-sterile goggles, a non-sterile hair net, non-sterile booties, and non-sterile under garments that were worn outdoors prior to entry to the clean room.

c). The clean room operator was observed re-using the gown/coveralls that was hanging on a hook in the anteroom.

OBSERVATION 5

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

a). Environmental monitoring for non-viable particulates in the ISO 5 zones is not performed at all under dynamic conditions. The firm only monitors non-viable air counts during the (b) (4) cleanroom certification by an outside vendor; lastly on (b) (4)

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b). The ISO 7 (b) (4) clean room, the ISO 7(b) (4) clean room, the ISO 7 anteroom, and the unclassified surrounding area are not continuously monitored for air pressure differentials during production. The only times readings are monitored are at the (b) (4).

c). Media plates used in the (b) (4) monitoring of microbiological activity on operator's glove tips and the ISO 5 zone work surfaces do not contain disinfectant neutralizers.

d). Environmental monitoring for viable air counts in the ISO 5 zones is not performed at least daily during periods of production. The firm only monitors viable air counts during the (b) (4) cleanroom certification by an outside vendor; lastly on (b) (4).

e). The work surfaces, inside the ISO 5 hoods, are not tested for microbial contamination at least daily during periods of production and at the end of operations. This monitoring is only performed (b) (4)

f). Operators' gloves are not tested for microbial contamination at least daily. Glove fingertips are only monitored (b) (4)

OBSERVATION 6
Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room and equipment to produce aseptic conditions.

a). Sporicidal agents are not used to disinfect the ISO 5 surfaces.

b). No disinfectant effectiveness studies have been performed to determine if disinfection agents are effective in aseptic processing areas.

c). Non-sterile wipes that are particle shedding (low lint) are used with sterile (b) (4) in disinfecting ISO 5 work surfaces.

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OBSERVATION 7
The separate or defined areas necessary to prevent contamination or mix-ups are deficient.

There are no separate facilities, for processing operations, to prevent contamination from the beta-Lactam injectable drug that is processed – Ceftazidime syringe. This beta-Lactam (b) (4) which is contained in (b) (4) (b) (4) (b) (4) (b) (4) There is no assurance that a potential(b) (4) and consequent(b) (4) spill would not contaminate other sterile drug products.

OBSERVATION 8
There shall be a written testing program designed to assess the stability characteristics of drug products. The results of such stability testing shall be used in determining appropriate storage conditions and expiration dates.

a). Your firm has not tested for sterility or potency over the assigned Beyond Use Date (BUD) for any of your sterile drug products. For example, your firm has not conducted complete testing to support the BUDs such as 90 days for Alprostadil 40mcg/ml injectable at refrigerated conditions. You have no stability studies to assure that the sterility and potency will be maintained over the time period of the BUD.

b). There is no antimicrobial effectiveness testing data for any sterile drug products containing preservatives, such as those for multiple-use; example – Papaverine/Phentolamine/Alprostadil injectable.

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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."