DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Chicago District Office 550 West Jackson Blvd., 15th Floor Chicago, IL 60661 312-353-5863 Industry Information: www.fda.gov/oc/industry	7/17-21/17; 7/27/17; 8/2/17; 8/24/17
	FEI NUMBER 3013441865

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Jacqueline R. Faine, Compliance Officer

FIRM NAME	STREET ADDRESS
Carepoint Healthcare, LLC dba Carepoint Pharmacy	9 East Commerce Drive
CITY, STATE AND ZIP CODE Schaumburg, IL 60173-5302	TYPE OF ESTABLISHMENT INSPECTED Producer of Sterile and Non-Sterile Drug Products

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DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

OBSERVATION 1

Personnel engaged in aseptic processing did not use aseptic techniques to ensure drug products remain sterile.

Specifically, we observed the technician perform the following poor aseptic practices during production of the following sterile drug products: Ampicillin-Sulbactam, 3 gram/100 mL 0.9% Sodium Chloride in each (b) (4) (b) (4) Rx # (b) (6) ; and Ceftriaxone for Injection USP, 2 grams/20 mL sterile water for injection in each sterile syringe for IV infusion, Rx # (b) (6)

1. The technician donned the sterile gown apparel in a way that may have caused the gown to become contaminated. For example, on 7/19/17 and 7/20/17 in the buffer room, the technician touched the sterile gown with her bare hands before sanitizing her hands.

2. The technician donned the sterile gloves in a way that may have caused the gloves to become contaminated. For example, on 7/20/17, we observed the technician place on her second glove incorrectly. She touched the sterile part of the second glove while trying to put it on.

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3. Personnel were observed leaning in the Laminar Air Flow Hood (LAFH). For example, on 7/19/17 we observed the technician leaning into the LAFH to reconstitute the sterile drug product, to withdraw the sterile saline from the bag and to fill the (b) (4) with sterile saline, and to add the sterile drug product to the (b) (4). On 7/20/17, we observed the technician leaning into the LAFH to produce the sterile drug product in syringes for IV infusion. On 7/19/17 and 7/20/17, the technician was observed leaning into the ISO 5 area of the LAFH with exposed skin around the eyes.

4. Personnel engaged in aseptic processing did not allow time for the (b) (4) to dry on her gloves. For example, on 7/19/17, the technician did not change the sterile gloves after cleaning the ISO 5 area in the LAFH, but sprayed them with sterile (b) (4) before opening the packages containing the sterile supplies such as the packaging for the sterile (b) (4). She did not allow time for the (b) (4) to dry on her gloves before proceeding with further sterile drug production.

OBSERVATION 2

Equipment, materials, and/or supplies are not disinfected prior to entering the aseptic processing areas.

Specifically, we observed the technician perform poor aseptic practices while transferring materials for the processing of the following sterile drug products: Ampicillin-Sulbactam, 3 gram/100 mL 0.9% Sodium Chloride in each (b) (4), Rx # (b) (6) and Ceftriaxone for Injection USP, 2 grams/20 mL sterile water for injection in each sterile syringe for IV infusion, Rx # (b) (6).

1. Equipment, materials, and/or supplies are not disinfected prior to entering the aseptic processing areas. For example on 7/19/17 and 7/20/17, the technician did not spray the outside of all the sterile supplies with sterile (b) (4) (b) (4) before placing them in the ISO 5 area of the LAFH.

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2. The technician placed non-sterile materials in the ISO 5 area of the LAFH. For example on 7/19/17 and 7/20/17, the technician removed the cap and opened the bottle of sterile (b) (4) inside of the ISO 5 area in the LAFH. The outside of this bottle was not wiped off in the ISO 7 area before bringing it inside of the ISO 5 area in the LAFH. She poured the (b) (4) on a sterile wipe (from the bag of open sterile wipes on the cart) to clean the hood before sterile production started.

3. We observed two pieces of unnecessary equipment inside the ISO 5 area of the LAFH during the production of the sterile drug products: a TPN machine (total parenteral nutrition machine used when TPN products are produced) and a balance. This equipment was not wiped off with sterile (b) (4) before sterile production started on 7/19/17 and on 7/20/17.

4. Materials intended to be sterile were observed to be exposed to lower than ISO 5 quality air. For example, an open bag of sterile wipes were observed on a stainless steel cart in the ISO 7 area and the technician used these wipes to clean the ISO 5 area in the LAFH before sterile production started. The sterility of the wipes could not be assured since the bag was not closed.

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OBSERVATION 3

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

Specifically, aseptic processing areas and equipment are not cleaned and disinfected according to 4.3.4 and 6.6 of the SOP "Pharmacy Compounding of Non-Hazardous Sterile Products".

- A sporicidal cleaner is not routinely used on the ISO 5 surfaces or clean-room.
- Cleaning procedures do not indicate a specific dwell time for all cleaning agents used.
- Cleaning logs reflect that the (b) (4) cleaning of easily cleanable work surfaces is not being conducted.
- The use of non-sterile (b) (4) was observed on both days of production (07/19/2017 and 07/20/2017) without the use of a "germicidal" cleaning agent prior per 6.6.4 of SOP "Pharmacy Compounding of Non-Hazardous Sterile Products".

OBSERVATION 4

Media Fills are performed in a manner that does not closely simulate production operations at the firm, incorporating as appropriate, worst-case activities and conditions commonly encountered during production.

Specifically,

- It was described by your firm's personnel on 08/02/2017 that the most strenuous process is the production of TPN products and the (b) (4) products for infusion, respectively. The production process of an (b) (4) based product for infusion, Ampicillin-Sulbactam, 3 gram/100 mL 0.9% Sodium Chloride, was observed on 07/19/2017. The sterile technician confirmed following production it was the most difficult product to produce. Currently the (b) (4), Catalog #(b) (4) " from (b) (4) is utilized for personnel monitoring. According to the Sterile Compounding Manager, this kit is followed verbatim without taking into account actual production practices. Furthermore, no person at the firm is currently qualified to conduct

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personnel training and monitoring or to evaluate test results.

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