DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973)331-4900	4/22/2025-4/29/2025* FEI NUMBER 3011110195

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Michele A. Young, Chief of Staff

FIRM NAME	STREET ADDRESS
East Orange VA Medical Center	385 Tremont Ave
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
East Orange, NJ 07018-1023	Producer of Sterile 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 OBSERVED:

OBSERVATION 1

Production areas have difficult to clean or contain porous, particle generating, or visibly dirty equipment or surfaces.

Specifically,

On 4/22/2025 I observed the following contamination in your firm's Segregated Compounding Area (SCA) located in room (b)(4)-202A:

- Rust was observed on the table legs of the work bench approximately 2 feet from the ISO-5 Sterile Compounding (b) (4).
- Discoloration was observed on the HEPA pre-filter that is located directly below an air return vent in the SCA. This pre-filter is a part of the ISO-5 Sterile Compounding (b) (4).

On 4/22/2025 I observed the following contamination adjacent to your firm's SCA located in room (b) (4)-167:

- Puddled liquid was observed in the bottom of a cabinet within the closet containing cleaners and a sink used for hand washing prior to production within the SCA. This closet is located directly adjacent to room (b) (4)-167 and the doorway to the closet is approximately 10 feet from the SCA entrance.

OBSERVATION 2

The sinks are present directly adjacent to the ISO 5 area.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Logan T Williams, Investigator X Logan T Williams Investigator Signed By: 2002955055 Date Signed: 04-29-2025 14:55:43	4/29/2025

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Michele A. Young, Chief of Staff	
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CITY, STATE, ZIP CODE, COUNTRY East Orange, NJ 07018-1023	TYPE ESTABLISHMENT INSPECTED Producer of Sterile Products

Specifically,

Your firm's Segregated Compounding Area (SCA) located in room (b) (4)-202A contains a sink that is approximately three feet from the ISO-5 Compounding Aseptic (b) (4) (b) (4) and one foot from a storage bin containing materials entered into the ISO-5 (b) (4). Your firm's technicians utilize wipes to dry hands that are located in the same storage bin as components that are introduced to the ISO-5 area, such as sterile gloves. This sink is located within the SCA. Your firm regularly utilizes this SCA to make drug products for Veterans.

OBSERVATION 3

Beta-lactam drugs were produced without providing adequate containment, segregation, and/or cleaning of work surfaces, utensils, and/or personnel to prevent cross-contamination.

Specifically,

Your firm does not have policies in place to deactivate Penicillin and Beta Lactam products after production. Your firm has produced approximately (b) (4) IV bags of Penicillin G Potassium and (b) (4) IV bags of Meropenem since January 1st, 2025, in your firm's main Segregated Compounding Area. In addition, your firm has not demonstrated that deactivation of Beta Lactam and Penicillin products occur with the cleaning agents used.

***DATES OF INSPECTION**

4/22/2025(Tue), 4/23/2025(Wed), 4/24/2025(Thu), 4/25/2025(Fri), 4/28/2025(Mon), 4/29/2025(Tue)

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	Logan T Williams, Investigator X Logan T Williams Investigator Signed By: 2002955055 Date Signed: 04-29-2025 14:55:43	4/29/2025

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 judgment, 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."