DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
109 Holton Street Winchester, MA 01890 (781)587-7500 Fax:(781)587-7556	6/8/2026-6/15/2026* FEI NUMBER 1073803

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Marri M. Fryar, Executive Director/CEO

FIRM NAME	STREET ADDRESS
Fayetteville VA Medical Center	2300 Ramsey St
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Fayetteville, NC 28301-3856	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 WE OBSERVED:

OBSERVATION 1

Microbial contamination was present in the.

Specifically,

On 05/08/2025, a surface sample collected from (b)(4) (S/N: (b)(4)), an ISO Class 5 (b)(4) used for the production of sterile drug products, yielded 4 cfu/plate, exceeding the action limit of (b)(4) cfu/plate. The sample was classified as Out of Compliance (OOC) and the following organisms were identified: *Cladosporium spp.* (pathogenic), *Corynebacterium tuberculostearicum, Staphylococcus saprophyticus*, and Fungal Overgrowth. Per email documentation provided by the firm, the (b)(4) (S/N: (b)(4)) was not used following the OOC result until passing recertification, which occurred approximately (b)(4) later. Your firm failed to investigate the cause of the OOC result and implement a corrective action plan as required by your Policy Number 797-2022, entitled, Microbiological Air and Surface Monitoring Program, version 2. Additionally, your firm was unable to demonstrate that the (b)(4) was not used for the production of sterile drug products during this period.

OBSERVATION 2

Failure to appropriately and regularly clean and disinfect or sterilize equipment located in the ISO 5 area.

Specifically,

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Erik W Koester, Investigator Syeda N Mahazabin, Investigator X Syeda N Mahazabin Investigator Signed By: Syeda N. Mahazabin - S Date Signed: 06-15-2026 14:12:19	6/15/2026

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- Areas of reddish-brown and opaque discoloration/staining were observed on the ceiling screen cover within the ISO-5 (b)(4) S/N: (b)(4).

- On 06/08/2026, we observed a technician conduct cleaning and disinfection of the ISO-5 (b)(4)) S/N: (b)(4) We observed that the technician failed to clean the recessed area of a (b)(4) on the side of the (b)(4). The technician was instructed to clean the (b)(4) and brown residue was observed on the wipe.

The aforementioned (b)(4) is utilized in the production of several sterile products including:

Piperacillin/Tazobactam 2.25gm/vial; Doxycycline Hyclate 100mg/vial; Ampicillin/Sulbactam1.5gm/vial; Vancomycin HCL 1gm/vial and Infliximab 100mg/vial

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,

- The firm has routinely produced both Beta-lactam and non-Beta-lactam drug products within the same ISO-5 (b)(4) S/N: (b)(4) and (b)(4) S/N: (b)(4). During this time the firm has failed to conduct decontamination of the (b)(4) to prevent potential cross-contamination. The firm's procedure, Cleaning and Disinfecting Compounding Areas only require the operator to apply sterile (b)(4) to surfaces (b)(4) production. For example, the firm produced Piperacillin/Tazobactam 4.5g/Vial Injection; Sodium Chloride 0.9% Injection Bag 100ml on 05/28/2026. The firm failed to conduct decontamination of the (b)(4) then produced Phosphorus 3mmol/Potassium 4.4 Meq/ml Injection; Sodium Chloride 0.9% Injection Bag 250ml.

- On 06/09/2026, we observed production within ISO-5 (b)(4)) S/N: (b)(4). We then observed that the technician only applied (b)(4) to the (b)(4) of

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Erik W Koester, Investigator Syeda N Mahazabin, Investigator	DATE ISSUED 6/15/2026

X Syeda N Mahazabin Investigator Signed By: Syeda N. Mahazabin - S Date Signed: 06-15-2026 14:12:19

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the (b)(4) and to no other surfaces. The firm's current unofficial cleaning procedure allows operators to only apply (b)(4) to the (b)(4) following the production of any Beta-Lactam products.

***DATES OF INSPECTION**

6/08/2026(Mon), 6/09/2026(Tue), 6/10/2026(Wed), 6/11/2026(Thu), 6/12/2026(Fri), 6/15/2026(Mon)

X Erik W Koester
Investigator
Signed By: ERIK W. KOESTER -S
Date Signed: 06-15-2026 14:12:53

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Erik W Koester, Investigator Syeda N Mahazabin, Investigator	X Syeda N Mahazabin Investigator Signed By: Syeda N. Mahazabin -S Date Signed: 06-15-2026 14:12:19	6/15/2026

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."