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	10/9/2025-11/5/2025* FEI NUMBER 3013438665

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Nicole M. Traut, FSS-Boston Quality Site Head

FIRM NAME	STREET ADDRESS
Fresenius Kabi Compounding, LLC	20 Dan Rd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Canton, MA 02021-2809	Outsourcing Facility

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

There is a failure to thoroughly review any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

Specifically, your firm detected defects in (b) (4) infusion and (b) (4) injection ports on some of the IV bag container closures of your compounded sterile drug products (CSP's). Defects include the port not being properly fused to the IV bag and may lead to leaking, port falling off the IV bag with minimal manipulation, or other container closure integrity issues. These defects affect units in multiple lots of multiple products, for example:

- Vancomycin HCl 1.25 grams added to 250 mL 0.9% Sodium Chloride Injection USP IV Bag, Preservative Free, Lot C274-000048802, MFG 10/6/2025, EXP 4/4/2026
- Phenylephrine HCl 20 mg added to 250 mL (80 mcg/mL) 0.9% Sodium Chloride Injection, Solution USP IV Bag, Lot C274-000048505, MFG 9/22/2025, EXP 3/21/2026

Your firm's investigation of port defects did not ascertain the full scope of IV bag lots affected, inspect retains from the known affected lots, notify customers of affected lots, or establish action items to prevent use of affected units. Your firm has received customer complaints for leaking IV bags and in some cases not identified the specific root cause. For example, COMP-2025-0334 for vancomycin HCl 1.5 grams added to 500 mL 0.9% Sodium Chloride Injection USP IV Bag lot C274-000045267 documents a customer complaint for 2 leaking IV bags. The definitive root cause was not identified, and customer samples were not returned/photographed. The implicated lot (C274-000045267) is known to contain supplier bags affected with the port defect.

AMENDMENT 1

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	Jonathan G Matrisciano, Investigator Lori M Newman, Investigator Daniel L Zheng, Investigator X Daniel L Zheng Investigator Signed By: Daniel L. Zheng -S Date Signed: 11-06-2025 09:14:20	11/6/2025

Additionally, your firm failed to initiate corrective or preventative action for potential root causes identified repeatedly in your investigations of customer complaints for leaking bags. For example, in at least six 2024 complaint investigations and seven 2025 complaint investigations, your firm identified manufacturing defects in the supplied bags and pressure on bags laying on top of each other during storage and shipping as a potential root cause. Your firm did not have documentation of communicating these complaints with your bag supplier, and your firm continues to store bags laying on top of each other in your packaging warehouse prior to shipping.

In 2024, your firm received approximately 79 bag leak complaints (out of a total 126 received) in which no damage was reported to the outside shipper box. In 2025, your firm received approximately 48 bag leak complaints (out of a total 67 received) in which no damage was reported to the outside shipper box.

OBSERVATION 2

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

Specifically,

a. Multiple examples were observed in which procedures regarding operator conduct were not established or followed:

1. During vancomycin reconstitution operations on 10/17/25, multiple instances were observed in which operator movements inside ISO [(b)(4)] (b)(4) laminar flow hoods obstructed first-pass air to uncapped vials of (b)(4) vancomycin. For example, during vial reconstitution for production of Vancomycin HCl 1.75g Bag lot C274-000048979 in Laminar Flow Hood [(b)(4)], we observed an operator's arms pass between first-pass air and pre- and post-dilution vials. This occurred while the operator was obtaining undiluted vials from the rack, returning reconstituted vials to the rack, and

replacing the diluent bag. In the same operation, five diluent bags were hung above the racks of undiluted vials on one hook. Your firm lacks data to demonstrate that first-pass air is not obstructed by the expanded silhouette of five diluent bags. Additionally, raw material vancomycin vials were observed underneath the propped electrical outlet cover in Hood (b)(4), obstructing first-pass air to several vials. Your operators reconstituted vancomycin vials in a way that fails to minimize the risk of bioburden.

2. Your operators performed rapid movements in ISO(b)(4) environments, disrupting laminar air flow. On 10/17/25, during reconstitution of (b) (4) vancomycin vials, operators were observed vigorously shaking diluted vials inside ISO(b)(4) laminar flow hoods, including for production of Vancomycin HCl 1.75g Bag lot C274-000048979 in Hood(b)(4) and production of Vancomycin HCl 1.25g Bag lot C274-000049063 in Hood(b)(4). Your cleanroom behavior procedure requires movements inside laminar flow hoods to be "slow and steady." Your reconstitution procedure indicates that operators should "gently shake or agitate" vials.

3. During post-production cleaning of the ISO(b)(4) hoods on 10/10/25, operators were observed leaning into Laminar Flow Hoods(b)(4) and(b)(4), including breaking the ISO(b)(4) plane with the (b) (4) goggles. Additionally, security camera footage from 10/3/25 shows an operator leaning into Laminar Flow Hood(b)(4) during pre-production cleaning. On 10/3/25, Hood(b)(4) was used for reconstitution, pooling, and filling of Vancomycin HCl 1.5g Bag lot C274-000048770. Your procedures prohibit operators from leaning into the ISO(b)(4) hoods. Your operators wear (b) (4) goggles for gowning into ISO(b)(4) areas, and leaning into the ISO(b)(4) hoods exposes the ISO(b)(4) environment to the operator's skin.

b. Your firm performs reconstitution and pooling of some lots of vancomycin 1.5 g bulk solution in the ISO(b)(4) mixing room (b) (4) and not inside an ISO(b)(4) hood. You did not show that sterile (b) (4) of the pooled vancomycin 1.5 g solution is validated to assure sterility of the finished

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vancomycin 1.5 g IV bag compounded sterile products. Your firm has produced approximately (b) (4) lots of vancomycin 1.5 g bulk solution in the ISO (b) (4) mixing room since 2/2025; for example, lot C274-000047479 of vancomycin 1.5 g bulk solution was produced in mixing room (b) (4) on 8/5/2025. After additional processing and (b) (4), the bulk solution was sterile (b) (4) in the ISO (b) (4) environment into 1.5 g vancomycin in 500 mL IV bags lot C274-000047480 on 8/6/2025. This product expires on 1/26/2026.

c. Your firm lacks data to show that operators use equipment in the ISO (b) (4) environment in a way that minimizes bioburden. For example, your firm does not perform environmental monitoring on personnel contact surfaces of scales and pumps used during reconstitution, pooling, and filling of all of the firm's drug products. The scales and pumps, which are stored outside ISO (b) (4) between uses, are not periodically treated with sporicidal agents, and operators are not required to sanitize gloves after touching them. During production of Vancomycin HCl 1.75g Bags lot C274-000048979 in ISO (b) (4) Hood (b) (4) on 10/17/2025, we observed supplies used in aseptic operations - including the calibration syringe, luer adapter, luer adapter caps, IV bag infusion port caps, (b) (4) pump tubing caps, and needle caps - placed on the surface of the (b) (4) pump between uses.

d. The firm lacks data to show that (b) (4) was performed effectively for all lots when transferring materials from the warehouse to classified areas. During (b) (4) operations on 10/10/25, multiple 500mL IV bags in the (b) (4) (b) (4) were observed leaned against other IV bags, obstructing surface exposure to (b) (4). These IV bags were being prepared for filling of Oxytocin (b) (4) Units Bag lot C274-000048939. Multiple 500mL IV bags in contact were also observed during (b) (4) of 500mL IV bags on 10/15/25. These IV bags were being prepared for filling of Oxytocin (b) (4) Units Bag lot

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C274-000048970. When (b) (4) is used, the firm does not perform additional wiping of materials staged for entry to classified areas.

e. Operators sanitized gloves before performing personnel monitoring. For example, during filling of drug product Vancomycin HCl 1.5g Bag lot C274-000048892 on 10/10/25, an operator sanitized their gloves and sleeves with (b) (4) wipes before conducting a weight check, closing a settling plate, and performing personnel monitoring immediately afterwards, consisting of (b) (4), and (b) (4). The firm lacked personnel monitoring data representative of filling activities.

f. Air flow visualization studies (smoke studies) are not representative of current production procedures.

1. Your firm's smoke studies do not show the same quantity or positioning of materials in the ISO (b) (4) hood as was observed in production. For example, on 10/17/2025 during production of vancomycin HCl 1.75 g lot C274-000048979 in ISO (b) (4) hood (b) (4), we observed (b) (4) racks of vancomycin HCl vials (approximately (b) (4) vials total) placed on the left side of the hood. However, your firm's smoke studies simulate only one (b) (4) rack of vials ((b) (4) vials total) on the side of the hood during production.

2. Your smoke study addendum PR-18-0015-A3 shows up to (b) (4) 1L diluent bags hanging on a single hook in the ISO (b) (4) hood during production. However, this video does not show the remainder of the production process to assess whether the multiple hanging bags might interfere with airflow to the product vials.

3. Your firm's smoke studies show the settle plate for passive air monitoring positioned in or near the center of the aseptic operating area within the ISO (b) (4) hood. On 10/10/2025 and 10/17/2025, we observed the settle plate placed to the side of the ISO (b) (4) hood, approximately 1-2 feet away from aseptic operations. SOP-0030 "Passive Viable Air

Monitoring with Settle Plates" states that the settle plate should be placed within (b) (4) from the working area.

4. Vials of sterile drug product used in compounding are uncapped prior to (b) (4) (b) (4), but your smoke study videos simulate vial uncapping inside the ISO (b) (4) hood. On 10/15/2025, we observed operators removing caps from rocuronium bromide injection vials using forceps in the pre-cleaning area prior to the vials' insertion into the (b) (4). However, your firm's smoke study videos show drug vials being passed into the ISO (b) (4) hood with the plastic caps still attached and simulate the operator removing the caps inside the ISO (b) (4) hood.

OBSERVATION 3

The responsibilities and procedures applicable to the quality control unit are not fully followed.

Specifically, your firm has been using drug products known to be defective (defective ports on (b) (4) IV bags) for compounding since 10/2024. Among the (b) (4) batches of CSP's made at least in part from the initially identified defective IV bag lot (lot 23SU10008), (b) (4) batches were fully distributed to customers. While DEV-2024-1626 states that this defect is highly detectable during visual inspection, your firm opened Issue-2024-0039 on 7/26/2024 for operators failing visual inspection requalification for IV bags.

SOP FSSBOS-SOP-0018 " Visual inspection of Compounded Sterile Products" indicates that the allowable defect limit for critical port defects is (b) (4) %, yet your firm released lots with port defects above (b) (4) %, such as vancomycin HCl 1 gram added to 250 mL 0.9% Sodium Chloride Injection USP IV Bag, Preservative Free lot C274-000040486 on 10/2/2024 with a port defect rate of 14.9% of the batch.

As of 10/25/2025, your firm identified that approximately (b) (4) supplier lots from your stock of (b) (4) IV bags contain affected units, and approximately (b) (4) lots of your finished CSP's contain affected units. Your firm has continued to detect port defects in IV bags as recently as 11/3/2025 (Event 2025-2512 opened 11/3/2025: Vancomycin 1g lot C274-000049392 exceeded limits for (b) (4) port defects: 49

defective units; limit: (b) (4) defective units). These (b) (4) IV bags continue to be used as container closures for your firm's CSP's.

OBSERVATION 4

Your examination and testing of samples did not assure that the drug product and in-process material conformed to specifications.

Specifically, on 10/10/2025, your firm's visual inspection hoods including E00113.00 in Room (b) (4) were observed to contain dust-like particles on the (b) (4) visual inspection backgrounds. Your firm also lacks a written procedure for cleaning of (b) (4) surfaces in the visual inspection hoods including backgrounds. On 10/16/2025, during visual inspection of lot C274-000048970 of oxytocin (b) (4) USP units added to 500 mL 0.9% Sodium Chloride Injection, USP IV Bag, we observed dust-like particles on the (b) (4) backgrounds in the visual inspection hoods that the inspectors were using.

OBSERVATION 5

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

Specifically, active viable air sampling was not performed at a time representative of production operations. The firm performs active viable air sampling after operators fully conclude a stage of drug production, i.e., reconstitution, pooling, or filling, in accordance with the firm's environmental monitoring procedures. Additionally, settling plates in the ISO (b) (4) hoods are not always placed in a location representative of production activities, as observed on 10/17/25 during vial reconstitution for Vancomycin HCl 1.75g Bag lot C274-000048979 in Hood (b) (4) and pooling of Oxytocin (b) (4) Units Bag lot C274-000048976 in Hood (b) (4), as well as on 10/10/25 during filling of Lidocaine 2% 5mL Syringe lot C274-000048894 in Hood (b) (4).

OBSERVATION 6

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

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Specifically,

a. On 10/10/25, a brown, rust-like residue was observed on the (b) (4) of multiple tables and laminar flow hoods, including all (b) (4) tables and all (b) (4) hoods in ISO (b) (4) Room (b) (4), (b) (4) tables and (b) (4) hoods in ISO (b) (4) Room (b) (4), and a table in ISO (b) (4) Room (b) (4). Your procedure governing laminar flow hoods requires operators to clean the (b) (4) with a de-rouging agent during (b) (4) cleanings if residues are observed, or to communicate with management if residue cannot be removed. Room (b) (4) and Room (b) (4) each contain (b) (4) ISO (b) (4) laminar flow hoods for production of all firm drug products. Room (b) (4) is used as the (b) (4) exit for the (b) (4) and for clean staging/storage of all materials going into Room (b) (4) and Room (b) (4) for drug production.

b. On 10/21/25, an iridescent, oily residue of unknown character was observed on the surface of a table in ISO (b) (4) Room (b) (4) on both sides of a (b) (4) pump. Your firm performs vial reconstitution and pooling for vancomycin drug products in Room (b) (4). This room is cleaned (b) (4).

OBSERVATION 7

Buildings used in the manufacturing and processing of a drug product are not maintained in a good state of repair.

Specifically,

a. On 10/10/25, paint chipping was observed on the lip of (b) (4) air returns in ISO (b) (4) Room (b) (4), one air return ISO (b) (4) Room (b) (4), and (b) (4) air returns in ISO (b) (4) Room (b) (4). Room (b) (4) and Room (b) (4) contain the ISO (b) (4) laminar flow hoods for production of all firm drug products. Room (b) (4) is used as the (b) (4) exit for the (b) (4) and for clean staging/storage of all materials going into Room (b) (4) and Room (b) (4) for drug production.

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b. On 10/21/25, paint chipping was observed in ISO (b) (4) Room (b) (4) on the door leading to ISO (b) (4) Room (b) (4). Your firm performs vial reconstitution and pooling for vancomycin drug products in Room (b) (4).

c. On 10/10/25, a divot in the floor was observed at the foot of Laminar Flow Hood (b) (4) in Room (b) (4).

***DATES OF INSPECTION**

10/09/2025(Thu), 10/10/2025(Fri), 10/14/2025(Tue), 10/15/2025(Wed), 10/16/2025(Thu), 10/17/2025(Fri), 10/20/2025(Mon), 10/21/2025(Tue), 10/22/2025(Wed), 10/23/2025(Thu), 10/24/2025(Fri), 11/05/2025(Wed)

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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 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."