DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
One Montvale Avenue Stoneham, MA 02180 (781)587-7500 Fax:(781)587-7556 ORAPHARM1_RESPONSES@fda.hhs.gov	1/30/2023-3/6/2023*
	FEI NUMBER 3013438665

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Deborah E. McHugh, Senior Director of Quality

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

OBSERVATION 1

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

Specifically, on 01/31/2023, production operators were observed performing preproduction cleaning of the interior of the ISO 5 (b)(4) HLFs located in ISO 7 Room 139. During the cleaning operations, multiple operators were observed leaning their bodies inside the ISO 5 (b)(4) LFHs in order to clean the interior of the (b)(4) LFHs. By leaning inside the ISO 5 (b)(4) LFHs, the operators blocked the path of the unidirectional airflow inside the (b)(4) LFHs immediately prior to performing production operations. Operators then manufactured Rocuronium 50mg per 5mL Syringe, Lot #(b) (4) in (b)(4) LFH # (b) (4) ; Phenylephrine HCl 20mg added to 250mL Bag, Lot # (b) (4) in (b)(4) LFH (b) (4) ; Vancomycin HCl 2g added to 500mL Bag, Lot # (b) (4) in (b)(4) LFH (b) (4) ; and Norepinephrine 4mg added to 250mL Bag, Lot #(b) (4) in (b)(4) LFH (b) (4) .

OBSERVATION 2

The accuracy, sensitivity, specificity and reproducibility of test methods have not been established.

Specifically, the USP <71> method suitability tests performed for your injectable Vancomycin drug products failed to recover *Bacillus subtilis* demonstrating that the (b) (4) were not adequately neutralizing the antibiotic in order to detect all potential microbial contamination.
Between June 11, 2021, and January 30, 2023, your firm used USP <71> to perform sterility testing on approximately (b) (4) batches of your injectable Vancomycin drug products that were distributed for use in treating patients.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Jonathan G Matrisciano, Investigator X Jonathan G Matrisciano Investigator Signed By: Jonathan G. Matrisciano -S Date Signed: 03-06-2023 13:35:39	3/6/2023

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CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Canton, MA 02021-2809	Outsourcing Facility

*DATES OF INSPECTION

1/30/2023(Mon), 1/31/2023(Tue), 2/01/2023(Wed), 2/02/2023(Thu), 2/06/2023(Mon), 2/07/2023(Tue), 2/08/2023(Wed), 2/09/2023(Thu), 2/13/2023(Mon), 2/14/2023(Tue), 2/15/2023(Wed), 2/16/2023(Thu), 2/27/2023(Mon), 3/06/2023(Mon)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Jonathan G Matrisciano, Investigator	X Jonathan G Matrisciano Investigator Signed By: Jonathan G. Matrisciano -S Date Signed: 03-06-2023 13:35:39	3/6/2023

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."