DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
158-15 Liberty Avenue Jamaica, NY 11433 (718) 340-7000 Ext:5301 Fax:(718)662-5661	5/5/2026-5/14/2026* FEI NUMBER 3001833549

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Luiz R. Neto, Plant Manager

FIRM NAME	STREET ADDRESS
Fresenius Kabi USA, LLC	3159 Staley Rd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Grand Island, NY 14072-2028	Sterile Drug Manufacturer

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

Your firm failed to establish adequate written procedures for production and process controls designed to assure that the drug products have the identity, strength, purity, and quality that they are purported or represented to possess.

Specifically, in 2024 your firm conducted studies to qualify the defect standards for your visible particulate container challenge (b) (4). However, you failed to assess the appropriateness of your current (b) (4) sterile vial inspection process after these Visual Inspection Method Qualification studies revealed significant degradation in visual inspection quality and capabilities when the vials were inspected by the (b) (4) method compared to 100% manual visual inspection. Your firm's current (b) (4) visual inspection process entails vials which are presented to inspectors via a conveyor system at pre-determined speeds (without ever determining how conveyor speed impacts visual inspection performance). For example:

1. Protocol #US-PU-1027-MVD-EQP-000116815 (*Determination of Probability of Detection* (b) (4) *with* (b) (4) *Fill of* (b) (4)), initiated in 8/2024. Examples of results from 100% manual inspection vs. the firm's current (b) (4) inspection, are as follows:
   a. (b) (4) stopper particulate (Unit ID: (b) (4)): 93.3% vs. 10.0%
   b. (b) (4) stopper particulate (Unit ID: (b) (4)): 83.3% vs. 0.0%
   c. (b) (4) fiber particulate (Unit ID: (b) (4)): 70.0% vs.13.3%
   d. (b) (4) particulate (Unit ID: (b) (4)): 70.0% vs. 13.3%

2. Protocol #US-PU-1027-MVD-EQP-000122295 (*Determination of Probability of Detection,* (b) (4) *with* (b) (4) *Fill of* (b) (4)), initiated 10/2024. Examples of results from 100% manual inspection vs. the firm's current (b) (4) inspection, are as follows:
   a. (b) (4) stopper particulate (Unit ID: (b) (4)): 83.3% vs. 43.3%

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Mindy M Chou, Investigator JoshRenzo N Ramilo, Investigator	X Mindy M Chou Investigator Signed By: 2000648922 Date Signed: 05-14-2026 15:25:32	5/14/2026

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b. (b) (4) stopper particulate (Unit ID: (b) (4)): 80.0% vs. 20.0%
c. (b) (4) stopper particulate (Unit ID: (b) (4)): 96.7% vs. 36.7%
d. (b) (4) stopper particulate (Unit ID: (b) (4)): 86.7% vs. 40.0%
e. (b) (4) fiber (Unit ID: (b) (4)): 73.3% vs. 33.3%
f. (b) (4) fiber (Unit ID: (b) (4)): 80.0% vs. 16.7%
g. (b) (4) fiber (Unit ID: (b) (4)): 73.3% vs. 33.3%
h. (b) (4) fiber (Unit ID: (b) (4)): 73.3% vs. 23.3%

OBSERVATION 2

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile did not include adequate validation of the aseptic and sterilization process.

Specifically,

(A) The qualification (b) (4) used to qualify visual inspectors do not always include defect samples at the lower limits of visual detection established during threshold studies. For example, Test (b) (4) ((b) (4) vial), which was used to requalify visual inspector (b) (6), (b) (7) on 1/21/2026, contains (b) (4) accept units and (b) (4) defect units. Of the (b) (4) defect units, (b) (4) contain foreign material particulates of the following types and sizes: (b) (4) . Your threshold study established a PoD of ≥(b) (4) % for (b) (4) ((b) (4) stopper) particulates; however, defects at this size are not represented in Test (b) (4)

(B) Your firm uses fog generated from (b) (4) and (b) (4) for airflow visualization studies in cleanrooms, including sterile drug product filling lines. However, Study/CC # (03) 26-016.V6, conducted on March 13, 2026, does not provide adequate evidence that the fog is neutrally buoyant. Video observations show the fog was discharged upward in bursts, reversed direction, and fell back.

(C) Your (b) (4) Sterilization Qualification Study #(b) (4)17-025 for the (b) (4) vial established a minimum validated F_0 of (b) (4) and (b) (4) at the worst-case location. However, per SOP US-PU-1027-SOP-OT-000096908, *Operation and Release Criteria for* (b) (4) *Sterilizer* (b) (4) the accepted F_0 value at end of cycle is (b) (4) . You have not demonstrated that an F_0 value as low as (b) (4) , as permitted by your SOP, is sufficient to achieve adequate sterilization for the (b) (4) vial.

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OBSERVATION 3

Verification of the suitability of the testing methods is deficient in that they are not performed under actual conditions of use.

Specifically, your firm does not perform comparative testing for all in-house analytical method transfer studies that compare analytical results between the transferring lab and your receiving lab to determine a successful method transfer. For example, you did not compare the results of the transferring lab with the results of your receiving lab for the transfer of the external labs in-house method ((b) (4)) for the *Determination of Impurities in* (b) (4) *Injection* ((b) (4)) from (b) (4) to FK Grand Island, executed under Protocol: NAM-MVD-FG-000111207.

***DATES OF INSPECTION**

5/05/2026(Tue), 5/06/2026(Wed), 5/07/2026(Thu), 5/08/2026(Fri), 5/11/2026(Mon), 5/12/2026(Tue), 5/13/2026(Wed), 5/14/2026(Thu)

X JoshRenzo N Ramilo
Investigator
Signed By: JOSH RENZO N. RAMILO -S
Date Signed: 05-14-2026 15:26:10

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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."