DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
New York District Office 158-15 Liberty Ave Jamaica, NY 11433 Ph: (718) 340-7000; Fax: (718) 662-5661 CDER-OC-OMQ-Domestic483Response@fda.hhs.gov Industry Information: www.fda.gov/oc/industry	03/16/2026-03/27/2026* FEI NUMBER 3014926340

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED
Mr. Samit K. Deb, Chief Technical Officer and President- Global Operations

TO: FIRM NAME	STREET ADDRESS
RK Pharma Inc.	401 N Middletown Rd Building 215/215A
CITY, STATE, ZIP CODE, COUNTRY Pearl River, NY 10965-1298	TYPE ESTABLISHMENT INSPECTED Drug Product 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 I OBSERVED:

OBSERVATION 1

Laboratory controls do not include the establishment of scientifically sound and appropriate specifications and test procedures designed to assure that drug products conform to appropriate standards of identity, strength, quality and purity. Specifically,

There is no assurance that your visual inspection process can reliably detect and reject vials containing visible particulates or critical defects, of batches intended for commercial distribution. During the review of your visual inspection procedure and acceptance criteria associated with (b)(4), we observed the following deficiencies:

A. Your visual inspector qualification (b)(4) contains particles ranging from (b)(4) only. The smallest non-fiber particle is (b)(4), and all other non-fiber particles are (b)(4) or (b)(4) (fibers).
B. Your qualification protocol requires (b)(4) detection (b)(4) but uses only particles (b)(4), which have a (b)(4) probability of detection, thereby not actually testing inspectors at the (b)(4) Probability of Detection (PoD) threshold (reject zone).
C. You have not established whether inspectors can detect particles near the visible limit (b)(4) range) and are qualifying inspectors only on easy-to-detect particles with (b)(4) probability of detection.
D. Protocol (b)(4) for qualification of visual inspection (b)(4) does not list the major defect categories in the preparation and qualification (b)(4) for inspectors, and no acceptance criteria are established for major defects; however, you have specified a defect limit of NMT (b)(4)

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	Robin Mathew Lata Mathew	Robin P. Mathew, Investigator Lata C. Mathew, PhD Preapproval Manager / Investigator	03/27/2026

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E. Your specified limits for critical defects (b)(4), major defects ((b)(4)), and minor defects ((b)(4)) lack scientific justification compared to acceptable AQL standards.

Category	100% Level 1	AQL Limit Level 2
Critical defect limit		(b)(4)
Major defect limit		(b)(4)
Minor defect limit		(b)(4)

All (b)(4) Exhibit batches (b)(4) passed the (b)(4) limit but major defect limit was at the upper end of the specification for batch (b)(4) at 100% limit considering the fact that the visual inspectors are not qualified to detect for particles in the (b)(4) range:

Category	100% Level 1	AQL Limit Level 2	(b)(4)		
Critical Defects	NMT	(b)(4)			
Major Defects	NMT				
Minor Defects	NMT				

F. The qualification does not represent actual production—your inspectors are qualified using small-volume vials ((b)(4) mL), but your drug product (b)(4)) is filled in (b)(4) mL vials, which are considered large-volume containers.

G. Some particles are being classified as 'Major, despite protocol saying all particles are Critical ((b)(4))

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Code	Type of defect as per Protocol (b)(4)	As per Batch Record
(b)(4)	White particle : Critical	Major
	Fiber : Critical	Major
	Black Particle / Brown particle : Critical	Major

OBSERVATION 2

Written records of investigations into do not always include the conclusions and follow-up. Specifically,

A. Your firm failed to adequately investigate repeated non-viable particle count (NVPC) excursions in the aseptic filling area and failed to implement effective corrective actions to prevent recurrence. Between November 2024 and January 2025, (b)(4) NVPC excursions occurred during (b)(4) media fills (Batches (b)(4) and (b)(4) and (b)(4) exhibit batches (b)(4)) of (b)(4) :

1. Media Fill batch# (b)(4) , dated (b)(4) - Micro analyst bumped NVPC probe during plate change which resulted in an excursion in the Filling chamber. Training was imparted as part of CAPA.

2. Media Fill batch# (b)(4) , dated (b)(4) : NVPC alert limit exceeded for (b)(4) particles (b)(4) minutes, from (b)(4) on 12/15/2024) in the Filling chamber during active filling. The root cause was attributed to the sampling probe being touched while changing environmental monitoring plates by the microbiologist and training was imparted as part of CAPA.

3. (b)(4) , Exhibit batch# (b)(4) (Investigation MDD-25-003): Particle count excursion occurred when the lid of a settle plate was dropped on the NVPC probe. Training was imparted as part of CAPA.

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Despite three separate incidents of personnel contact with the NVPC probe, each investigation identified only operator retraining as the corrective action. Your investigations did not evaluate other potential root causes such as facility design or the probe location. Your firm did not implement appropriate preventive actions to prevent reoccurrence.

4. (b)(4), Exhibit batch# (b)(4) The NVPC count for (b)(4) particles in filling chamber reached alert limit ((b)(4) particles) due to solution spillage due to the stopper being stuck in the filling turret. The investigation concluded this was an accident; no preventive action was proposed to address stopper jamming or equipment malfunction.

5. (b)(4), Exhibit batch# (b)(4) The NVPC count for (b)(4) particles in capping chamber reached alert limit ((b)(4) particles). The investigation attributed the root cause to a false alarm potentially triggered by vibration and high sensitivity of the system. No preventive action was proposed considering it as an isolated event.

B. Your firm experienced recurring (b)(4) out-of-specification results in the two exhibit batches ((b)(4)) submitted as part of (b)(4) application. (b)(4) failures were observed in exhibit batch (b)(4) -Specification: NMT (b)(4)) and (b)(4) The in-process sample testing from (b)(4) Exhibit Batches (b)(4) and (b)(4)) and (b)(4) ((b)(4) and (b)(4)) also failed to meet the NMT (b)(4) limit for (b)(4)). The failure was attributed to the lack of marking on the (b)(4) needle for fixing the needle in a (b)(4) position. Even after the (b)(4) needle (b)(4) position was identified and marked for subsequent batches, (b)(4) and (b)(4) Exhibit Batch (b)(4) still failed, indicating the corrective action was inadequate.

Further review identified that the application holder's stability data used a different product configuration. The (b)(4) batches (Batch (b)(4) and Batch (b)(4)) were prepared under a

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(b)(4) environment, (b)(4) and (b)(4) in (b)(4) glass vials by (b)(4) The bulk solution of Batch (b)(4) was prepared without a (b)(4) environment, (b)(4) and (b)(4) in (b)(4) glass vials followed by (b)(4) without (b)(4). The exhibit batches were (b)(4) using (b)(4) with a (b)(4) needle, different filling equipment, and different process parameters. Additionally, the investigation states that the product is stable to any oxidative degradation; however, the data shows that the (b)(4) impurity (b)(4) under oxidative condition. The data contradicts the investigation's conclusions and does not support the (b)(4) of the specification from (b)(4)

***DATES OF INSPECTION**

03/16/26, 03/17/26, 03/18/26, 03/19/26, 03/20/26, 03/23/26, 03/25/26, 03/26/26, and 03/27/26.

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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."