DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
CDER/OPQ/OPMA/DPMA VI 10903 New Hampshire Avenue; White Oak Building 51, Room 2269 Silver Spring, MD 20993 E-mail: OPMABLAInspection483Responses@fda.hhs.gov	09/04/2025-09/12/2025
	FEI NUMBER 3014250111

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Jayanth Sridhar, Ph.D., CEO, Global Head of Biologics

FIRM NAME	STREET ADDRESS
Dr. Reddy's Laboratories, LTD, Biologics	Survey No. 47 and 44 (Part), Bachupally Village, Bachupally Mandal, Medchal Malkajgiri District
CITY, STATE, ZIP CODE, COUNTRY Telangana, 500090, India	TYPE ESTABLISHMENT INSPECTED Drug Substance and 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, WE OBSERVED:

OBSERVATION 1

The Quality Unit has not established adequate procedural controls and oversight to ensure the accuracy of environmental monitoring data. Environmental monitoring data from data collection sheets are manually entered into uncontrolled electronic spreadsheets, which are subsequently used to generate reports and graphical analyses. During the inspection, multiple discrepancies and inaccuracies were identified between the source data and the corresponding reports. Due to inaccurate and incomplete environmental monitoring data, the effectiveness of corrective and preventive actions (CAPA) implemented in response to Observation 2 from the Form FDA 483 issued October 2023 cannot be adequately assessed. Specifically,

A. Deviation reports contained inaccurate data on mold recoveries.
   i. Deviation DV2000016762 report lists inaccurate mold counts data which differ from source data form (FORM-BTO-QC-0108, Doc. Control no. 72).

B. (b) (4) Trend Analysis Summary Report for Environmental Monitoring in (b) (4) RP-BTO-003811, Version 1.0, approved on April 8, 2025) contained inaccurate data on mold recoveries compared to corresponding deviation reports or discrepancies:

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SEE REVERSE OF THIS PAGE	Madushini N Dharmasena -S Baikuntha P. Aryal -S Digitally signed by Baikuntha P. Aryal -S Date: 2025.09.12 16:18:44 +05'30' JIANGSONG JIANG -S (Affiliate) Digitally signed by JIANGSONG JIANG -S (Affiliate) Date: 2025.09.12 06:58:45 -04'00'	Madushini Dharmasena, Ph.D., Senior Pharmaceutical Quality Assessor Baikuntha Aryal, Ph.D., Pharmaceutical Scientist Jiangsong Jiang, Ph.D., Pharmaceutical Scientist	9/12/2025

i. Section 4.1. No. of Fungal Recoveries in Grade C and D areas as per [(b) (4)] graph (Figure-2: Graphical representation of [(b) (4)] Fungal recoveries in Grade-C & D from [(b) (4)] Fungal trend in Grade-C & D) lacked a y-axis label. Although the firm stated the y-axis represents cumulative mold recoveries (CFU) per [(b) (4)] mold recovery data from related deviations (DV2000016618, DV2000016662, and DV2000016965) were not accurately included in the analysis.

ii. Section 4.2. Fungal counts recovery in Grade-C Settle plate monitoring excluded deviations (DV2000017128 and DV2000015438) for analysis.

iii. Section 4.3. Fungal counts recovery in Grade-C Active air sampling excluded deviations or contained inaccurate data (DV2000015799, DV2000015522, DV2000018464) for analysis.

iv. Section 4.4. Fungal counts recovery in Grade-D Settle plate monitoring contained the following discrepancies:

   a. Graph 4.4.1 heading incorrectly stated "graphical representation of fungal counts recovery in Grade D Active air monitoring," while the graph was labeled [(b) (4)] Fungal counts in Settle plate Grade-D".

   b. Fungal counts recovery in Grade-D Settle plate monitoring contained inaccurate data from deviations (DV2000016762).

v. Section 4.5. Fungal counts recovery in Grade-D Active air sampling excluded deviations or contained inaccurate data (DV2000017472 and DV2000016662) for analysis.

C. Summary of retrospective assessment for incident related to environmental monitoring excursions in [(b) (4)] facility (Duration: [(b) (4)] to [(b) (4)] (document No. RP-BTO-004435, Version 1.0, Approved on September 1, 2025) contained incomplete and inaccurate

data presentation. The summary graph entitled "Mold recoveries: No. of Instances with mold recoveries observed with ≥ (b)(4) count from (b)(4) facility (From (b)(4) to (b)(4)" failed to include all documented mold counts ≥ (b)(4) CFU for grade-D classified areas from (b)(4) to (b)(4)

OBSERVATION 2

The firm failed to establish adequate document control procedures and oversight mechanisms to ensure appropriate management of written documents. Specifically,

The current DOCHUB system permits users to download approved documents in Microsoft Word format without embedded approval signatures. This system configuration creates the potential for unauthorized document modification, as users can alter content and subsequently save documents in PDF format, generating uncontrolled copies. This practice is inconsistent with the firm's own work instruction document (WI-GLOB-IT-0304, effective July 12, 2024), which restricts export or printing of uncontrolled document copies to authorized document coordinators and system administrators only. Specifically, documents (No. RP-BTO-001232, RP-BTO-001234, RP-BTO-001235, RP-BTO-001237 and RP-BTO-001238) provided in PDF format (in response to records requests pursuant to Section 704(a)(4) of the Federal Food, Drug, and Cosmetic Act) displayed approval status but lacked the required approval signatures of reviewing and approving officials and approval dates.

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OBSERVATION 3

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile did not include adequate aseptic techniques during aseptic filling setup for (b) (4) Batch No. (b) (4) Specifically,

A. Precautions to reduce the potential block of first air were not followed during aseptic fill line set up for (b) (4) filling on September 8, 2025 to assure sterility of the unprotected sterile surfaces.

   i. During stopper bowl installation, a part of the open stopper bowl was placed below the non-sterile (b) (4) which blocked first air for the open stopper bowl.

   ii. ~~During stopper bowl installation, a part of the open stopper bowl was placed below the non-sterile (b) (4) which blocked first air for the open stopper bowl.~~ The operator was observed blocking first air to stoppers in the stopper bowl while using the (b) (4) at (b) (4) to open the (b) (4) to add stoppers to the stopper bowl. The smoke study video (at time stamp April 21 2025 (b) (4) Video name (b) (4) also shows (b) (4) blocking the first air to stoppers in the stopper bowl while opening the (b) (4) to add more stoppers to the stopper bowl.

   iii. During installation, the (b) (4) were mounted onto the non-sterile (b) (4) (b) (4) As a result, the non-sterile (b) (4) blocked first air for the (b) (4) (b) (4) during filling operation.

   iv. ~~During stopper bowl installation, a part of the open stopper bowl was placed below the non-sterile (b) (4) which blocked first air for the open stopper bowl.~~ After the (b) (4) covers were removed with the tweezers, the operator was observed blocking first air to the unprotected (b) (4) while adjusting the

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	Baikuntha P. Aryal -S Digitally signed by Baikuntha P. Aryal -S Date: 2025.09.12 16:16:12 +05'30'	Baikuntha Aryal, Ph.D., Pharmaceutical Scientist	9/12/2025
	JIANGSONG JIANG -S (Affiliate) Digitally signed by JIANGSONG JIANG -S (Affiliate) Date: 2025.09.12 07:01:25 -04'00'	Jiangsong Jiang, Ph.D., Pharmaceutical Scientist	

tubes and (b) (4) with (b) (4) The smoke study videos (at Time stamp April 20, 2025 (b) (4) (video and at time stamp April 20, 2025 (b) (4) (video (b) (4) also show the operator's (b) (4) blocking the first air to open while adjusting the (b) (4)

B. (b) (4) were utilized on (b) (4) during operations. However, post-filling sampling procedures involved contact plate sampling of only (b) (4) thereby preventing assurance of sterility for (b) (4) surfaces.

C. The sterility of (b) (4) could not be assured due to the placement of a (b) (4) (b) (4) positioned below the (b) (4) at the initiation of filling operations to collect (b) (4) (b) (4) The (b) (4) collected in the (b) (4) presented a risk of (b) (4) Additionally, the (b) (4) cannot be considered sterile as it undergoes sanitization only during (b) (4) procedures rather than sterilization.

D. Small area of open skin was noticed between the goggles and the mask of one of the operators during the fill line set up. Open skin was also noticed on the smoke study video of (b) (4) interventions (Time stamp April 21, 2025 (b) (4) video name (b) (4)

OBSERVATION 4

The risk assessment (QUA-BTO-2275 - Risk assessment for viral cross-contamination control in drug product manufacturing at the (b) (4) facility, version 2, approved on August 8, 2025) for viral control at Dr. Reddy's Laboratories is inadequate to mitigate the potential virus cross

contamination risk of (b) (4) drug product (DP) and does not align with the current industry standards and ICH Q5A guidelines. The manufacturing of (b) (4) DP intended for the United States market is conducted in a shared manufacturing facility (b) (4) which concurrently processes multiple drug products for non-United States markets, including (b) (4) (b) (4) (b) (4) The drug substance for these non-United States market products is manufactured in facilities (b) (4) with the exception of (b) (4) which is manufactured in (b) (4) Unprocessed bulk harvest materials for non-United States market products manufactured in (b) (4) do not undergo routine adventitious virus testing for commercial production batches. While (b) (4) DP manufacturing within (b) (4) utilizes dedicated product contact equipment, non-United States market DP that have not undergone the adventitious virus testing share the same Restricted Access Barrier Systems (RABS). Most shared surfaces are sanitized but not sterilized between product changeovers. Although the risk assessment proposes cleaning and sanitization strategies, these strategies fail to demonstrate elimination of viral cross-contamination risk.

OBSERVATION 5

Written documents are inadequate to ensure proper documentation and analysis of critical manufacturing operations. Specifically,

A. Report VALRP-BTO-002395, Summary report for airflow visualization study and assessment of aseptic interventions during vial filling (b) (4) (Version 1.0, approved on September 3, 2025), failed to provide a comprehensive analysis of the smoke study videos and contained only a checklist of interventions performed. The report did not adequately evaluate or document

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critical observations from the video footage that could impact sterility assurance. Specifically, raw smoke study videos (file name (b) (4) Time stamp: August 21, 2025 (b) (4) (b) (4) showed some smoke moving against the flow direction with observable turbulence, indicating potential disruption of unidirectional airflow patterns. However, this event was not documented, analyzed, or addressed in the corresponding report.

B. Report VALRP-BTO-002193-50 ml, Revalidation of (b) (4) 01), (version 1.0, approved on February 20, 2025), does not contain complete record of data and comprehensive analysis for major tests, including (b) (4) (b) (4) test) and endotoxin challenge study. Each test result is documented with only a single sentence described as "Observations," which fails to provide the detailed data analysis and comprehensive evaluation necessary to demonstrate that the equipment consistently performs as intended.

C. SOP-BTO-PR-0393, Aseptic Assembling and disassembling of Sterilized Accessories of Vial Filling and Stoppering Machine (b) (4) VF-01), (Version12, effective date August 8, 2025), Step (b) (4) lists an operation that was not performed. Specifically, step (b) (4) required to (b) (4) RABS (b) (4) at the (b) (4) of the filling machine. However, this operation was not performed during the (b) (4) filling line setup on September 8, 2025.

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