DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
CDER/OPQ/OPMA/DPMA VI Attn: Christopher Downey, Ph.D., Division Director 10903 New Hampshire Avenue; White Oak Building 51/Room 2269 Silver Spring, MD 20993-0002 E-mail: OPMABLAInspection483Responses@fda.hhs.gov	6/16/2026 - 6/19/2026 and 6/22/2026 – 6/25/2026
	FEI NUMBER 3014250111

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Anoop Rajashekar, Head of Quality Biologics & CGT	
FIRM NAME Dr. Reddy's Laboratories Ltd.	STREET ADDRESS Survey No. 47 & 44 (Part)
CITY, STATE, ZIP CODE, COUNTRY Bachupally (Village & Mandal), Telangana, India	TYPE ESTABLISHMENT INSPECTED Drug Product and Drug Substance 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

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile do not include adequate aseptic practices. During filling of (b) (4) drug product batch number (b) (4) on June 18, 2026, in the (b) (4) filling line, inadequate aseptic practices were observed. Specifically,

A. The (b) (4) and stopper bowl were assembled into the (b) (4) and were uncovered prior to initiation of the (b) (4) decontamination cycle. As a result, these sterilized components were exposed to the (b) (4) decontamination agent prior to filling operations, compromising the sterility of these items. Sterilized components introduced into the (b) (4) should not be subjected to conditions that could compromise their sterility assurance.

B. During loading of (b) (4) sterilized stoppers into the (b) (4), the (b) (4) (b) (4), which is not sterilized and is only exposed to the (b) (4) decontamination cycle, is positioned directly above the (b) (4) When (b) (4), the (b) (4) blocks unidirectional first air to the (b) (4), exposing the sterilized (b) (4) to potential microbial contamination.

C. During loading of the (b) (4) sterilized stoppers into the (b) (4), a large number of stoppers were observed making direct contact with an unsterilized (b) (4) positioned above the (b) (4) Contact between sterilized stoppers and an unsterilized surface compromise the sterility of the stoppers prior to their placement on vials.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
	AYYAPPAN RATHAKRISHNAN -S Digitally signed by AYYAPPAN RATHAKRISHNAN -S Date: 2026.06.25 06:42:02 -04'00' ALEXANDER R. SOHR -S Digitally signed by ALEXANDER R. SOHR -S Date: 2026.06.25 06:46:49 -04'00' Maria G. Gutierrez-hoffmann -S Digitally signed by Maria G. Gutierrez-hoffmann -S Date: 2026.06.25 06:49:47 -04'00'	Ayyappan Rathakrishnan, Ph.D., Pharmaceutical Scientist Alexander Sohr, Ph.D., Pharmaceutical Scientist Maria Gutierrez-Hoffmann, Ph.D., Senior Pharmaceutical Scientist	June 25, 2026

D. During installation of the (b) (4), each (b) (4) was assembled onto a non-sterile (b) (4). Although each (b) (4) was individually protected by a cover prior to installation, the top of each protective cover was observed contacting the unsterile (b) (4). Upon removal of the protective cover, the cover was slid along the full length of the (b) (4), such that the top portion of the cover contacted the entire length of the (b) (4), including the (b) (4). This practice compromises the sterility of the (b) (4) and presents a direct contamination risk to the drug product.

E. The (b) (4), under which vials are capped during the stoppering operation, is positioned such that it blocks unidirectional first air to all vials passing beneath it. The (b) (4) (b) (4) is not sterilized and is only exposed to the (b) (4) decontamination cycle. Because all vials must pass under this (b) (4) during stoppering, this unsterilized surface is in direct proximity to open vials and exposed stoppers, representing an uncontrolled contamination risk to the drug product.

F. During filling of (b) (4) drug product batch number (b) (4) on June 22, 2026, in the (b) (4) Restricted Access Barrier System (RABS) vial filling line (Grade A within a Grade B environment), inadequate aseptic practices were observed. Specifically,

i. Operators were observed moving back and forth between the Grade B area and the Grade A air-supplied area outside the RABS through which stoppered vials transit via conveyor belt to the capping machine. Although a (b) (4) is present between the operators and the stoppered vials on the conveyor, operators were observed reaching (b) (4) (b) (4) into the Grade A zone to manually discard vials identified as lacking stoppers or as (b) (4). This practice introduces personnel, who have been present in the lower-classified Grade B environment, into direct proximity with potentially (b) (4) vials within the Grade A zone, compromising the sterility

of the drug product. The repeated ingress and egress of operator arms (b) (4) (b) (4), as well as operators extending over the (b) (4), disrupts the integrity of the Grade A air supply and increases the risk of microbial contamination of the drug product. This inadequate aseptic practice is visible at minute 10:59:19 in airflow simulation video IMN09, titled "Removal of unstoppered or (b) (4) or fallen vials over (b) (4) (b) (4) conveyor (Smoke Study, (b) (4))", filmed on August 22, 2025.

OBSERVATION 2

Aseptic processing environmental monitoring procedures are inadequate in the (b) (4) filling line. Specifically,

A. On June 24, 2026, following filling of (b) (4) drug product batch number (b) (4), environmental monitoring failed to include viable surface monitoring of the (b) (4) (b) (4) and stopper bowl. The inadequate (b) (4) design does not allow for effective monitoring strategies for these indirect product-contact surfaces, which compromises sterility assurance of the drug product as the potential microbial load on these components during filling operations remains unknown.

B. On June 23, 2026, following filling of (b) (4) drug product batch number (b) (4) and (b) (4) drug product batch number (b) (4), improper (b) (4) fingertip contact plate monitoring technique was observed, as approximately only one second of non-rolling finger contact with the contact plates was observed. This inadequate contact time undermines the reliability of environmental monitoring data.

C. On June 23, 2026, during environmental monitoring of the (b) (4) (b) (4) module of the (b) (4) following filling of (b) (4) drug product batch number (b) (4) complete absence of a non-viable particle monitor in the transfer conveyor

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area during (b) (4) unloading was observed. This constitutes a critical gap in the environmental monitoring program as adequate air quality control during a sterility-critical operation cannot be demonstrated.

OBSERVATION 3

The (b) (4) drug substance manufacturing process lacks adequate controls to prevent microbial contamination of in-process intermediates. Specifically, (b) (4) (b) (4) microorganism, was identified in the (b) (4) (batch number (b) (4) indicating contamination events across multiple unit operations.

OBSERVATION 4

Aseptic practices observed in air visualization studies (b) (4) drug product filling operations are inadequate in that first air was obstructed in different (b) (4) critical zones during aseptic processing interventions. Specifically,

i. Airflow visualization (smoke) studies conducted on 17/12/2024 (December 17, 2024) for Intervention: Filling machine (b) (4) adjustment vial maximum load (b) (4) at (b) (4), show that a (b) (4) positioned above the (b) (4) would likely block first air to all vials as they are transported in the (b) (4)

ii. Airflow visualization (smoke) studies conducted on 19/12/2024 (December 19, 2024, 19:22:22) for Intervention: Adjustment of stoppering machine parts (b) (4), show that a (b) (4) positioned above the (b) (4) and a (b) (4) hand blocked first air to exposed stoppers.

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The (b) (4) and/or (b) (4) hand were positioned such that they blocked first air to either open vials or exposed stoppers (direct product-contact surfaces) in Grade A critical zones within the (b) (4) during inherent and non-inherent interventions, increasing the risk of microbiological contamination of the sterile drug product.

OBSERVATION 5

The visual inspection program for (b) (4) drug product is inadequate. Specifically,

A. The classification of defect categories (i.e., critical, major, and minor) is not adequately justified. For example, black and colored particles, which present a significant risk to patient safety and are indicative of potential contamination, have been inappropriately classified as major defects rather than critical defects.

B. Visual inspection qualification kits include vials marked with numbers visible to personnel performing qualification testing. This practice compromises the integrity of the qualification process, as inspectors may become familiar with the identity and location of defective vials prior to qualification testing.

OBSERVATION 6

Your firm failed to review in-process bioburden testing results for (b) (4) drug substance, as microbial colony growth was detected in multiple in-process (b) (4) samples. The microorganism recoveries were not identified, and root cause investigations were not performed. Specifically,

A. (b) (4) Batch No. (b) (4) : Bioburden testing conducted on April 25, 2025, yielded (b) (4) microbial colonies.

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B. (b) (4) Batch No. (b) (4) : Bioburden testing conducted on May 2, 2025, yielded (b) (4) microbial colony.

C. (b) (4) Batch No. (b) (4) : Bioburden testing conducted on May 10, 2025, yielded (b) (4) microbial colonies.

OBSERVATION 7

Your firm failed to ensure that operators working in aseptic manufacturing areas are adequately trained, as evidenced by deficient On-the-Job Training (OJT) records for personnel in the (b) (4) area. Specifically,

Review of the On-the-Job Training Record (record number (b) (4) for Employee ID: (b) (6) shows that individual skill training sessions for critical aseptic manufacturing operations were documented as lasting as few as 29 minutes (Participate in BPR execution and closure activity, documented November 10, 2025, (b) (4) and 9 minutes (Procedure for operation and cleaning of (b) (4) LAF, documented November 10, 2025, (b) (4) .

These session durations do not provide reasonable assurance that the employee received sufficient training to competently perform complex aseptic operations, including equipment cleaning and sterilization activities that are critical to product sterility assurance.