DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
United States Food and Drug Administration 12420 Parklawn Drive, Room 2032 Rockville, MD 20857 Industry Information: www.fda.gov/oc/industry	09/01/2025 - 09/05/2025
	FEI NUMBER 3002807544

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Mr. Ged O'shea, Site Leader

FIRM NAME	STREET ADDRESS
Dr. Reddy's Laboratories (EU) Ltd.	Steanard Lane
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Mirfield, West Yorkshire, WF14 8HZ, UK	API Manufacturer

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DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

OBSERVATION 1

Failure to establish adequate specifications, sampling plans, and testing procedures to ensure that raw materials and APIs meet accepted quality standards and are consistent with the manufacturing process. Specifically,

A. Your firm failed to perform an adequate assessment to determine whether microbial testing is required for the finished active pharmaceutical ingredient (API), (b) (4) This API is intended for use in the manufacture of (b) (4) drug products (b) (4) and utilizes (b) (4) water as an ingredient during (b) (4) is intended for US market distribution, and since 2020, (b) (4) batches (Batch (b) (4) have been distributed into the US market. Given that this API is intended for (b) (4) use and (b) (4) water is incorporated during (b) (4) your firm should have conducted a risk assessment or any other evaluation to determine appropriate microbial testing requirements, to assure that the (b) (4) API have the quality, and purity they purport or are represented to possess.

B. Your firm failed to perform Burkholderia cepacia testing on your USP (b) (4) Water used as an ingredient during (b) (4) of (b) (4) API and (b) (4) API. (b) (4) API is intended for (b) (4) use, and since 2020, (b) (4) batches (Batch (b) (4) have been distributed into the US market. (b) (4) API is shipped to the firm's main facility in India to be used in (b) (4) which are intended to be distributed into the US market.

OBSERVATION 2

Certificates of analysis from raw material suppliers are accepted in lieu of testing each component for

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conformance to written specifications, without performing at least one component-specific identity test or establishing the reliability of the supplier's analyses through appropriate validation at appropriate intervals. Specifically,

During the inspection conducted from September 1-5, 2025, record review revealed that your firm received (b) (4) (b) (4) lots of (b) (4) (Batch (b) (4) from (b) (4) between December 2024 and June 2025. These lots were released to production based solely on the supplier's certificate of analysis. Your firm failed to validate (b) (4) analytical methods since establishing the business relationship in (b) (4) In addition, no identity or microbiological testing was performed to ensure that the (b) (4) conform to established standards of quality and purity.

(b) (4) is used during the (b) (4) stage of (b) (4) processing as part of the (b) (4) process. (b) (4) API is intended for use in the manufacture of (b) (4) finished drug products.

OBSERVATION 3

Failure to adequately validate written procedures for the cleaning and maintenance of equipment.

Your firm did not perform cleaning validation to demonstrate the effectiveness of its cleaning procedures for the (b) (4) used to package (b) (4) API. According to the equipment cleaning records, the (b) (4) has been cleaned (b) (4) times since the last batch of (b) (4) API was packaged on (b) (4) However, during the inspection walkthrough conducted on September 1, 2025, we observed what appeared to be (b) (4) residue on the (b) (4) located on the top of the (b) (4) despite the equipment being identified as clean. Therefore, by not performing cleaning validation for the (b) (4) your firm fails to ensure complete removal of product residues and demonstrate that cleaning procedures are effective in preventing cross-contamination between different batches.

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OBSERVATION 4

Written records of investigations into unexplained discrepancies do not always include the conclusion and follow-up.

Investigations initiated and performed by your Quality Unit in response to laboratory investigation reports (OOS) for active pharmaceutical ingredients, are not always comprehensive to determine all potential root causes. Additionally, Corrective and Preventive Actions (CAPAs) as a result of investigations are not always comprehensive to address root causes or adequately documented to have been performed. For Example,

A. Since 2021, your firm has initiated six OOS investigations for [redacted] (b) (4) API related to [redacted] (b) (4) impurities stability testing at 24, 36, and 48-month timepoints, all of which were confirmed as valid OOS results. These investigations include: OOS/21/001 dated January 11, 2021 (batch [redacted] (b) (4) OOS/22/004 dated February 4, 2022 (batch [redacted] (b) (4) OOS/24/021 dated August 19, 2024 (batch [redacted] (b) (4) OOS/25/005 dated February 19, 2025 (batch [redacted] (b) (4) and OOS/25/006 dated February 21, 2025 (batch [redacted] (b) (4) Your firm has not adequately addressed this recurring deficiency despite the repeated nature of these failures. Your firm's root cause analysis attributes these OOS results to hydrolysis in the presence of water, potentially due to stability sample packaging deficiencies.

The investigations revealed additional significant deficiencies in your quality systems. OOS/24/021 resulted in a product recall for batch [redacted] (b) (4) after your investigation identified production process issues and the discovery of a previously missed out-of-trend (OOT) result at an earlier testing timepoint. Similarly, OOS/25/005 revealed that your firm had failed to identify and investigate an OOT and OOS result at a previous testing station, indicating failures in data review and trending. Furthermore, although OOS investigations 25/005 and 25/006 have been closed and the results confirmed as valid, your firm appears to have failed to notify customers of these product quality failures as required by your quality agreements.

B. From 2003 to the current inspection, your firm initiated at least four OOS investigations (OOS/23/003, dated January 9, 2023; OOS/23/004, dated January 19, 2023; OOS/25/004, dated January 24, 2025; and OOS/25/016, dated July 25, 2025) for out-of-specification assay results for [redacted] (b) (4) API batch numbers [redacted] (b) (4)

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[redacted] Your firm's root cause analyses for these investigations consistently identified the same recurring issues: sonication deficiencies and the potential use of [redacted] glassware instead of the required [redacted] glassware. However, CAPA 290013144, dated January 19, 2023, which detailed additional procedures for sonication, proved inadequate as evidenced by the occurrence of additional OOS results in 2025, demonstrating ineffective corrective actions. Furthermore, although your firm identified the critical need fo[redacted] glassware during sample preparation and testing in 2023, this deficiency was not addressed until the initiation of CAPA 290019376 on July 30, 2025, a delay of over two years that allowed the same root cause to persist and contribute to repeated OOS occurrences.

C. OOS Investigation 24/031, dated October 24, 2024, was initiated for KSM [redacted] used in the manufacture of [redacted] API, with out-of-specification results of [redacted]% and [redacted]% versus the specification of NLT [redacted]% (as is). The OOS investigation was initiated on October 24, 2024; however, the investigation was not completed until approximately April 16, 2025, nearly six months later, reportedly due to prioritization of other investigations. Your firm's identified root cause of "gross failure and variation between sample weights" lacks adequate scientific justification to explain the observed analytical results. Furthermore, by the time the investigation was conducted, the original analyst involved in the testing had departed your firm, potentially compromising the completeness and accuracy of the investigation. Your firm failed to initiate adequate corrective and preventive actions (CAPA) and did not request extensions to complete the investigation within established timeframes as required by your firm's OOS procedure.

OBSERVATION 5

The responsibilities and procedures applicable to the quality control unit are not in writing and fully followed.

A. Quality unit oversight over quality control operations is deficient, including laboratory electronic systems and data review.

Your firm currently maintains [redacted] networked HPLC and [redacted] networked GC instruments which utilize Empower 3. Your Quality Unit does not always review all electronic raw data generated by all HPLC/GC laboratory equipment

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and has not demonstrated a clear understanding of various communication errors and circumstances that can lead to aborted, interrupted, or incomplete sequences during HPLC and GC testing using Empower 3 software.

During the inspection, we observed at least 28 sample set projects in Empower 3 where interruptions occurred in the form of project integrity failures. These failures were not adequately reviewed and evaluated by your Quality Unit, and no laboratory incidents were initiated by your firm at the time of these failures.

The interrupted sequences were observed during the review of "Project Integrity Failed" messages, which generated "Data Incomplete" chromatographic data. During the inspection, we were able to verify the incomplete data related to API and KSM analysis. This prompted the software to convert "data incomplete" chromatograms (where no chromatograms were observed) to observable chromatograms, a conversion that your firm did not perform.

During the inspection, your firm retrieved this incomplete data and performed test analysis calculations for a sample set to evaluate the interrupted sample set. Furthermore, our review found that your firm has not performed the necessary investigations and risk assessments to determine and understand the root cause for these interrupted sequences.

B. Your firm's self-inspection program fails to effectively utilize quality data from ongoing monitoring activities. SOP No. MIR/07/026/08, "Self Inspection (Internal Audit)" (effective date June 13, 2024), establishes that internal audit frequency should be based on previous audit findings, including those from customer and regulatory audits. However, this procedure excludes findings from your firm's own Quality Walkthrough program conducted under SOP No. MIR/07/080/01, "Quality Walkthroughs" (effective date May 18, 2023). Our review of approximately (b) (4) (b) (4) of Quality Walkthrough data revealed too numerous to list deficiencies, including inappropriate approved and expired raw material storage, that your firm identified but failed to address systematically. Your firm does not generate incidents for Quality Walkthrough findings, eliminating the ability to trend deficiencies and identify recurring problem areas. As a result, important quality information that could help determine when and where to conduct internal audits is not being used, creating a disconnect between your ongoing quality monitoring and formal self-inspection activities.

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OBSERVATION 6

Document control procedures under Quality Unit oversight are inadequate.

During our walkthrough on 09/01/2025, an email document dated August 27, 2025, was discovered in your firm's outside trash bin detailing a quality walkthrough of Area (b) (4) building where (b) (4) API is manufactured. This walkthrough identified multiple deficiencies including ancillary items such as hoses and adapters in wrong boxes, dusty bags and boxes, and peeling (b) (4) on the ceiling that was not properly adhered. According to your firm's SOP No. MIR/07/080/01, titled "Quality Walkthroughs" (effective date May 18, 2023), (b) (4) quality walkthroughs are performed by the quality assurance unit to focus on adherence to good manufacturing practices; however, your firm indicated this was an "informal quality walkthrough" that was not documented in the quality unit system.

Additionally, your firm utilizes shred bins for record disposal without maintaining written procedures detailing shredding operations and which documents are permitted to be shredded. During inspection of the QA and QC office, the following records requiring retention for traceability purposes were observed in shred bins awaiting third-party destruction:

-Torn paper with handwritten warehouse material numbers for reconciliation.
-Handwritten notes summarizing (b) (4) water sampling points.
-Two draft incident reports for incident #200435667 regarding an anomaly with water supply (b) (4) during routine maintenance.
-QC analytical worksheet for determination of purity and (b) (4) of (b) (4) bearing analyst signature.

OBSERVATION 7

Manually managed materials in the warehouse and facilities are not separated during storage.

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This is a repeat observation from the last inspection, and your firm's corrective actions appear to have been inadequate. We reviewed Incident 200433432, dated December 2, 2024, which documented materials that were labeled as approved despite being past their retest date. Quality Walkthroughs dated (b) (4) (b) (4) identified deficiencies including inadequate segregation of materials and rejected materials in your warehouse facilities. Additionally, there is no justification for your firm's failure to open incidents as a result of the deficiencies observed during the Quality Walkthroughs performed by QA.

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