DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032 Rockville, MD 20857 CDER-OC-OMQ-International483Response@fda.hhs.gov	12/04/2025-12/12/2025
	FEI NUMBER 3009193040

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Mr. M S Madhu Sundar, Head Global Manufacturing

FIRM NAME	STREET ADDRESS
Dr. Reddy's Laboratories Limited	FTO-SEZ, Process Unit-01, Devunipalavalasa (Village), Ranasthalam (Mandal)
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Srikakulam, Andhra Pradesh, India 532409	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

There is a failure to thoroughly review any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

Specifically,

A. On 4/28/2025, you recorded non-conformances 310028189 and 310028200 for (b) (4) (b)(4) ((b) (4) for Dissolution by HPLC. The OOS results were recorded for (b) (4) Batch No's. (b)(4) (OOS No. 310028189) and (b)(4) (OOS No. 310028200). Both the batches failed the dissolution test for Tablet Unit-(b) (4) % (Batch No. (b)(4)) and (b) (4) % (Batch No. (b)(4)) against the Specification NLT (not less than) (b) (4) % (Q) of the labeled amount of (b)(4) dissolved in (b) (4)

The above two batches were analyzed in a set of three batches, Batch No's; (b) (4) (b) (4) in that order) by the same analyst ((b) (6)). In Phase I, you confirmed the OOS result via Re-Measurement Testing. No root cause was identified in Phase I. You assumed that "OOS result might be the cause of paddle not placed for subjected unit (Unit(b) (4) ". Based on this hypothesis, you repeated the analysis with fresh sample preparation and based on the passing results (DS-(b) (4) % for Batch No. (b)(4) , DS-(b) (4) % for Batch No. (b)(4)),

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you invalidated the initial OOS results and released the batch.

You carried out Phase II Manufacturing investigation only to verify the various process parameters. Your Site QA Head (b) (6) stated that the (b) (4) is on (b) (4) test and (b) (4) batch or (b) (4) batch whichever is earlier is tested for description, (b) (4) assay, and KF. You stated that the (b) (4) for the subject batches Batch No's (b)(4) and (b)(4) were 2nd and 3rd batches for 2025 and did not need testing.

On 12/9/2025, your analyst (b) (6) reviewed FORM-FS01-QC-0358 Version 4.0, Check List for the Dissolution Analysis for the dissolution test for the implicated batches and confirmed that the paddles were placed as per the numbering. The analyst also confirmed in the Check List that Tablets were disintegrated completely at the end of the run. These recorded information by the analyst (at the time of analysis) in the Check List does not support the root cause and retesting.

The (b) (4) Batch No's (b)(4) and (b)(4) were used to manufacture (b)(4) (b)(4) Batch No's (b)(4) (Mfg. date 4/6/2025 and Expiry date (b) (4) and (b)(4) (Mfg. date 4/15/2025 and Expiry date (b) (4) respectively. You shipped a total of (b)(4) bottles ((b)(4) tablets) of the above bathes to the US market.

B. On 1/23/2025, you recorded a major deviation, DV2000020047 for (b)(4) mg for Dissolution by HPLC. The deviation was recorded for Batch No. (b)(4) when an extraneous peak at (b) (4) was recorded for Tablet Unit-(b) (4) % against to standard area response, Specification NMT(b) (4) %. Remeasurement of the Same vial confirmed the extraneous peak, but this peak was missing from the Benck top solution. Phase I investigation did not reveal any assignable root cause. You concluded that the dropper (that was used to transfer the test solution into the HPLC vial) could be the most probable cause for the extraneous peak. You then made new sample and based on the passing dissolution test values, you invalidated the initial results and released the batch.

The (b) (4) Batch No. (b)(4) was used to manufacture (b)(4) (b)(4) Batch No. (b)(4) (Mfg. date 1/11/2025 and Expiry date (b) (4) You shipped a total of (b) (4) bottles (b) (4) tablets) of the above bathes to the US market.

C. You have received multiple market complaints for (b)(4) and made several markets recalls on a select campaign batches. You unsubstantiated the Market Complaints for the (b)(4) batches that were not part of this campaign. E. g. on 1/28/2025 you received a Market Complain # 200433853 for (b)(4) Batch No's. (b)(4) and (b)(4). The pharmacy reported, "One tablet with the incorrect imprint on it which matches the (b) (4) strength however the color of the tablet is correct as similar to other tablets." These two batches were not part of the campaign that were implicated for the market recall. You assumed that the tablets from a "recall batch" were mixed at the pharmacy.

OBSERVATION 2

Control procedures are not established which validate the performance of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process material and the drug product.

Specifically, you qualified your Tablet Compression Machine ID # PR034 and (b) (4) (b) (4) ID # PR034 in Room (b)(4) as per the Performance Qualification Report FTS1PRPR034-01 (Effective date 8/8/2013). On 3/16/2024 the (b) (4) ID # PR034 underwent breakdown during the manufacturing of (b)(4) Batch No. (b)(4). You replaced (b) (4) ID # PR034 with a different (b) (4) ID # PR182 and continued with the manufacturing of (b)(4) Batch No. (b)(4). As of 12/12/2025, you have not requalified your Tablet Compression Machine ID # PR034 and (b) (4) (b) (4) ID # PR182 assembly in Room (b)(4). The make and model of the (b) (4) (b) (4) ID's # (b) (4) are different. Your Head of Production (b) (6) stated that the working principles for (b) (4) are same thus requalification is not

needed.

You manufacture multiple drug products on Tablet Compression Machine ID # PR034 and (b) (4) ID # PR182 in (b)(4) for the US market. E. g. (b)(4), (b)(4), (b)(4), (b)(4), (b) (4)), (b)(4), (b)(4), (b) (4), (b)(4), (b)(4), and (b)(4).

OBSERVATION 3

Written procedures are not established for the cleaning and maintenance of equipment, including utensils, used in the manufacture, processing, packing or holding of a drug product.

Specifically, you practice cleaning validation for equipment trains for the worst-case molecule. The cleaning validation for your Tablet Compression Machine ID # PR034 and (b) (4) ID # PR034 in (b)(4) was conducted in an equipment train for (b) (4) Tablet as the worst-case molecule as reported in Cleaning Validation Report for (b) (4) Tablets VALRP-FS01-000310 (Effective date 10/6/2020). On 3/16/2024 the (b) (4) (b)(4) ID # PR034 underwent breakdown during the manufacturing of Batch No. (b)(4). You replaced (b) (4) ID # PR034 with a different (b) (4) (b) (4) ID # PR182. After changing the equipment, you did not re-validate the cleaning of the new equipment train. Your Head of Production ((b) (6)) stated that the surface area of PR182 ((b)(4) ^{2}) is higher than PR034 ((b)(4) ^{2}). After multiple requests, you were unable to provide surface area calculations for the (b) (4) ID # PR034 for verification.

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OBSERVATION 4

Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the final specifications prior to release.

Specifically,

A. Section 5.10.6 of your procedure, SOP-GLOB-QC-0085 Version 13.0 Good Analytical Practices (Effective date 7/25/2025) requires (b) (4) measurements from each preparation for assay test methods by HPLC. However, you have validated the assay test methods by HPLC from a single measurement from each preparation. E. g.

   a. (b) (4) Tablets USP (b) (4) mg (b) (4) Assay Method Validation Report No. RP-FS01-000060 Version 2.0 (Effective date 3/27/2020). Linearity of test method was established from concentration range (b) (4) µgm/mL – (b)(4) µgm/mL (b) (4) % - (b)(4) % of the standard solution) at (b) (4) intervals with a single measurement at each concentration. You routinely use this test method to release (b) (4) Tablets USP (b) (4) mg (b) (4) to the US market.

   b. (b) (4) in (b) (4) Table (b) (4) mg/(b) (4) mg, Assay (by HPLC) Method Validation Report No. RP-FS01-002324 Version 1.0 (Effective date 7/11/2024). Linearity of test method was established from concentration range (b) (4) % to (b) (4) % (of the standard solution) at (b) (4) ntervals with a single measurement at each concentration. You have used this test method for the exhibit batches of (b) (4) (b) (4) Tablet (b) (4) mg/(b) (4) and (b) (4) mg (b) (4) that are manufactured to support (b) (4)

   c. (b) (4) in (b) (4) Tablet (b) (4) mg/(b) (4) mg, Assay (by HPLC) Method Validation Report No. RP-FS01-002337 Version 1.0 (Effective date

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7/11/2024). Linearity of test method was established from concentration range (b) (4) to (b) (4) % (of the standard solution) a (b) (4) ntervals with a single measurement at each concentration. You have used this test method for the exhibit batches of (b)(4) (b)(4) that are manufactured to support (b) (4)

B. Your procedure SOP-FS01-PR-0067 Version 14.0 Production Procedure and Controls (Manufacturing + Packing) (Effective date 12/13/2023) does not ensure that the visual inspectors are adequately qualified. Section 5.2.30 requires taking (b)(4) units of good tables and add defective tables. These tablets are mixed and used as test kit to qualify the visual inspectors. There is no information about the type of defects and the number of defective tables in the test kit. Review of an inspector evaluation form, FORM-FS01-PR-0328 Version 2.0 executed on 10/11/2025 for an Inspector (b) (6) confirmed that (b) (4) defective tables were added and were identified by the Inspector (b) (6). However, the form did not have information about the number of good tables used in the test kit. Your Production Head (b) (6) confirmed that it was the standard practice to qualify the Visual Inspectors. Your Production Manager also stated that the firm has created a new procedure to qualify the visual inspector, SOP-FS01-QA-0025 Version 1.0 Inspection Evaluation Process (Effective date 12/7/2025). As of 12/11/2025, you have not implemented the procedure, and you also did not have the test kit.

You have recorded multiple market complaints for defective tablets, capsules, and commingled products. E. g. Market Complaint No's. 200434402 (physical defects in capsules), 200434810 (foreign products), 200425820 (comingled tablets), 200436426 (discolored tablets with black spots), 200433853 (tablet is the correct color, but the imprints match the (b) (4) strength).

OBSERVATION 5

Written procedures are not followed for the sampling of drug substance and excipients.

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Specifically, your sampling practices are not scientifically sound and appropriate to ensure that your raw materials conform to established standards of quality and purity. Section 5.5.2.1 of your SOP-GLOB-QC-0113 Version 15.0 Sampling and Testing of Raw Materials (Effective date 5-Nov-2025) requires use of (b) (4) to collect samples from (b) (4) of the containers or bags. You use sterile scoop (b) (4) cm) and (b) (4) spoons to collect the samples for the active pharmaceutical ingredients (APIs). You have recorded multiple OOS results for drug products for related substances where APIs were sampled with sterile scoops and (b) (4) spoons. Some such examples are listed in **Table 1.**

Table 1. Sampling of APIs (select examples)

Entry	API Batch No.	Sampling tool	Drug Product Name	Batch No.	OOS No.	Test
1	(b)(4)	Sterile scoop	(b)(4)	(b)(4)	310028627	Related Substances
2	(b)(4), (b)(4)	Measuring scoop and (b)(4) spoon	(b)(4) (b)(4)	(b)(4)	310028958	Related Substances

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