DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032 Rockville, MD 20857	7/10/2025-7/18/2025*
	FEI NUMBER 3012414462

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. Shailendra Jha, Site Head

FIRM NAME	STREET ADDRESS
Dr. Reddy's Laboratories Limited	Formulations Technical Operations, FTO-11, Survey No 30,31 & Part of (28,32,33,34,39), APIIC Industrial Park,
CITY, STATE, ZIP CODE, COUNTRY Pydibhimavaram, Ransthalam, Andhra Pradesh, 532409 India	TYPE ESTABLISHMENT INSPECTED Sterile Drug 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:
PRODUCTION SYSTEM

OBSERVATION 1

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not written.

Specifically,

Your SOP entitled, "Procedure for cleaning of (b) (4) along with vial filling, stoppering and sealing machine, (b) (4) capping machine, (b) (4) system (b) (4) & (b) (4) RABS", SOP-FT11-PR-0118, Version 8.0, Effective 29-Apr-2025 allows the use of non-sterile (b) (4) to clean the surfaces of the (b) (4) during the end of the batch. There is no statement in the SOP to prohibit the introduction or use of non-sterile (b) (4) during set up activities. Furthermore, the SOP does not specify if the (b) (4) sanitization agents that are routinely used during cleaning the surfaces of the Grade A (b) (4) are sterile. According to the Global Head Quality/Pharmacovigilance, there is no risk because the surfaces of the Grade A (b) (4) will be decontaminated with (b) (4) prior to aseptic production.

OBSERVATION 2

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Patty P Kaewussdangkul, Investigator Jigar R Patel, FDA Center Employee	X Patty P Kaewussdangkul Investigator Signed By: Patty P. Kaewussdangkul -S Date Signed: 07-18-2025 04:31:37	7/18/2025

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032 Rockville, MD 20857	7/10/2025-7/18/2025* FEI NUMBER 3012414462

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Mr. Shailendra Jha, Site Head	
FIRM NAME Dr. Reddy's Laboratories Limited	STREET ADDRESS Formulations Technical Operations, FTO-11, Survey No 30,31 & Part of (28,32,33,34,39), APIIC Industrial Park,
CITY, STATE, ZIP CODE, COUNTRY Pydibhimavaram, Ransthalam, Andhra Pradesh, 532409 India	TYPE ESTABLISHMENT INSPECTED Sterile Drug Manufacturer

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile did not include adequate validation of the aseptic process.

Specifically,

On July 17,2025, we watched your most recent static and dynamic smoke studies performed in (b) (4) for your (b) (4) and in (b) (4) (b) (4) which are used to manufacture sterile drug products that are distributed in the United States. Poor visualization was seen due to inadequate generation of smoke to ensure that sweeping unidirectional airflow is present to protect exposed sterile (b) (4) stoppers under the sensor, protect vials that are loaded (b) (4) and unloaded (b) (4) stoppered but not sealed) from (b) (4)

OBSERVATION 3

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,

On 7/11/2025, we watched the firm's visual inspection process of (b) (4) drug products for presence of particulate matter of (b) (4) for (b) (4) Injection, (b) (4) mg/vial, Batch # (b) (4) and observed the visual inspector hold, tilt (b) (4) drug product containers forward and back (b) (4) (b) (4) against the (b) (4) background of the visual inspection booth but fail to rotate the vials 360° against the (b) (4) background to ensure that any particles or defects present in the vials will be visible to the eye. Furthermore, the (b) (4) vials of (b) (4) are then rolled in the gloved hand of the visual inspector which does not provide adequate contrast required to ensure that particles similar to

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032 Rockville, MD 20857	7/10/2025-7/18/2025* FEI NUMBER 3012414462

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Mr. Shailendra Jha, Site Head	
FIRM NAME Dr. Reddy's Laboratories Limited	STREET ADDRESS Formulations Technical Operations, FTO-11, Survey No 30,31 & Part of (28,32,33,34,39), APIIC Industrial Park,
CITY, STATE, ZIP CODE, COUNTRY Pydibhimavaram, Ransthalam, Andhra Pradesh, 532409 India	TYPE ESTABLISHMENT INSPECTED Sterile Drug Manufacturer

the (b) (4) of the (b) (4) can be visually detected.

OBSERVATION 4

Equipment used in the manufacture, processing, packing or holding of drug products is not of adequate size to facilitate operations for its intended use.

Specifically,

The (b) (4) System (Equipment ID: (b) (4) equipment is used in the compounding process of (b) (4) products (b) (4) injection, (b) (4) mg/mL (b) (4) The equipment (b) (4) which is critical process parameters. (b) (4) The (b) (4) system equipment was not qualified to verify the equipment capacity which can define (b) (4) This is particularly more important for the higher scale (b) (4) commercial scale manufacturing batches where the drug (b) (4) phase is processed in (b) (4) sub-lots each and the risk of accumulation in the tank may lead to carryover (b) (4)

OBSERVATION 5

Examination and testing of samples is not done to assure that in-process materials conform to specifications.

Specifically,

During the compounding process of (b) (4) Injection (b) (4) mg/vial, the (b) (4) of the (b) (4) (in-process bulk) during the manufacturing process is established as critical process parameter

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Patty P Kaewussdangkul, Investigator Jigar R Patel, FDA Center Employee	X Patty P Kaewussdangkul Investigator Signed By: Patty P. Kaewussdangkul -S Date Signed: 07-18-2025 04:31:37	7/18/2025

(CPP). The (b) (4) requirement is (b) (4) There is (b) (4) sensor that directly comes in contact with the in-process bulk in the vessel that provides accurate (b) (4) readings. As the product is transferred to the next stage of the manufacturing process, the (b) (4) sensor will no longer be in contact with the product and the firm relies on the (b) (4) reading of the (b) (4) vessel to measure the in process bulk (b) (4) At time of discovery, it was not known whether the (b) (4) reading of the (b) (4) vessel is an accurate and/or reliable method to measure the CPP to ensure that the (b) (4) of the in process bulk (b) (4) was within specification for the duration of the manufacturing process. Approximately (b) (4) batches of (b) (4) Injection (b) (4) mg/vial or (b) (4) mg/vial) have been distributed to the United States.

QUALITY SYSTEM

OBSERVATION 6

Drug product production and control records, are not reviewed and approved by the quality control unit to determine compliance with all established, approved written procedures before a batch is released or distributed.

Specifically,

A) On 7/10/2025, we observed a microbiologist read (b) (4) air plates that were used to monitor the Grade A environment during the Media fill # (b) (4) of the (b) (4) Line and enter the counts in their electronic Laboratory Information Management System (LIMS). According to the Microbiology Head, microbial counts are verified by a supervisor to verify that counts are accurate. However, the supervisor failed to document the readings during the secondary verification despite LIMS having the capability to enter counts to ensure the integrity of the microbial data generated.

B) The firm manufactured (b)(4) submission/PPQ batches for (b)(4) Injection (b)(4) mg (b)(4) ml (b)(4) mg/ml) (b)(4) (b)(4) and (b)(4) submission/PPQ batches for (b)(4) Injection (b)(4) mg (b)(4) ml (b)(4) mg/ml) (b)(4) The executed report of the PPQ batches is required to record the in-process fill weight check (b)(4) The firm recorded the actual fill weight data in protocol pages; however, the batch record does not require second person verification of the results and the PPQ report is missing the weighing scale print slips of the fill weight in-process controls test for batches (b)(4) and (b)(4) The Batch record review by quality unit was deficient as it was not able to detect the supporting raw data were missing in the batch report.

OBSERVATION 7

There is a failure to thoroughly review any unexplained discrepancy whether or not the batch has been already distributed.

Specifically,

Your firm's corrective and preventative actions implemented after deviations and out of specification investigations are not properly checked for effectiveness or adequacy to prevent recurrence.

A) Deviation number 200431248 was initiated due to a Grade A excursion found on (b)(4) (b)(4) The investigation performed resulted in a root cause of a dirty (b)(4) (b)(4) which is used to (b)(4) According to the Operations Head, a CAPA was implemented involving cleaning of the (b)(4) using a wipe saturated with (b)(4) visual checks by production and IPQA prior to the start of (b)(4) and aseptic production however,

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032 Rockville, MD 20857	7/10/2025-7/18/2025* FEI NUMBER 3012414462

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Mr. Shailendra Jha, Site Head	
FIRM NAME Dr. Reddy's Laboratories Limited	STREET ADDRESS Formulations Technical Operations, FTO-11, Survey No 30,31 & Part of (28,32,33,34,39), APIIC Industrial Park,
CITY, STATE, ZIP CODE, COUNTRY Pydibhimavaram, Ransthalam, Andhra Pradesh, 532409 India	TYPE ESTABLISHMENT INSPECTED Sterile Drug Manufacturer

the firm failed to demonstrate that their cleaning process of the (b) (4) is repeatable and reproducible.

B) Out of specification (OOS) investigation numbers OOS-FT11-24-011, OOS-FT11-24-012, 310027423, 310026670, 310027608, and 310027727: A total of six OOS notifications have been logged for the product (b) (4) injection, (b) (4) mg/mL (b) (4) All the OOS results were recurring in nature as they were related to failure of the (b) (4) (b) (4) The corrective and preventive action (CAPA) was focused only on the probable root cause for failure of (b) (4) accuracy found in the respective OOS investigations. However, despite the recurring OOS, the preventive actions were not adequate to propose actions that can proactively assess the detections and mitigation of the risk of all the probable failure modes that did not occur before.

C)Deviation number 20041971: On Sep 7, 2022, during (b) (4) (after (b) (4) incubation at (b) (4) degrees) visual inspection of the media fill batch number (b) (4) (media filled (b) (4) two cracked (b) (4) were observed. As part of investigation corrective and preventive action (CAPA) number 200401323, to minimize the defects during batch operation, it was decided to create a training module for the alignment of the (b) (4) capping machine settings and to train the (b) (4) line manufacturing team on the module. The (b) (4) line manufacturing team was trained on the module. However, the CAPA failed to implement the improved setup instruction in the equipment setup standard operating procedure (SOP-FT11-PR-0096) and failed to ensure that future training would accommodate the detailed instructions provided in the training module..

D) Deviation number 200424689: On Dec 15, 2023, post 100% visual inspection it was observed that for the drug product (b) (4) injection, (b) (4) mg/mL (b) (4) batch numbe (b) (4) the

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Patty P Kaewussdangkul, Investigator Jigar R Patel, FDA Center Employee	X Patty P Kaewussdangkul Investigator Signed By: Patty P. Kaewussdangkul -S Date Signed: 07-18-2025 04:31:37	DATE ISSUED 7/18/2025

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032 Rockville, MD 20857	7/10/2025-7/18/2025*
	FEI NUMBER 3012414462

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Mr. Shailendra Jha, Site Head

FIRM NAME	STREET ADDRESS
Dr. Reddy's Laboratories Limited	Formulations Technical Operations, FTO-11, Survey No 30,31 & Part of (28,32,33,34,39), APIIC Industrial Park,
CITY, STATE, ZIP CODE, COUNTRY Pydibhimavaram, Ransthalam, Andhra Pradesh, 532409 India	TYPE ESTABLISHMENT INSPECTED Sterile Drug Manufacturer

critical rejects [(b) (4)]%) exceeded the specification of [(b) (4)]%. As a part of the corrective and preventive action (CAPA) it was decided that batch manufacturing record (BMR) to be revised with increasing number of in-process control (IPC) sample quantity for visual checks from [(b) (4)] to [(b) (4)] units and the action to be completed by Feb 1, 2024. The intended BMR prepared in Sep 2024 for proposed commercial batches did not implement the in-process changes as per CAPA.

***DATES OF INSPECTION**

7/10/2025(Thu), 7/11/2025(Fri), 7/14/2025(Mon), 7/15/2025(Tue), 7/16/2025(Wed), 7/17/2025(Thu), 7/18/2025(Fri)

X Jigar R Patel
FDA Center Employee
Signed By: 2002843671
Date Signed: 07-18-2025 04:32:13

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Patty P Kaewussdangkul, Investigator Jigar R Patel, FDA Center Employee	X Patty P Kaewussdangkul Investigator Signed By: Patty P. Kaewussdangkul - S Date Signed: 07-18-2025 04:31:37	7/18/2025