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	7/20/2026-7/29/2026*
	FEI NUMBER 3011171511

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Madhu Sundar, Global Head Quality & Pharmacovigilance

FIRM NAME	STREET ADDRESS
Dr. Reddy's Laboratories Ltd.	Fto-Sez - Process-Unit - 02, Survey No. 70, 71 & 73, Devunipalavalasa (V)
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Ranasthalam Mandal, Srikakulam, Andhra Pradesh, 532409 India	Human Rx Drug Manufacturer (Finished Dosage)

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

Laboratory controls do not include the establishment of scientifically sound and appropriate specifications designed to assure that in-process materials conform to appropriate standards of identity, strength, quality and purity.

Specifically, the (b) (4) specification (SP-CFTO-014787) did not include testing for (b) (4) until June 30, 2026. Prior to this date, (b) (4) used in the equipment cleaning and in the manufacture of capsules, tablets, and ointments distributed to the U.S. market was not tested or controlled for (b) (4)

OBSERVATION 2

Each component is not tested for conformity with all appropriate written specifications for purity, strength, and quality.

Specifically, your firm failed to perform adequate identity testing on incoming shipments of (b) (4) in accordance with the USP monograph. Over the past twelve months, approximately (b) (4) batches of drug product were released to the U.S. market using (b) (4). For example:
(b) (4) Lot #(b) (4), received on (b) (4), was used in the manufacture of (b) (4) Capsules, finished batch #(b) (4) This batch was shipped to the U.S. on (b) (4) and subsequently distributed to (b) (4) drug distributors within the U.S.

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Ronda R Loyd Jones, Investigator
Milton J De Jesus Tavarez, Investigator

X Milton J De Jesus Tavarez Investigator Signed By: MILTON J. DE JESUS-TAVAREZ -S Date Signed: 07-29-2026 09:50:30

DATE ISSUED
7/29/2026

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OBSERVATION 3

Your firm failed to have systems in place to enable compliance with the verification requirements of the DSCSA.

Specifically, Guideline GUI-GLOB-QA-0069, Handling of Counterfeit Medicines, does not address trading partners required obligations, including but not limited to:

- Verify product identifiers using interoperable electronic systems.
- Affix serialized identifiers on each package.
- Validate accompanying product history and information.
- Maintain a staff training program at defined intervals.

***DATES OF INSPECTION**

7/20/2026(Mon), 7/21/2026(Tue), 7/22/2026(Wed), 7/23/2026(Thu), 7/24/2026(Fri), 7/27/2026(Mon), 7/28/2026(Tue), 7/29/2026(Wed)

X Ronda R Loyd Jones
Investigator
Signed By: RONDA R. LOYD-JONES -S
Date Signed: 07-29-2026 09:53:38

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Ronda R Loyd Jones, Investigator Milton J De Jesus Tavarez, Investigator	X Milton J De Jesus Tavarez Investigator Signed By: MILTON J. DE JESUS-TAVAREZ -S Date Signed: 07-29-2026 09:50:30	7/29/2026