DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032 Rockville, MD 20857 Industry Information: www.fda.gov/oc/industry	03/01/2020 - 03/05/2020
	FEI NUMBER 3005447965

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Mr. Yaramshetty Krishna Rao, Site Head

FIRM NAME	STREET ADDRESS
Dr. Reddy's Laboratories, Ltd. - CTO 5	Peddadevulapally, Tripuraram Mandal
CITY, STATE AND ZIP CODE Nalgonda, Telangana, 508207, India	TYPE OF ESTABLISHMENT INSPECTED API Manufacturer

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

Production System

1. Your system for reprocessing of APIs and API intermediates is insufficient.

a) For example, you do not adequately identify reprocessed batches of (b) (4) API and API intermediates with a unique material number or provide an identifier in the batch number which differentiates (b) (4) API manufactured using reprocessed material from (b) (4) API manufactured under normal conditions without incident.

b) You do not adequately place (b) (4) API reprocessing process validation (PV) and commercially reprocessed lots on appropriate stability monitoring to demonstrate continued process capability throughout the lifecycle of the validated procedure, by ensuring (with stability testing of commercially reprocessed batches) that reprocessed APIs and API intermediates (post PV) are consistently meeting the specified quality attributes in accordance with USP monograph criteria and throughout the shelf life of the APIs which have been manufactured using reprocessed materials.

c) Your procedure for skip testing allows skip testing for batches of (b) (4) API (b) (4) and API intermediate (b) (4) which have been previously rejected and reprocessed. Yet you have provided no appropriate justification why reduced testing should be acceptable for (b) (4) API and API intermediate batches which have initially been rejected due to failure of quality attributes.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
		Christopher S. Keating, Investigator Tomika L. Bivens, Analyst	03/05/2020

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Laboratory System

2. Retest periods for reference standards used in the QC laboratory for analysis of APIs and API intermediates are not established with supporting analytical data.

You have not appropriately validated the effective shelf lives of reference standards provided by third-party suppliers, which are used for QC testing of (b) (4) API and API intermediates. Your specified retest period of (b) (4) for third-party supplied API and API-impurity reference standards is taken from your analytical standard SOP and no validation studies have been performed to support this statement.

3. Failure to maintain laboratory equipment used in the analytical testing of APIs and API intermediates to ensure that the equipment is suitable for use in the execution of USP monograph testing methods.

You have not qualified your HPLC columns used for release testing of (b) (4) USP API to ensure that the column performance is appropriate and suitable to perform testing, to include, but not limited to, the specified USP monograph method for chromatographic purity/related substances. Per your firm's QC manager, you created a second analytical method to adequately resolve the (b) (4) impurity from the main (b) (4) (b) (4) peak, due to "poor column performance/degradation". However, you have not qualified the columns to determine the number of injections which the column can be used before it is no longer able to achieve systems suitability and must be discarded/replaced.

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