DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
CDER/OPQ/OSIAB White Oak Building 51, Room 4316 10903 New Hampshire Ave, Silver Spring, MD 20993 001-301-796-3254 Industry Information: www.fda.gov/oc/industry	03/05/2018 - 03/09/2018* FEI NUMBER 3003184497

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Dr. Sunil Bawane, Sr. Director & Site Head Manufacturing

FIRM NAME	STREET ADDRESS
Dr. Reddy's Laboratories, Ltd. (Chemical Tech Ops - III)	Plot No. 116, IDA Bollaram, Bollaram, Jinnaram
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Medak, Telengana, 502325, India	Active Pharmaceutical Ingredients Manufacturer

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

Quality System

OBSERVATION 1

The responsibilities and procedures applicable to the quality control unit are not fully followed. Specifically,

A. Your Quality Unit failed to close multiple CAPAs within the (b) (4) allowable timeframe and a justification to extend the completion timeframe was not requested. Specifically, your Quality Unit did not request an extension to the following CAPAs:

CAPA No.	Initiation Date	Due Date	Closure date
200223950	02/13/17	(b) (4)	(b) (4)
200203437	10/17/16		02/28/18
200204765	10/25/16		02/28/18
200204723	10/25/16		04/25/17
200211138	11/30/16		03/07/18
200211835	12/05/16		03/07/18
200212526	12/08/16		03/07/18
200213288	12/13/16		03/07/18
200214127	12/19/16		03/07/18
200251795	07/31/17		02/27/18

B. The Empower 3 audit trail used in the QC laboratory for data acquisition system revealed on 02/14/2018 that Sample Set ID 2793, Sample Method #14318050 was aborted after injection #6 during system suitability for Agilent HPLC #QC-143. Per SOP #GQA032-01 (Handling of Incidents) 09/15/2017 effective date, an incident report is to be raised. However, at the time of the inspection no incident report was generated or explanation was

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documented on why this sample set was aborted.

C. Your firm has not established Quality Agreements with some of its starting materials suppliers, such as the supplier for (b) (4) used to manufacture (b) (4) for the US market. This practice is contrary to what is described in Section 5.5.2.1 (Quality Assessment) and Step #1.1.18 (Quality Agreement) of Annexure GQA020/ A04 (Documentation Requirement (b) (4) Form #GOA020/ F03-00) of SOP #GQA020-00 (Vendor Management) 05/15/2017 effective date.

D. Per Step #3.9 of SOP #GQA053-00 (Electronic Data Management for Laboratory Instruments System), "backup data shall be assessed to verify successful completion of the backup process. In the event, if the backup process fails, the same shall be investigated through an incident notification as per SOP: GQA032 Handling of incident." This practice is not being performed by the firm based on two failures recorded on 02/09/2017 and 12/27/2017.

OBSERVATION 2

Procedures describing the handling of written and oral complaints related to API materials are not followed. Specifically,

A. Complaint #200262075 was received and initiated on 10/09/2017 for particle size OOS ((b) (4) (b) (4) USP) for Batch # (b) (4) The conclusion of the complaint investigation states that the firm "require sample from the customer to confirm the particle size variation observed." However, the investigation did not reveal if the firm received the requested sample from the customer and tested. A final investigation report has not been issued.

B. Complaint #200235463 was received on 04/19/2017 and initiated on 04/20/2017 for (b) (4) (b) (4) Batches # (b) (4) and (b) (4) on 04/19/2017 due to the presence of a (b) (4) bag found in the material. The conclusion of the complaint investigation states that "SOP on Packing & Repacking shall be revised by including this requirement." However, there was no CAPA reference number in the investigation. At the time of the inspection, the SOP for Packing & Replacing has not been update.

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C. Complaint #200219745 was received and initiated on 01/20/2017 for (b) (4) Ph. Eur Batch # (b) (4) due to OOS in Particle Size Results (b) (4). Per SOP #01-005/09 (Complaints) effective date 04/11/2016, if unable to meet the due date an extension is to be requested with justification and approval. On (b) (4) a justification for extension was written and approved by the QA Manager after the due date (b) (4) The complaint investigation did not include a conclusion and actions taken by the firm. Although the firm provided several follow-up responses to the customer dated 02/21/2017 and 05/09/2017, there is no reference of these actions in the preliminary complaint investigation report.

D. Your Quality Unit failed to close complaint investigations within the allowable timeframe and a justification to extend the completion timeframe was neither requested within the (b) (4) timeframe nor closed within the complaint investigation completion timeframe. Specifically, your Quality Unit did not request an extension to the following complaints within the (b) (4)

Complaint No.	Product	Date Opened	Due Date	Date Closed
200262075	(b) (4) USP)	10/09/17	(b) (4)	(b) (4)
200219745	(b) (4) Ph. Eur	01/20/17		05/19/17
200269998	(b) (4)	12/01/17		01/06/18
200235463	(b) (4)	04/20/17		(b) (4)

Facilities & Equipment

OBSERVATION 3

Buildings used in the manufacturing, processing, packing of API finished materials are not maintained in a good state of repair. Specifically,

A. Ceiling area above the opening of (b) (4) # (b) (4) -01 and (b) (4) # (b) (4) -17 used for (b) (4) (b) (4) production is not maintained in a manner that will prevent foreign object from falling inside the (b) (4) when opened. The ceiling needs repairs and is cracked. In addition, there is a big hole in the ceiling above the opening of (b) (4) # (b) (4) -06/01 used for (b) (4) production ((b) (4) is the Intermediate used for (b) (4) (b) (4) API for the US market).

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Material System

OBSERVATION 4

Separate or defined areas to prevent contamination or mix-ups are deficient regarding operations related to the quarantine storage of API finished materials prior to release. Specifically,

(b) (4) drums of (b) (4) finished API Batch # (b) (4) with quarantine labels were observed inside the (b) (4) Room (Packaging/Cleanroom) on 03/05/2018 and were manufactured on 01/07/2018. The firm packaged (b) (4) more batches of (b) (4) (Batch # (b) (4)) in that room on (b) (4) while this quarantine batch remained in that room and a line clearance was performed. No explanation was provided for why these (b) (4) drums remained in the room nearly two months after manufacturing

Production System

OBSERVATION 5

There is no assurance that the equipment used in the production of (b) (4) and (b) (4) API are always maintained and/or kept in/under proper conditions for manufacturing operations and to prevent the contamination of the products handled and/or processed in the equipment. The following conditions were observed on 03/05/2018, during the walkthrough the production areas in (b) (4) -Block (used to produce (b) (4) and (b) (4) for the US market):

A. A piece of (b) (4) material was observed inside (b) (4) # (b) (4) -12 used for (b) (4) production and the equipment was issued a "cleaned" status and visually inspected.

B. A piece of fabric thread was observed inside (b) (4) # (b) (4) -14 used for (b) (4) production. In addition, the (b) (4) was observed with presence of holes and was placed in use on 01/10/18, cleaned, and visually inspected on 02/17/18. The area around the gasket of the cover was observed with (b) (4) stain color.

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C. Presence of product was observed inside the following production equipment although the equipment was cleaned and visually inspected after cleaning:

a) (b) (4) # (b) (4) -20 and (b) (4) # (b) (4) -09/02 located in Cleanroom (b) (4) -Block Building # (b) (4) used for (b) (4) finished API production.
b) (b) (4) # (b) (4) 06/01 used for (b) (4) production.
c) (b) (4) ID # (b) (4) -03 that is used for (b) (4) production.
d) (b) (4) # (b) (4) -01 used for (b) (4) production although considered cleaned and verified.
e) On the (b) (4) inside (b) (4) # (b) (4) 17/01 used for (b) (4) production.
f) On the shaft inside (b) (4) # (b) (4) -14/02 used for (b) (4) production.

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