DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Ave, Bldg 51, Rm 4225 Silver Spring, MD 20993 (301) 796-3334, Fax (301) 847-8738	9/11/2017-9/15/2017
	FEI NUMBER 3002807544

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: Ged, O'Shea, Site Head

FIRM NAME	STREET ADDRESS
Dr. Reddy's Laboratories (EU) Ltd	Steanard Lane
CITY, STATE, ZIP CODE, COUNTRY Mirfield, West Yorkshire, WF14 8HZ, UK	TYPE ESTABLISHMENT INSPECTED Manufacture

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 I/WE OBSERVED:

OBSERVATION 1

Procedures are not established or followed.

Specifically,

Your firm failed to follow procedures to file a report for the following:

- No Change Control/Management of Change (MOC) was opened following OOS 15/015, dated 21 July 2015 which stated to "update (b) (4) to include that the material is susceptible to static and sample may be erroneously weight. Include not to rehandle the glassware" as the corrective action. However, the MOC #200250489 was not filed until 24 July 2017 and completed until 2 years later on 18 Aug 2017.
- No Change Control/Management of Change (MOC) was opened/created for the discontinued used and removal of laboratory equipment UPLC 24 in 2015 that was used in the testing of (b) (4) API.
- No Change Control/Management of Change (MOC) was created for the rewording of raw material sampling labels from "QC Sampled" to "Sampled" to correctly represent that raw material sampling is conducted by warehouse staff and not Quality Control (QC) staff.
- No incident or deviation was documented for the shutdown of HVAC for Area (b) (4) during production of (b) (4) during (b) (4) stage on 30 Oct 2014, which was discovered during the investigation of an Environmental Monitoring OOS Notification #200112172, dated 15 Nov 2014.

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OBSERVATION 2

Cleaning procedures or clean status is not established.

Specifically,

- During the review of the Quality Risk Management Plan for Area (b) (4) and Cleaning Rationale 161/060/MW/13, dated 11 Oct 2014 and the Report for (b) (4) Equipment 161/022/MW/17, dated 08 Aug 2017. The cleaning procedures are not validated for equipment used in production of (b) (4) API. Such as the disassembling of (b) (4) ID # (b) (4) 0015 prior to cleaning.

- During the walk through of the warehouse on 12 Sept 2017, I observed in the (b) (4) equipment storage area with several accessories/portable machine/dismantled machine parts used in manufacturing of (b) (4) API that were not identified as clean or dirty. Examples of the equipment accessories include the following, but not limited to the glass (b) (4) bottles, Conical flask, transfer hoses, and (b) (4) . The last use of the equipment was documented in batch record (b) (4) on 15 Nov 2015. Additionally there are no clean hold times established in the procedures.

OBSERVATION 3

Manually managed materials in the warehouse are not separated during storage.

Specifically,

- The Retain Samples of various materials such as (b) (4) are stored in freezers identified as Quarantine and Approved along with finished material that are Quarantine or Approved.
- (b) (4) API labeled "Reprocess" was stored along with "Approved" material in the (b) (4) refrigerator since 21 Oct 2016.
- Additionally, raw materials of (b) (4) used for the production of (b) (4) API was stored in the Quarantine area since 6 April 2016. There are no allocated timeframes for storage of Quarantine materials.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
		15 Sept 2017