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 Springs, MD 20993 (301)796-3334 Fax:(301)847-8738	4/19/2017-4/28/2017* FEI NUMBER 3002949099

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. V. Venkatanarayan , VP Site Head

FIRM NAME	STREET ADDRESS
Dr. Reddy's Laboratories Ltd.	No 41 Bachupally Village & Mandal, Medchal Malkajgiri District
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Bachupally, Telangana, 500090India	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:
LABORATORY SYSTEM

OBSERVATION 1

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

Specifically,
a) You continue to (b) (4) samples prior to microbiological testing as evidenced by your Sampling Procedure for (b) (4) Intermediates & Finished products, SOP FTCQA034-10, effective April 18, 2017. You confirmed the standard practice of (b) (4) samples for microbiological testing of finished drug products. These tests are performed on select finished drug products, including but not limited to: (b) (4) intended for shipment to the U.S.
b) A total of 350 capsules were collected for chemical analysis of (b) (4) Capsules USP (b) (4) mg Batch Numbe (b) (4) intended for shipment to the U.S. The batch size was (b) (4) capsules. The Record of Analysis shows out of the total 350 capsules collected from a (b) (4) sample obtained by sampling from the (b) (4) containers, 113 capsules were used for testing.

This is a repeat observation from the 2015 inspection.

OBSERVATION 2

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Laboratory records are deficient in that they do not include a complete record of all data obtained during testing.

Specifically, when incidences arise during analyses, your analysts do not contemporaneously document the circumstance and occurrence on the analytical worksheets and/or checklists. For examples, during the testing of (b) (4) Tablets USP (b) (4) mg Batch Number (b) (4) intended for shipment to the U. S., your Electrolab Dissolution Tester sample collector required maintenance twice and pH meter, equipment ID QCE832, did not provide a stable reading. The analyst did not document the problem(s) with the dissolution tester sample collector on either occasion nor did he document the problem with the pH meter on the analytical worksheets.

This is a repeat observation from the 2015 inspection.

OBSERVATION 3

Backup data is not assured as exact, complete and secure from alteration, erasure or loss through keeping hard copy or alternate systems.

Specifically, your quality unit does not ensure appropriate controls are exercised over Empower 3 and other computer related systems in that:

a) Your quality unit does not review your HP Enterprise Service Portal ticketing system, used to communicate work requests to your IT department, and approve ticket requests prior to fulfillment on GMP regulated systems.

b) Your quality unit does not review system activities logs to identify unapproved events or incidences.

c) You have not verified data restoration from backed-up data obtained from your Empower 3 software application installed on or around August 2016.

d) Your quality unit approves unlocking previously locked projects as part of incidence investigations. As an example, your quality unit approved unlocking projects from January 2016 – December 2016 of

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finished product test results projects, in-process test results projects, and stability test results projects as part of an incidence investigation into an extra peak observed in the Uniformity of Dosage chromatograph for (b) (4) Tablets USP (b) (4) mg Batch Number (b) (4) intended for shipment to the U.S.

e) Your quality unit does not ensure appropriate privileges are assigned to user roles. (b) (4) reviewers have privileges in your Empower 3 software application including but not limited to: modifying integration parameters; modifying component times; modifying constants; reinjecting samples; and altering running sample sets. Analyst privileges include but are not limited to: modifying integration parameters; modifying component times; modifying constants; accessing real time plot walk-up; and accessing real time review from run samples.

f) Your quality unit does not regularly review or evaluate user roles and privileges assigned to users of software applications used in HPLC and GC testing such as Assay, Related Substance, and Residual Solvent testing used for the release of drug products intended for shipment to the U.S.

g) Your QC Supervisor stated your analysts, as a standard practice, conduct trial auto-integration of sample sets in the preview window within the Empower 3 software application used with instruments such as HPLCs and GCs to conduct product release testing for products intended for shipment to the U.S., prior to processing and saving data. Trial auto-integrations are not saved.

OBSERVATION 4

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, you do not always follow official USP monographs when testing drug products for release and distribution to the U.S. in that from the time (b) (4) for (b) (4) mg was approved on (b) (4) until sometime after September 01, 2015 analysts used a hair dryer to dry your

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working standard instead of a (b) (4) as specified in USP (b) (4) > monograph for identification of (b) (4) by IR.

OBSERVATION 5

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

Specifically, you do not always follow your written procedures. For example,
a) During testing of (b) (4) Tablets USP (b) (4) mg Batch Number (b) (4) intended for shipment to the U. S. market, on April 20, 2017 your analyst recorded the water in the water bath for the Electrolab Dissolution Tester as clear. I observed the water in the water bath was not clear as required in your written procedure for operation and calibration of the Electrolab Dissolution Tester. I also observed unidentified whitish (b) (4) floating in the water bath. Your QC Supervisor reviewed the instrument set-up and approved the analyst to proceed with the testing without documenting the unclear water in the water bath.

b) During the above mentioned analysis, the sample arm on the sample collector would not move and the sample arm on the sample collector did not dispense the sample into the sample tubes. However, your analyst did not document either occurrence on the analytical worksheets as required by your written procedure for documentation of analytical data.

c) After maintenance service on the Electrolab Dissolution Tester, your Lab Support Team did not calibrate the instrument as required by your written procedure for operation and calibration of the Electrolab Dissolution Tester. The head of your QC laboratory provided written documentation contradicting your written procedure stating it was not necessary to calibrate the instrument after maintenance.

d) Your Lab Support Team did not calibrate pH meter QCE832 from March 23, 2017 through April 19, 2017 as required by your written procedure for operation and calibration of pH meters. I asked the Head

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of your QC Laboratory why (b) (4) calibrations were not performed. The Head of your QC Laboratory contradicted your written procedure stating pH meters are not calibrated (b) (4) they are calibrated before use.

OBSERVATION 6

Routine calibration, inspection and checking of automatic, mechanical and electronic equipment is not performed according to a written program designed to assure proper performance. Electronic records are used, but they do not meet requirements to ensure that they are trustworthy, reliable and generally equivalent to paper records.

Specifically, your quality unit does not adequately control the distribution of CoA's and Record of Analysis in that there is no indication on the CoA or the Record of Analysis when a change is made and a new iteration is generated from your SAP system for the same batch. As an example, you removed the original CoA for (b) (4) mg Batch Number (b) (4) and replaced the original CoA. There is no indication on the replacement CoA it is a second iteration.

OBSERVATION 7

The quality control unit lacks authority to fully investigate errors that have occurred.

Specifically, your quality unit does not always ensure all investigations are scientifically sound and complete. For example, your OOS investigation for (b) (4) and (b) (4) mg/ (b) (4) mg (b) (4) Tablets Batch Number (b) (4) for Assay did not identify the root cause and recommended the investigation to your Manufacturing and Science Technology team (MSAT) to identify the root cause. Your OOS investigation assigned a corrective action and preventive action to reject the batch. MSAT proposed to change from reporting the assay test results to reporting the average blend uniformity as the assay result. A root cause was not identified in the investigation conducted by MSAT and a corrective and preventive action was not provided other than changing the way the assay results are reported and rejecting the batch. Subsequently, you also rejected batches (b) (4) and (b) (4) without identifying a root cause. MSAT also proposed the error in the assay was due to

sample size and sample bias. Your investigation did not include review and/or revision of your sampling plan.

OBSERVATION 8

Individuals responsible for supervising the manufacture and processing of a drug product lack the education, training and experience to perform their assigned functions in such a manner as to assure the drug product has the safety, identity, strength, quality and purity that it purports or is represented to possess.

Specifically, your current training is not sufficient in that employees in supervisory positions such as your QC Supervisor and the Head of your QC Laboratory do not always follow written procedures when performing assigned functions:

a) I observed your QC Supervisor approve your Electrolab Dissolution Tester for analysis when the water in the water bath used for testing (b) (4) Tablets USP (b) (4) mg Batch Number (b) (4) intended for shipment to the U. S. market was not clear.

b) The Head of your QC Laboratory provided both written and oral statements indicating it was not necessary to calibrate your Electrolab Dissolution Tester after maintenance as required by your written procedure for operation and calibration of the Electrolab Dissolution tester.

OBSERVATION 9

Establishment of the reliability of the component supplier's report of analyses is deficient in that the test results are not appropriately validated at appropriate intervals.

Specifically, you do not always establish the reliability of your suppliers CoAs in that you reported (b) (4) total (b) (4) in (b) (4) Batch Number (b) (4) and the manufacturer's CoA reported (b) (4) total (b) (4) You did not open an investigation into the variance in test results to evaluate the reliability of the suppliers CoA.

OBSERVATION 10

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Employees engaged in the manufacture and processing of a drug product lack the education, training and experience required to perform their assigned functions.

Specifically, your current training does not ensure consistent compliance with your standard operating procedures in that your QC Laboratory analysts do not always follow written procedures when performing assigned functions:
a) Your analyst incorrectly recorded the water in the water bath used for testing (b) (4) (b) (4) Tablets USP (b) (4) mg Batch Number (b) (4) intended for shipment to the U. S. market as clear when the water in the water bath was not clear.

b) Your analyst did not follow your written procedure for calibration and operation of pH meters in that your analyst incorrectly wiped the bulb of the glass pH electrode after rinsing with water and held the pH electrode less than 2 inches deep in the test solution when trying to obtain the pH of the dissolution media.

OBSERVATION 11
Reserve samples from representative sample lots or batches of drug products selected by acceptable statistical procedures are not examined visually at least (b) (4) for evidence of deterioration.

Specifically, you do not examine reserve samples at least (b) (4) for evidence of deterioration.
a) On June 23, 2015 and again on June 10, 2016 you opened the same reserve sample bottle of (b) (4) Capsules Batch Number (b) (4) for visual examination. Your operator stated you inspect the same reserve sample bottle for each reserve sample visual examination. After each visual examination your operator reseals the bottle and returns the bottle to your reserve storage racks.

b) Your visual examination includes reconciliation of the tablet or capsule count and verification of the original tablet or capsule appearance description. The visual examination of (b) (4) Capsules Batch Number (b) (4) ncluded verification that capsules are (b) (4) filled with a (b) (4)

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(b) (4) and banded with a (b) (4) The visual examination does not include examination for evidence of deterioration or other abnormalities.

***DATES OF INSPECTION**

4/19/2017(Wed),4/20/2017(Thu),4/21/2017(Fri),4/24/2017(Mon),4/25/2017(Tue),4/26/2017(Wed),4/27/2017(Thu),4/28/2017(Fri)

4/28/2017

X Cheryl A Clausen
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