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	1/7/2019-1/15/2019*
	FEI NUMBER 3009193040

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Ganadhish Kamat, Executive Vice President & Global Head of Quality

FIRM NAME	STREET ADDRESS
Dr Reddy's Laboratories Limited	Fto-Sez Unit 1, Surv. 59-60, 62 & 72, Sect. 9-14, 17-20, Devunipalavalasa
CITY, STATE, ZIP CODE, COUNTRY Ranashthalam Mandal, Srikakulam, Andhra Pradesh, 532409 India	TYPE ESTABLISHMENT INSPECTED (b) (4) Dosage Drug Products

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

There is a failure to thoroughly review any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

1. Investigation was not performed of (b) (4) API lots when (b) (4) stability batches (b) (4) had (b) (4) impurity results above (b) (4) ppm during stability testing. (b) (4) impurity is (b) (4) from the API chemical synthesis process and does not increase after chemical synthesis. The specification for the API is not more than (b) (4) ppm.

No studies were conducted to evaluate uniformity of (b) (4) in the API during supplier qualification. No studies were conducted to evaluate uniformity of any impurities in the finished dosage during process validation.

The same API lot (b) (4) used for (b) (4) batch (b) (4) was used to manufacture commercially distributed lot (b) (4) of (b) (4) tablets.

2. Investigation OOS 310013508 opened for (b) (4) OOS results above the release specification of not more than (b) (4) ppm for lots (b) (4) (b) (4) of (b) (4) tablets was not thorough and did not follow procedure SOP GQA035 "Handling Out of Specification Results". The investigation identified the use of (b) (4) tubes as a probable root cause, but could not confirm (b) (4) tubes were used in the preparation of the

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	Justin A Boyd, Investigator - Dedicated Drug Cadre Rumany C Penn, Investigator - Dedicated Drug Cadre X Rumany C Penn Investigator - Dedicated Drug Cadre Signed By: 2001145008 Date Signed: 01-16-2019 13:34:14	1/15/2019

OOS samples. The investigation did not evaluate why the sample from lot (b) (4) that was prepared at the same time as the OOS samples did not detect any impurity.

The OOS results were invalidated and new samples were tested. The retest was done on a (b) (4) (b) (4) rather than the (b) (4) required by procedure SOP GQA035 after invalidating an OOS result.

3. The final investigation of complaint number 200217023 reference PC-04Jan2017-100909 of "(b) (4) (b) (4)', in (b) (4) (b) (4) mg released batch (b) (4) did not extend review into other batches of the same product ((b) (4) (b) (4) mg) which had already been distributed. In addition, the investigation did not include analytical testing such as assay or uniformity analysis of the returned sample or of the reserve samples of this batch or of other related batches.

4. Investigation OOS 310013534 opened for (b) (4) (b) (4) mg tablet batch (b) (4) (b) (4) assay OOS at the (b) (4) did not include expansion of the investigation to include prior batches. Hypotheses for root cause include that (a) the trained analyst inappropriately mixed the sample causing segregation of the sample or (b) there was an inappropriate sampling method which did not allow for uniform collection. The quality unit stated that the investigation did not expand to investigate prior batches made to evaluate if the results yielded valid results.

OBSERVATION 2

Appropriate controls are not exercised over computers or related systems to assure that changes in master production and control records or other records are instituted only by authorized personnel.

1. (b) (4) PR186, used for in-process testing of tablets, utilizes a common password, the operator can change the time and date, and electronic source data is not maintained. Operators can choose to use instrument PR186 or instrument PR541, which is configured with user access controls and storage of electronic data. The electronic data generated on PR541 is not reviewed.

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2. The pH and conductivity meter QC276 is capable of storing electronic records of all measurements taken. The system was not configured on January 07, 2019 to require the results be stored electronically.

OBSERVATION 3

Laboratory controls do not include the establishment of scientifically sound and appropriate test procedures designed to assure that drug products conform to appropriate standards of identity, strength, quality and purity.

1. Procedures for reviewing analytical chromatography data and audit trails lack guidance on how to perform the review. For example, how to ensure the correct processing method is used and how to ensure there are no unreported samples.

2. The audit trail for the Malvern Particle Analyzer identifies "Measurement record 19 created in (b) (4) occurring at 15:03 and 15:45 on April 18, 2016. Only the record from 15:45 was available in the electronic data. A review of this audit trail documented on form FTS1QC057/F03 did not detect this discrepancy.

OBSERVATION 4

Written production and process control procedures are not followed in the execution of production and process control functions and documented at the time of performance.

1. The following procedures were lacking in instruction or were not followed appropriately by operators:

- Tablet (b) (4) Machines "Handling of Alarms and Event Log Review" FTS1PR119/F02-00
  - On Jan 07, 2019, the operator selected acknowledge of the alarm "(b) (4) (b) (4) > MAXIMUM" on Tablet (b) (4) Machine #PR249 during production of

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(b) (4) (b) (4) mg batch (b) (4) but did not take any action. The procedure listed above does not include written procedures on actions to be taken during this situation

- FTS1PR119/A03 "Handling of Alarms and Event Log Review" FTS1PR119/F02-00
  - On Jan 10, 2019, the operator selected acknowledge of the alarm "DP PRODUCT. MAXIMUM" on (b) (4) #PR138 during production of (b) (4) (b) (4) mg batch (b) (4) but did not take any action. The procedure listed above states to (b) (4) during this alarm. This procedure was also not readily available to the operator during ongoing operations.

2. On January 07, 2019 at approximately 11:20, leaking oil was observed from equipment PR 187 in (b) (4), which was not operating at the time. It was reported that an operator had observed this discrepancy at approximately 9:30. There is no mechanism for the operator to record this discrepancy at the time it is observed. A record was not made in the maintenance system until 12:39 to further investigate the discrepancy.

***DATES OF INSPECTION**
1/07/2019(Mon), 1/08/2019(Tue), 1/09/2019(Wed), 1/10/2019(Thu), 1/11/2019(Fri), 1/14/2019(Mon), 1/15/2019(Tue)

X Justin A Boyd
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