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	6/12/2017-6/16/2017 FEI NUMBER 3009193040

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Vellaian Karuppiah , Site Head	
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	**TYPE ESTABLISHMENT INSPECTED**
Ranashthalam Mandal, Srikakulam , Andhra Pradesh , Dist-532 409India	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 Systems

OBSERVATION 1

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, in testing results of (b) (4) Powder (b) (4) mg packed in sachets for exhibit batches lots (b) (4), (b) (4), (b) (4) we observed:

1. On 16 December 2015, the initial release testing results was generated using manual integration for related substance testing for all three exhibit batches.

2. Different processing methods were used to process system suitability solution, standard, and sample injections for the following release testing and stability samples:

A. (b) (4) Powder

- release testing
  - (b) (4), (b) (4) and (b) (4)
- accelerated samples
  - 3 month, lots (b) (4), (b) (4)
  - 6 month, lots (b) (4), (b) (4)
  - 5 month, lots (b) (4), (b) (4) and (b) (4)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Stacie A Woods, Investigator Lata C Mathew, Generic Drug User Fee Amendments (GDUFA)	xStacie Woods	6/16/2017

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- 6 month, lots (b) (4), (b) (4)

B. (b) (4)

In addition, related substance for assay testing for (b) (4) which is a component in (b) (4) (b) (4) Powder (b) (4) mg, was also processed using separate processing methods for system suitability solution, standard, and sample injections during the 3 and 6 month long term and accelerated stability samples, and 5 month accelerated stability sample of exhibit lots (b) (4) (b) (4)

C. (b) (4) Tablets

- (b) (4) mg tablets, lot (b) (4) packed in (b) (4) and (b) (4) count bottles, for nine month long term stability sample.
- (b) (4) mg tablets, lot (b) (4) packed in (b) (4) and (b) (4) count bottles, for nine month long term stability sample.
- (b) (4) mg tablets, lots (b) (4) (b) (4), (b) (4) and (b) (4) for initial release testing sample.
- (b) (4) mg tablets, lot (b) (4) for initial release testing sample.

X Lata Mathew 6/16/17

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