DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Food and Drug Administration, CDER/OC/OMPQ/DIDQ HFD-325 10903 New Hampshire Avenue, Building 51, Room 4218 Silver Spring, MD 20993 PH: +1 301 276-8261 ATTN: Mr. Concepcion Cruz Industry Information: www.fda.gov/oc/industry	02/13/2017 - 02/17/2017, 02/20/2017 - 02/21/2017
	FEI NUMBER 3005447965

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Rahul P. Pradhan, Director, Location Head - CTO-5

FIRM NAME	STREET ADDRESS
Dr. Reddy's Laboratories Ltd, Chemical Tech Ops - V	Peddadevulapallly - 508 207, Tripuraram Mandal
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Nalgonda Dist., Telangana, India	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 (I) (WE) OBSERVED:

OBSERVATION 1

The specificity of test methods has not been established. Specifically,

A. Your firm fail in perform the stress (forced degradation) studies for the (b) (4) USP non- compendia optical purity test by HPLC analytical test method during the test method validation. The validation number 20 - (b) (4) MV-002, dated 06/26/2002 does not contain the specificity/selectivity studies necessary to demonstrate the suitability and adequacy of the analytical test method and specifications, S - 08 - (b) (4) - USP/13, used for the release and stability testing of this Active Pharmaceutical Ingredient (API). In addition, the current HPLC chromatographic purity test profile was found different than that obtained during the method validation. The retention time for (b) (4) peak changed from about (b) (4) minutes in the validation to (b) (4) minutes during the routine testing.

B. The data supporting validation activities performed by your firm to demonstrate the suitability and adequacy of the analytical method used for the release and stability testing of (b) (4) USP Active Pharmaceutical Ingredient (API) was found to be inadequate and incomplete. Data and documents presented by your firm supporting the validations number: 20 - (b) (4) MVR - 001 - 10 for the non- compendia Related Substances analytical test method and specification, S - 08 - (b) (4) - USP/07, does not contain the specificity/selectivity studies necessary to determine if the method is a stability indicating method for the testing of the API. Validation documents showed that the Validation of the methods does not contain complete forced degradation studies. Degradation of (b) (4) main peak was not achieved. In addition, the routine analytical test method specification, S - 08 - (b) (4) - USP/07, failed to contain the precision standard system suitability (%RSD) that (b) (4) the injection of the sample solution.

Nevertheless, the validation of the test methods were approved by QCU.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
		Reba A. Gates, GDUFA Lead Investigator Jose Lopez Rubet, Chemist	02/21/2017

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OBSERVATION 2

Procedures describing the calibration of instruments are deficiently written or followed. Specifically,

a) The calibration of the Gas Chromatographic (GC) instruments was incomplete. The review of the (b) (4) Operational Calibration for the Agilent GC/Headspace (GC/HS) QC- 206, conducted by the outside contractor and (b) (4) in-house calibration, did not include the HS oven temperature, noise and drift, signal to noise and detector accuracy tests as part of the GC/HS calibration. The GC instruments were used for the Residual Solvents test determination for released of the API's and raw materials.

b) The micro balance, QC- 465, was used outside its calibration range (usage range: 10 mg to 2 g) for the testing of (b) (4) USP Active Pharmaceutical Ingredient (API) during released and stability studies. The firm performed and documented the weight of (b) (4) mg, (b) (4) mg, (b) (4) mg, (b) (4) mg and (b) (4) mg for the standards of the related substance test for (b) (4) USP, batch number (b) (4) using the balance number QC-465 that was certified for weights in the range of 10 mg to 2 g. In addition, the linearity of this balance was performed with three points starting with 10 mg and the accuracy with 10 mg that do not support the use of the balance below 10 mg.

OBSERVATION 3

Records maintained of any modification of an established method employed in testing do not include the reason for the modification, the data to verify that the modification produced results that are at least as accurate and reliable for the material being tested as the established method. Specifically,

Your firm failed to follow the USP monograph identification test method for the Ultraviolet Absorption <197U> that defined how to perform the test and calculate the results for (b) (4) API's. For (b) (4) it was noted that the absorbance readings were obtained at a maximum wavelength other than (b) (4) nm as prescibed by the USP test monograph. During the review of (b) (4) batches (b) (4) (b) (4) it was observed that the absorbance was determined at approximately (b) (4) nm instead of the exact wavelength of (b) (4) nm as established by the USP test monograph.

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Also, the final calculations were performed with the absorbance readings instead of absorptivity as prescribed by the USP monograph. These modifications to the USP test method and calculations formulas were not validated or the equivalencies demonstrated.

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