	DEPARTMENT (FOOD)	OF HEALTH AND HUMAN SER AND DRUG ADMINISTRATION	RVICES		
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Food and Drug Administration, CDER/OC/OMPQ/DIDQ HFD-325 10903 New Hampshire Avenue, Building 51, Room 4218			DATE(S) OF INSPECTION 02/13/2017 - 02/17/2017, 02/20/2017 - 02/21/2017		
Silver Spri	Silver Spring, MD 20993 PH: +1 301 276-8261 ATTN: Mr. Concepcion Cruz			FEI NUMBER	
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NAME AND TIT	Industry Information: www.fda.gov/oc/industry  NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED			3005447965	
	P. Pradhan, Director, Location Head - CTO-5				
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CITY, STATE A	ND ZIP CODE		OF ESTABLISHMENT INSPECTED		
Nalgonda D	ist., Telangana, India	Manufacturer			
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DISTRICT OFFICE ADDRESS AND PHONE NUMBER  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			DATE(S) OF INSPECTION 02/13/2017 - 02/17/2017, 02/20/2017 - 02/21/2017 FEI NUMBER		
Industry Information: www.fda.gov/oc/industry			3005447965		
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Nalgonda Dist	t., Telangana, India	Manufacturer			
Operational (b) (4)  detector accident determine  b) The micro of (b) (4) performed accident determine  of the related QC-465 that	d substance test for (b) (4)  Was certified for weights in the range of with three points starting with 10 mg and	HS oven temperature, tion. The GC instrume materials.  s calibration range (usa gredient (API) during (b) (4) mg,	conducted by the outs noise and drift, signal ents were used for the age range: 10 mg to 2 released and stability mg and (b) (4) mg and (b) (4) mg is using the bestion, the linearity of the	side contractor and I to noise and Residual Solvents g) for the testing studies. The firm g for the standards alance number his balance was	
for the modi	Intained of any modification of an establishment of the data to verify that the modification, the data to verify that the modification at the establishment of the data to verify that the modification is the establishment.	fication produced resu	Its that are at least as		
Your firm fa that defined (b) (4) (b) (4) nm as po	illed to follow the USP monograph iden how to perform the test and calculate th it was noted that the absorbance rescibed by the USP test monograph. Due at approximately (b) (4) nm instead of the o	tification test method in the results for (b) (4) readings were obtained uring the review of (b) (4) it was ob	for the Ultraviolet Abs  I at a maximum wavel  batch served that the absorb	API's. For ength other than es <sup>(b) (4)</sup> ance was	
monograph.					
	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND T	TTLE (Print or Type)	DATE ISSUED	
SEE REVERSE OF THIS PAGE	all to the Shabet	Reba A. Gates, GDUFA		02/21/2017	
		Jose Lopez Rubet, Chem	list	A	
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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER

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 DATE(S) OF INSPECTION 02/13/2017 - 02/17/2017, 02/20/2017 - 02/21/2017

FEI NUMBER 3005447965

Industry Information: www.fda.gov/oc/industry

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

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

FIRM NAME

Dr. Reddy's Laboratories Ltd, Chemical Tech Ops - V

CITY, STATE AND ZIP CODE Nalgonda Dist., Telangana, India STREET ADDRESS

Peddadevulapallly - 508 207, Tripuraram Mandal

TYPE OF ESTABLISHMENT INSPECTED

Manufacturer

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.

SEE REVERSE OF THIS PAGE EMPLOYEE(S) SIGNATURE

EMPLOYEE(S) NAME AND TITLE (Print or Type)

DATE ISSUED

Reba A. Gates, GDUFA Lead Investigator

02/21/2017

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INSPECTIONAL OBSERVATIONS

Jose Lopez Rubet, Chemist

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