	DEPARTMENT OF HEAL FOOD AND DRUC			
DISTRICT ADDRESS AND PHON			DATE(S) OF INSPECTION 12/4/2023-12/8/2023	
Rockville, MI	vn Drive, Room 2032 D 20857		FEI NUMBER	
,			3009483004	
NAME AND TITLE OF INDIVIDUA	AL TO WHOM REPORT ISSUED			
Dr. Ranjana B	B Pathak, Global Head of Qual			
FIRM NAME		STREET ADDRESS	_	
Dr Reddy's La	aboratories Limited	Innovati 54	on Plaza, Survey Nos 4	12, 45, 46 &
CITY, STATE, ZIP CODE, COUN	TRY	TYPE ESTABLISHME	ENT INSPECTED	
	Medchal-Malkajgiri,	Drug Tes	ting Establishment	
Telangana, 50	00090 India			
	bservations made by the FDA representative(s) not represent a final Agency determination rega			
	implemented, or plan to implement, corrective a			
action with the FDA	representative(s) during the inspection or submi	it this informati		
questions, please con	tact FDA at the phone number and address above	/e.		
	TION OF YOUR FIRM I OBSERVED:			
OBSERVATIO	DN 1			
Laboratory reco	rds are deficient in that they do not	include a co	omplete record of all data o	btained during
testing.				
Specifically, lab	poratory data generated to demonstra	ate samenes	ss of (b) (4) In	jection (b) (4)
(b) (4)	to the reference list	ed drug (R	RLD) for secondary structu	are by Circular
	tropolarimeter lacks accuracy and r	. .	,	5
Diemoisin Spee	hopolulineter lucks accuracy and i			
The sameness	study to demonstrate that the test	drug.(b)	(4) Injection	is the same as
reference listed	drug (RLD) was conducted as pe	r protocol	# PDSP-(b) (4) INI-SAM-	
	aluation of Sameness for Secondary			
	aluation of Sameness for Secondary	/ Structure	by CD Spectropolarimeter	
(D) (4) API at	nd Injection". During this study	three subm	ission batches of the firi	n's Test Drug
(b) (4)	batch #(b) (4)		were com	pared with the
three RLD batcl	hes (batch #(b) (4)	D	During this study samples w	ere scanned for
	ism under varying conditions of te			
		b) (4)		
	pii		4 1 ° C	$\mathbf{C} = 1 \cdot \mathbf{D} = \mathbf{C} \cdot \mathbf{I}$
(L) (A)			was reported in Sameness	• •
	J-SAM-834-00. The firm approve	ed this rep	port on $12/9/2016$ and su	bmitted to the
Agency to supp	oort (b) (4)	Duri	ng the review of the analy	tical laboratory
	EMPLOYEE(S) SIGNATURE		I	DATE ISSUED
SEE REVERSE OF THIS PAGE	Saleem A Akhtar, Investigato	/_	Saleem A Akhtar	12/8/2023
			Investigator Signed By: 2001638440 Date Signed: 12-08-2023	
			X 16:37:28	
FORM FDA 483 (09/08)	PREVIOUS EDITION OBSOLETE INS	PECTIONAL	DBSERVATIONS	PAGE 1 of 12 PAGES

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION						
DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION					
12420 Parklawn Drive, Room 2032	12/4/2023-12/8/2023					
Rockville, MD 20857	FEI NUMBER 3009483004					
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED						
Dr. Ranjana B Pathak, Global Head of Qual	ity					
FIRM NAME	STREET ADDRESS					
Dr Reddy's Laboratories Limited	Innovation Plaza, Survey Nos 42, 45, 46 & 54					
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED					
Bachupally, Medchal-Malkajgiri, Telangana, 500090 India	Drug Testing Establishment					
	1					

raw data following deficiencies were observed:

- A. <u>Original electronic data is omitted and not reported</u>: For example:
 - a. On 11/25/2016, Lab Analyst ^{(b) (6)} prepared sample of Dr. Reddy's Test Drug batch and tested for Circular Dichroism at room temperature conditions ^{(b) (4)} °C) (b) (4) using CD Spectropolarimeter (equipment ID: AA266). The spectra scan was created at (b) (4) and identified as "DRL42 (b) (4) C 251116". However, review of the meta data indicated the presence of other spectra scan for the same batch (b) (4) created under room temperature conditions i.e., ^{(b)(4)} °C. This spectra was created at(b) (4) and was identified as "N_DRL42(b) (4) C_251116". The Lab Analyst stated after the first scan at (b) (4) she observed fluctuation in temperature when the same sample was being heated in the cuvette to be tested at^{(b) (4)} °C. The analyst discarded the sample in the cuvette and retested the sample even though the original scan at (b) (4) was created before the temperature fluctuation was observed. The QC Lab did not report the spectra created at(b) (4) in analysis. The only spectra in the analysis was that was created at (b) (4) The quality unit did not raise any incident to investigate the temperature fluctuation. This incident was not reported to the agency until it was discovered during the inspection.
 - b. Laboratory data generated on 11/28-29/2016 pertaining to Circular Dichroism study for RLD batch # (b) (4) and Test Drug (DRL batch (b) (4) was not reported and invalidated without scientific justification. This data was generated as per following information:

SEE REVERSE OF THIS PAGE	EMPLOYEE(S)SIGNATURE Saleem A Akhtar,	Investigator	Saleem A Akhtar Investigator Signed By: 2001638440 Disgraded: 12-08-2023 16:37/28	date issued 12/8/2023
FORM FDA 483 (09/08)	PREVIOUS EDITION OBSOLETE	INSPECTIONAL OBSERVATIO	ONS	PAGE 2 of 12 PAGES

DEPA	RTMENT OF HEALTH AND HUM				
DISTRICT ADDRESS AND PHONE NUMBER	FOOD AND DRUG ADMINISTRAT	DATE(S) OF INSPECTION			
12420 Parklawn Drive, Room 20 Rockville, MD 20857	12/4/2023-12/8/2023 FEI NUMBER				
NOCRVIIIE, MD 20037		3009483004			
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED					
Dr. Ranjana B Pathak, Global	Head of Quality STREET ADDRESS				
Dr Reddy's Laboratories Limit		on Plaza, Survey Nos 4	2, 45, 46 &		
	54	_			
CITY, STATE, ZIP CODE, COUNTRY Bachupally, Medchal-Malkajgiri, Drug Testing Establishment					
Telangana, 500090 India	,				
Sr. No. Spectra Ide	entified as	Date			
1 (b) (4)	_WIFI_ProductpH_2811	16 11/28/2016 1:51 PM			
2 (b) (4)	WIFI_pH ^{(b) (4)} 281116	11/28/2016 2:53 PM			
3 (b) (4)	WIFI_pH 281116	11/28/2016 3:13 PM			
4 (b) (4)	WIFI pH o Product	11/28/2016 4:08 PM	-		
pH 281116					
5 (b) (4)	WIFI pH ^{(b) (4)} to Product	11/28/2016 4:29 PM	-		
pH 281116					
<u> </u>	ductpH 291116	11/29/2016 1:54 PM	-		
	oductpH ^{(b)(4)} 291116	11/29/2016 2:32 PM	-		
8 DRL41 pH		11/29/2016 3:42 PM	-		
	to ProductpH_291116	11/29/2016 4:22 PM	-		
	^{b) (4)} to ProductpH 291116	11/29/2016 4:48 PM	-		
· · · · · · · · · · · · · · · · · · ·	5	nvestigation Report (# LIR-	/		
8 8 9	1 5	scientist while adjusting the	1		
(1.) (-)		ading the pH". However, th			
^{(b) (6)} did not document this fact in her laboratory notebook when she adjusted the pH for all these samples on $11/28/2016$ and $11/29/2026$. Instead, the analyst recorded this					
		n a week later on $12/7/20$			
		16-980 indicated the firm of	1		
		lidated all then scans and sa			
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l					
EMPLOYEE(S) SIGNATURE SEE REVERSE Saleem A Akhtar	, Investigator		DATE ISSUED		
OF THIS PAGE	,	Saleem A Akhtar Investigator Signed By: 2001638440	, ., 2020		
		Signed By: 2001638440 Date Signed: 12-08-2023 16:37:28			
			-		

DISTRICT ADDRESS AND PHONE NUMBER 12420 Parklawn Drive, Room 2032 Rockville, MD 20857 NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Dr. Ranjana B Pathak, Global Head of Quality	DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION						
Rockville, MD 20857 FEI NUMBER 3009483004 NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED							
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED							
Dr. Banjana B. Pathak, Global Head of Quality							
bi. Ranjana b rachaky biobar nead or gauricy							
FIRM NAME STREET ADDRESS							
Dr Reddy's Laboratories Limited Innovation Plaza, Survey Nos 42, 45, 4 54	6&						
CITY, STATE, ZIP CODE, COUNTRY TYPE ESTABLISHMENT INSPECTED							
Bachupally, Medchal-Malkajgiri, Drug Testing Establishment Telangana, 500090 India							

Fresh samples of Test Drug DRL batch (b) (4) were prepared and tested on the same date (11/30/2016) when the LIR-A-AD-16-980was initiated. This discrepancy was not discussed in the Sameness Study Report PDSR(b) (4) INJ-SAM-834-00 that was submitted to the Agency.

- c. The Lab Analyst ^{(b) (6)} stated she used pH meter equipment ID: AA363 to adjust the pH of RLD and Test Drug batches used to Circular Dichroism test. Review of the equipment use logbook (ARD0525/15; a 100-page bound book) indicated the last entry on this book was made page 98 on 11/26/2016. Blank page 100 of this notebook was voided with an additional note stating, "Page 99 is missing". The site started a new equipment use logbook (ARD0374/16) for this pH meter AA363 and recorded the pH reading of the RLD batch (b) (4) on 11/28/2016 (the 3 preparations that were invalidated). The site Quality Head provided the scanned copy of the use logbook ARD0525/15 and stated the original notebook has been destroyed as per the firm's policy. The site failed to provide a reasonable justification why page 99 of this book got missing and why the site voided page 100 of this notebook.
- B. <u>Original electronic data is not attributable</u>: Lab Analyst ^{(b) (6)} scanned about 11 samples of Dr. Reddy's Laboratories (DRL) batches of the Test Drug (TD) and Reference Listed Drug (RLD) batches under varying temperature conditions using CD Spectropolarimeter (equipment ID: AA266) and generated the CD spectra using software Spectra Manager/v2.15. The spectra pertaining to these 11 samples (as shown below) were named in a way that it could not be established as which spectra belongs to which specific batch of DRL batch or RLD batch.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S)SIGNATURE Saleem A Akhtar,	Investigator	Saleem A Akhlar Intestigator Signed By: 2001638440 Date Signed: 12-08-2023 16:37:28	date issued 12/8/2023
FORM FDA 483 (09/08)	PREVIOUS EDITION OBSOLETE	INSPECTIONAL OBSERVATIO	ONS	PAGE 4 of 12 PAGES

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FORM FDA 483 (09/08) PREVIOUS EDITION OBSOLETE INSPECTIONAL OBSERVATIONS PAGE 5 of 12 PAGES	FORM FDA 483 (09/08)	PREVIOUS EDIT	ION OBSOLETE IN	SPECTIONAL (DBSERVATIONS	PAGE 5 of 12 PAGES	

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DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032	12/4/2023-12/8/2023
Rockville, MD 20857	FEI NUMBER 3009483004
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Dr. Ranjana B Pathak, Global Head of Qual	ity
FIRM NAME	STREET ADDRESS
Dr Reddy's Laboratories Limited	Innovation Plaza, Survey Nos 42, 45, 46 & 54
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Bachupally, Medchal-Malkajgiri, Telangana, 500090 India	Drug Testing Establishment
(b) (4) mg/mL) is comparable to the Innovator's Refere	nce Listed Drug (RLD).

OBSERVATION 2

Determinations of conformance to appropriate written specifications for acceptance are deficient for drug products.

Specifically, you do not have detailed control procedures in place to review technical data generated utilizing complex analytical techniques and equipment to ensure the reported data is accurate and complete.

and (b) (of (b) (4 (b) (4) Spectrom content in	4) .) eter (1 (b) (4	Content in (b) API. During NMR, equipment	g this study three ex we ID: AA574) to qua site does not have co	MR Spectroscop nibit batches of re tested using antify (b) (4)	y" to sup (b) (4) Nuclear	port (b) r Magne	(4) shelf life API (batch # tic Resonance
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	1	SEC-	MALLS	Molecular weig	ght	AA265	(b) (4)	
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				Capped C-term	inal ratio			
	3	(b) (4) Analyzer	(b) (4)		FS044		
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Rockville, MD 20857			1	FEI NUMBER 3009483004	072025
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)r. Ran	njana B Pathak, Global	Head of Qual	ity street address		
	dy's Laboratories Limi	ted		n Plaza, Surv	ey Nos 42, 45, 46 &
Bachupa	^P CODE,COUNTRY Ally, Medchal-Malkajgi Ana, 500090 India	ri,	TYPE ESTABLISHMENT Drug Test	INSPECTED ing Establish	ment
	Optical Emission				
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9	ICPMS (Inductively	Low molecular	r weight ^{(D) (4)}	AA584	(b) (4)
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1.0				AA585	-
10	HRMS (High	Structural E		FA1242	
	Resolution Mass	and Samene	ESS		
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	HybridQuadrupole	and Samene	ess		
	Orbitrap Mass				
	Spectrometer			FA1290	-
12	Small angle V Day	(b) (4)		AA393	-
12	Small angle X-Ray	(b) (4)		AA393	
13	Scattering (SAXS)			AA447	-
15	SYNAPT G2-Si	Structural E and Samene		AA44 /	
14	(HRMS)			AA563	-
14	Atomic Force Microscopy (AFM)	Nanoparticle Diameter	e size allu	AAJ05	
15	Zetasizer Nano ZSP		- size	AA383	-
16	XRD	Particle (b)	()	AA387	
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	17 LC MS ABSCIEX 4500			Mass Identification		AA52	7	(b)	(4)
	18	METI	ROHM DROGRAPH	Reduced ^{(b) (4)} content Ionic impurities		FA83.	3	()	
	19	Ion (Chromatograph			AA29	1		
	20	Ion (Chromatograph	Ionic impuritie	S	FA13	02		
	21	SHIN	ADZU GCMS	Organic impur	ities	FA12	77		
	22	AGIL	ENT GCMS	Organic impur	ities	FA124	47		
	23 Shimadzu GC-MS C		Organic impurities		AA66	5			
	24 AGILENT GCMS		Organic impurities		AA78	AA788			
	25 LCMS 5500		Organic impurities		FA12	FA1289			
	26 LCMS 6500 Organic imput		ities FA1353		53				
Th	The site's Quality Head stated the firm does not have technique specific control procedures in place to								
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INSPECTIONAL OBSERVATIONS

FORM FDA 483 (09/08)

PREVIOUS EDITION OBSOLETE

PAGE 9 of 12 PAGES

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION						
DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION					
12420 Parklawn Drive, Room 2032	12/4/2023-12/8/2023					
Rockville, MD 20857	FEI NUMBER 3009483004					
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED						
Dr. Ranjana B Pathak, Global Head of Quality						
FIRM NAME	STREET ADDRESS					
Dr Reddy's Laboratories Limited	Innovation Plaza, Survey Nos 42, 45, 46 & 54					
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED					
Bachupally, Medchal-Malkajgiri, Telangana, 500090 India	Drug Testing Establishment					

review data generated from these equipment.

OBSERVATION 3

Employees are not given training in the particular operations they perform as part of their function and current good manufacturing practices.

Specifically, the firm's Quality Unit failed to ensure all the employees involved in day to day GMP activities have completed the required training. During the review of the training program, it was observed that an employee in lead role was overdue for an SOP training, "Countermeasures: Do it the right way on Kaizen Optimizer" for more than two years.

Following is a list (not all inclusive) of the trainings that were observed overdue:

Training Do	escription	Document No.	Employee ID	Employee	Du	e Date
				Role		
Countermea	sures: Do it the right	3PE00164	(b) (6)	Feam Lead	Dee	: 4, 2021
way on Kaiz	zen Optimizer		(\sim) (\circ)			
User Manag	ement for GxP	SOP-IPDO-CAD-		Гeam Lead	No	v 28, 2022
Computerize	ed Systems (3.0)	0170 3.0				
CHANGE C	CONTROL	SOP-IPDO-CDQ-		Геат Lead	Feb	17, 2023
PROCEDUI	RE (3.0)	0028 3.0				
HANDLING	G OF INCIDENTS	SOP-IPDO-CDQ-		Геат Lead	Ma	y 4, 2023
AND DEVL	ATIONS (5.0)	0001 5.0				
DOCUMEN	TING THE	SOP-IPDO-CAD-		Геат Lead	Ma	y 8, 2023
				-		
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FORM FDA 483 (09/08)

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PAGE 10 of 12 PAGES

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ockville, MD 20857			3009483	3004	
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. Ranjana B Pathak, Global	Head of Qual	Lity			
/ NAME	-	STREET ADDRES	SS		
Reddy's Laboratories Limit	ed	Innovat 54	tion Plaza	a, Survey N	os 42, 45, 4
Y, STATE, ZIP CODE, COUNTRY			HMENT INSPECTED		
chupally, Medchal-Malkajgir	i,	Drug Te	esting Est	cablishment	
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cGMP in Drug Manufacturing -	3QA00148			eam Lead	May 28, 2023
2023					
Good Analytical Practices (8.0)	SOP-GLOB-0	QC-		eam Lead	May 30, 2023
	0085-8.0				
Reprocessing of analytical data	SOP-IPDO-C	AD-		eam Lead	Jun 3, 2023
for non-chromatographic	0181 2.0			Calli Lead	5 dii 5, 2025
U I	0101 2.0				
systems for batch release And					
method validation in GMP					
laboratories (2.0)					
Analytical Method Transfer (9.0	SOP-GLOB-	QC-		eam Lead	Jul 6, 2023
	0010-9.0				
Rounding Rules (5.0)	SOP-GLOB-0	QA-		Analytical	Sep 23, 2023
	0010-5.0			xpert	

The employee training (including the GMP training) program is implemented as per SOP-IPDO-CDQ-0004, "Employee Training". This SOP does not specify minimum number of days within which the employees have to complete the required training.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S)SIGNATURE Saleem A Akhtar, Investigator	Satesm A Akhtar Investigated Signed By: 2001638440 Date Signed: 12-08-2023 16:37:28	DATE ISSUED
FORM FDA 483 (09/08)	PREVIOUS EDITION OBSOLETE INSPECTIONAL OBSERVATI	ONS	PAGE 11 of 12 PAGES

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION						
DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION					
12420 Parklawn Drive, Room 2032		12/4/2023-12/8/2023				
Rockville, MD 20857		FEI NUMBER				
		3009483004				
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED		I				
Dr. Ranjana B Pathak, Global Head of Quality						
FIRM NAME	STREET ADDRESS	EET ADDRESS				
Dr Reddy's Laboratories Limited	Innovati 54	novation Plaza, Survey Nos 42, 45, 46 &				
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED					
Bachupally, Medchal-Malkajgiri,	Drug Testing Establishment					
Telangana, 500090 India		5				

SEE REVERSE OF THIS PAGE	EMPLOYEE(S)SIGNATURE Saleem A Akhtar, Inv	estigator	Saloem A Akhtar Investgator Signed By: 2001638440 Date Signed: 12-08-2023 16:37:28	DATE ISSUED
FORM FDA 483 (09/08)	PREVIOUS EDITION OBSOLETE	INSPECTIONAL OBSERVATIO	ONS	PAGE 12 of 12 PAGES