Laboratory Accreditation Standard		-	Food and Drugs Laboratory, Nizampura, Vadodara, Gujarat ISO/IEC 17025: 2005				
Certificate Number Discipline Last Amended on		T-1446	I	ssue Date	09.12.2016		
		Biological Testing	N	/alid Until	08.12.2018 1 of 3		
		-	F	Page			
S. No.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed		of Testing / of Detection		
I.	DRUG & PHARM	ACEUTICALS					
1.	Gentamicin In- Injectable Preparations	Microbiological Assay of Antibiotics, Diffusion Method By Bacillus pumilus NCTC 8241	BP-2015, Page V 396	10.0 to 1	110.0 %		
2.	Gentamicin In- Eye / Ear Drops	Microbiological Assay of Antibiotics, Diffusion Method By Bacillus pumilus NCTC 8241	BP-2015, Page V 396	10.0 to 1	120.0 %		
3.	Neomycin Sulfate Cream USP	Microbiological Assay	USP-38, Pg. No. 4511	10.0 to 1	135.0 %		
4.	Neomycin Sulfate Ointment USP	Microbiological Assay	USP-38, Pg. No. 4511	10.0 to 1	135.0 %		
5.	Parenterals	Sterility	IP-2014 Page No. 59 (Direct Inoculation-Method-B)) (Compli	Qualitative (Complies/ Does not comply)		
6.	Pharmacopoeial Parenteral Preparations (Small Volume Parenterals and Large Volume Parenterals)	Bacterial Endotoxin	I.P. 2014, Volume I, 2.2.3 Page No. 28. USP-38, Volume I, <85> Page 151 (Gel Clot Method)	(Compli	Qualitative (Complies/ Does not comply)		
7.	Parenterals	Sterility	IP-2014, Page No. 59 (Membrane Filtration-Method-	Qualitat A) (Compli comply)	es/ Does not		

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Certificate Number		T-1446		Issue Date	09.12.2016		
Disci	ipline	Biological Testing	V	Valid Until	08.12.2018		
Last Amended on		-		Page	2 of 3		
S. No.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed		of Testing / of Detection		
8.	Black Disinfectant Fluid	Rideal Walker Coefficient (RWC)	Schedule of Drugs & Cosmeti Rules – 1945	ics 4 to 25	RWC		
9.	Ciprofloxacin Eye Drops	Sterility MF	I.P. 2014, Page No. 1403	(Compli	Qualitative (Complies/ Does not comply)		
10.	Diazepam Injection	Sterility	I.P. 2014, Page No. 1547	Qualitat (Compli comply)	es/ Does not		
		Bacterial Endotoxin		(Compli	Qualitative (Complies/ Does not comply)		
11.	Diclofenac Injection	Sterility MF	I.P. 2014, Page No. 1551	Qualitat (Compli comply)	es/ Does not		
12.	Frusemide Injection	Sterility	I.P. 2014, Page No. 1834	Qualitat (Compli comply)	es/ Does not		
		Bacterial Endotoxin		Qualitat (Compli comply)	es/ Does not		
13.	Norfloxacin Eye Drops	Sterility MF	I.P. 2014, Page No. 2352	Qualitat (Compli comply)	es/ Does not		
14.	Ofloxacin Ophthalmic Solution	Sterility MF	I.P. 2014, Page No. 2368	Qualitat (Compli comply)	es/ Does not		

	oratory editation Standa	-	Food and Drugs Laboratory, Nizampura, Vadodara, Gujarat ISO/IEC 17025: 2005				
Certi	ficate Number	T-1446	T-1446 Biological Testing -		09.12.2016		
Disc	ipline	Biological Testing			08.12.2018		
Last	Amended on	-			3 of 3		
S. No.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed		of Testing / of Detection		
15.	Ranitidine Injection	Sterility	I.P. 2014, Page No. 2645	(Compli	Qualitative (Complies/ Does not comply)		
16.	Ciprofloxacin Injection	Sterility MF	I.P. 2014, Page No. 1400	Qualitati (Complic comply)	es/ Does not		
		Bacterial Endotoxin		Qualitati (Compli- comply)	es/ Does not		
17.	Dextrose Injection	Sterility MF	I.P. 2014, Page No. 1542	age No. 1542 Qualitative (Complies/ Does comply)			
		Bacterial Endotoxin		Qualitati (Compli- comply)	es/ Does not		
18.	Levofloxacin Infusion	Sterility MF	I.P. 2014, Page No. 2086	Qualitati (Complic comply)	es/ Does not		
19.	Ofloxacin Infusion	Sterility MF	I.P. 2014, Page No. 2368	(Compli	Qualitative (Complies/ Does not comply)		