

**KAMLAAMRUT PHARMACEUTICAL LLP.**

(Survey no. 53, 56, 57, Near Kamla Amrut Industrial Park, Indrad, Ta-Kadi, Dist.-Mehsana, Gujarat, 382715, India)

QUALITY CONTROL DEPARTMENT**CERTIFICATE OF ANALYSIS**

Generic Name : Levofloxacin Infusion 0.5 %w/v With Sodium Chloride 0.9 %w/v

Product Name :

Batch No. : AC4374001	A.R. No. : KAPL/FP/24/AC4374001
Batch Size : 2450 Ltrs.	Quantity sampled : 25 Nos.
Fill Volume : 100 ml	Received Date : 23/10/24
Mfg. Date : 10/2024	Testing Date : 24/10/24
Exp. Date : 09/2026	Completion Date : 07/11/24

Sr. No.	Tests	Observation	Specifications	Reference to Test Method
1.0	Description	A Clear and yellow solution Confirms	A yellow to greenish yellow solution essentially free from visible particles.	In-House
2.0	Identification:			
2.1	Identification by HPLC	Confirms	The chromatogram obtained with the test solution corresponds to the chromatogram obtained with standard solution	In-House
3.0	pH	5.01 Confirms	Between 3.8 to 5.8	In-House
4.0	Extractable volume	102.0 ml Confirms	The volume is not less than the nominal volume.	In-House
5.0	Particulate matter			
5.1	Particulate matter for ≤ 100 ml nominal volume			In-House
	For $\geq 10\mu\text{m}$	15.00 particles per container Confirms	Not more than 6000 particles per container	
	For $\geq 25\mu\text{m}$	1.67 particles per container Confirms	Not more than 600 particles per container	
6.0	Assay of Sodium Chloride	0.8909%w/v 98.99% Confirms	Between 95.0% to 105.0% of the Label claim(Label Claim:0.9% w/v)	In-House
7.0	Assay of Levofloxacin (By HPLC)	0.4934 %w/v 98.69% Confirms	Between 90.0% to 120.0% of the Label claim (Label Claim:0.75% w/v)	In-House

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Sr. No.	Tests	Observation	Specifications	Reference to Test Method
8.0	Bacterial Endotoxins	<0.25 EU/ml Confirms	Not more than 0.50 EU/ml	In-House
9.0	Sterility	Sterile Confirms	It must be sterile	In-House

Remarks: The finish product **Confirms** with the defined specifications.

	Analysed by	Checked by	Verified by
Signature			
Date	07/11/24	07/11/24	07/11/24
Name	Priya Patel	Dhruv Nayi	Jigar Patel
Designation	Q.C. Analyst	Q.C. Officer/Executive	Asst. Manager Q.C