

**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 (500mg/100ml)

Product Name :

Batch No. : AC4374002	A.R. No. : KAPL/FP/24/AC4374002
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.	IP Monograph
2.0	Identification:			
2.1	Identification by HPLC	Confirms	The chromatogram obtained with the test solution corresponds to the chromatogram obtained with standard solution	IP Monograph (2.4.14)
3.0	pH	4.72 Confirms	Between 3.8 to 5.8	IP Monograph (2.4.24)
4.0	Extractable volume	102.0 ml Confirms	The volume is not less than the nominal volume.	IP Monograph
5.0	Particulate matter			
5.1	Particulate matter for $\leq 100$ ml nominal volume			IP Monograph (2.5.9)
	For $\geq 10\mu\text{m}$	53.33 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	0.9026 %w/v 100.29% Confirms	Between 95.0% to 105.0% of the Label claim (Label Claim: 0.9% w/v)	IP Monograph
7.0	Assay of Levofloxacin (By HPLC)	0.4830 %w/v 96.61% Confirms	Between 90.0% to 120.0% of the Label claim (Label Claim: 0.75% w/v)	IP Monograph (2.4.14)

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Issue Date: 06/01/23

Eff. Date: 07/01/23

Page No. : 1 / 2

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8.0	Bacterial Endotoxins	<0.25 EU/ml Confirms	Not more than 0.50 EU/ml	IP Monograph (2.2.3)
9.0	Sterility	Sterile Confirms	It must be sterile	IP Monograph (2.2.11)

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

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

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Page No. : 2 / 2