

**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 : Ciprofloxacin Injection IP

Product Name :

Batch No. : AC4314001

A.R. No. : KAPL/FP/24/ AC4314001

Batch Size : 5900 Ltrs.

Quantity sampled : 25 Nos

Fill Volume : 100ml.

Received Date : 22/10/24

Mfg. Date : 10/2024

Testing Date : 23/10/24

Exp. Date : 09/2027

Completion Date : 06/11/24

Sr. No.	Tests	Observation	Specifications	Reference to Test Method
1.0	Description	A clear to Slightly Yellow Solution Confirms	A clear to Slightly Yellow solution essentially free from visible particles.	IP Monograph
2.0	Identification:			
2.1	Identification by Thin layer Chromatography	Confirms	The Principal band in the chromatogram obtained with the test solution corresponds to that in the chromatogram obtained with standard solution.	IP Monograph (2.4.17)
3.0	pH	3.98 Confirms	Between 3.5 and 4.6.	IP Monograph (2.4.24)
4.0	Extractable volume	102.0ml. Confirms	The volume is not less than the nominal volume.	IP Monograph
5.0	Particulate matter			
5.1	Particulate matter for >100 ml nominal volume			IP Monograph (2.5.9)
	For $\geq 10\mu$	-NA-	Not more than 25 particles per ml	
	For $\geq 25\mu$	-NA-	Not more than 03 particles per ml	
5.2	Particulate matter for ≤ 100 ml nominal volume			IP Monograph (2.5.9)
	For $\geq 10\mu\text{m}$	16.67 particles per container Confirms	Not more than 6000 particles per container	
	For $\geq 25\mu\text{m}$	5.00 particles per container Confirms	Not more than 600 particles per container	

Revision No.: 00

Issue Date: 30/12/22

Eff. Date: 31/12/22

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Fill Volume : 100ml.	Received Date : 22/10/24
Mfg. Date : 10/2024	Testing Date : 23/10/24
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Sr. No.	Tests	Observation	Specifications	Reference to Test Method
6.0	Lactic acid	0.3351 mg Confirms	Between 0.288 mg and 0.352 mg for each mg of ciprofloxacin.	IP Monograph (2.4.14)
7.0	Assay of Sodium Chloride	0.8968%w/v 99.64% Confirms	Between 95.0% and 105.0% of The label claim (Label claim: 0.9%w/v).	IP Monograph
8.0	Assay of Ciprofloxacin	0.2032% w/v 101.58% Confirms	Between 90.0% and 110.0% of the label claim (Label claim: 0.2%w/v).	IP Monograph (2.4.14)
9.0	Ciprofloxacin ethylenediamine analog	CEDA:-0.10% Confirms	Not more than 0.5%.	IP Monograph
10.0	Bacterial Endotoxins	<0.125 EU/mg Confirms	Not more than 0.25 EU/mg.	IP Monograph (2.2.3)
11.0	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	06/11/24	06/11/24	06/11/24
Name	Priya Patel	Dhruv Nayi	Jigar Patel
Designation	Q.C. Analyst	Q.C. Officer/Executive	Asst. Manager Q.C.