

**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 : Metronidazole Injection IP (0.5% w/v)

Product Name :

Batch No. : AC4234001

A.R. No. : KAPL/FP/24/AC4234001

Batch Size : 7500 Ltrs.

Quantity sampled : 25 Nos

Fill Volume : 100 ml

Received Date : 25/10/24

Mfg. Date : 10/2024

Testing Date : 25/10/24

Exp. Date : 09/2027

Completion Date : 08/11/24

Sr. No.	Tests	Observation	Specifications	Reference to Test Method
1.0	Description	A clear and Pale Yellow Solution Confirms	A clear and almost colourless to pale yellow solution essentially free from visible particles.	IP Monograph
2.0	Identification:			
2.1	Identification by IR	Confirms	The infrared absorption spectrum of the residue is concordant with the reference spectrum of Metronidazole.	IP Monograph (2.4.6)
2.2	Reaction of primary aromatic amines	Confirms	An intense orange or red colour and, usually, a precipitate of the same colour are produced.	IP Monograph (2.3.1)
3.0	pH	5.46 Confirms	Between 4.5 and 7.0.	IP Monograph (2.4.24)
4.0	Related Substances	In the chromatogram obtained with the test solution the area of any secondary peak is not more than the area of the peak due to 2-methyl-5-nitroimidazole in the chromatogram obtained with reference solution:0.0302% Confirms	In the chromatogram obtained with the test solution the area of any secondary peak is not more than the area of the peak due to 2-methyl-5-nitroimidazole in the chromatogram obtained with reference solution (0.5%).	IP Monograph (2.4.14)
5.0	Extractable volume	102.0 ml Confirms	The volume is not less than the nominal volume.	IP Monograph

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Sr. No.	Tests	Observation	Specifications	Reference to Test Method
6.0	Particulate matter			IP Monograph (2.5.9)
6.1	Particulate matter for >100 ml nominal volume.			
	For $\geq 10\mu\text{m}$	-NA-	Not more than 25 particles per ml	
	For $\geq 25\mu\text{m}$	-NA-	Not more than 03 particles per ml	
6.2	Particulate matter for ≤ 100 ml nominal volume.			IP Monograph (2.5.9)
	For $\geq 10\mu\text{m}$	18.33 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	
7.0	Assay			
7.1	Assay of Metronidazole	0.5051% w/v 101.04% Confirms	Between 90.0% to 110.0% of the label claim. (Label claim:0.5%w/v)	IP Monograph (2.4.7)
7.2	Assay of Sodium Chloride	0.7795% w/v 98.68% Confirms	Between 95.0% to 105.0% of the label claim. (Label claim:0.79%w/v)	IP Monograph
8.0	Bacterial Endotoxins	<0.175 EU/mg Confirms	Not more than 0.35 EU/mg	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	08/11/24	08/11/24	08/11/24
Name	Priya Patel	Dhruv Nayi	Jigar Patel
Designation	Q.C. Analyst	Q.C. Officer/Executive	Asst. Manager Q.C.