

**KamlaAmrut Pharmaceuticals LLP****QUALITY CONTROL DEPARTMENT****CERTIFICATE OF ANALYSIS**

Generic Name	: METRONIDAZOLE INJECTION IP (0.5% W/V)		
Product Name	: 0.5 % METRONIDAZOLE INJECTION IP - 100ML (INFECCYL IV) - AMERICAN - NH (W/O -C)		
Batch No.	: AC2236001	A.R. No.	: KAPL/FP/26/AC2236001
Batch Size	: 3500 Ltr	Quantity sampled	: 25 Nos
Fill Volume	: 100 ML	Received Date	: 01/08/2026
Mfg. Date	: 01/07/2026	Testing Date	: 03/08/2026
Exp. Date	: 30/06/2029	Completion Date	: 20/08/2026

Sr. No.	Tests	Observation	Specifications	Reference to Test Method
1.0	Description	A clear and almost colourless to pale yellow solution.	A clear and almost colourless to pale yellow solution essentially free from visible particles.	IP Monograph
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	5.52	Between 4.5 and 7.0.	IP Monograph (2.4.24)
4.0	Related Substances	Tinidazole Imp.: 0.0166 % any secondary Imp.: 0.0150% Total Imp.: 0.0314 %	Tinidazole related compound A NMT : 0.15% Any Secondary Imp NMT : 0.15% Total Impurity NMT : 2.0%	IP Monograph (2.4.14)
5.0	Extractable Volume	102.0 ml	The volume is not less than the nominal volume.	IP Monograph
6.1	Particulate matter for > 100 ml nominal volume	-N/A-	Not more than 25 particles per ml Not more than 03 particles per ml	IP Monograph (2.5.9)
6.2	Particulate Matter for ≤ 100ml Nominal Volume	13.3 Particles per container 0.0 Particles per container	Not more than 6000 particles per container Not more than 600 particles per container	IP Monograph (2.5.9)
7.0	Assay of Metronidazole	0.4918 %w/v 98.36 %	Between 90.0% to 110.0% of the label claim. (Label claim:0.5%w/v)	IP Monograph (2.4.7)
8.0	Assay of Sodium Chloride	0.8006 %w/v 100.08 %	Between 95.00 % to 105.00 % of the label claim. (Label claim:0.80 %w/v)	IP Monograph
9.0	Bacterial	<0.175 EU/mg	NMT 0.35 EU/mg	IP Monograph (2.2.3)

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10.0	Sterility	Sterile	It must be sterile	IP Monograph (2.2.11)

Remarks : The finish product confirms with the defined specifications.

	Analysed by	Checked by	Verified by
Date	20/08/2026	20/08/2026	20/08/2026
Name	Jinal Patel	Jaypal Vaghela	Vijay Prajapati
Designation	QC Officer	QC Executive	QA Manager
Revision No.: 2.00	Issue Date: 31/07/2025	Eff. Date: 01/08/2025	Page 2 of 2

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