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 :INFECGYL IP

Batch No. : AC4235002	A.R. No. : KAPL/FP/25/ AC4235002
Batch Size : 7500 Ltrs.	Quantity sampled : 25 Nos
Fill Volume : 100 ml	Received Date : 01/10/25
Mfg. Date : 09/2025	Testing Date : 03/10/25
Exp. Date : 08/2028	Completion Date : 19/10/25

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	Identification by HPLC	Confirms	In the Assay, the principal peak in the Chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with reference solution (a).	IP Monograph
3.0	pH	5.56 Confirms	Between 4.5 and 7.0.	IP Monograph (2.4.24)
4.0	Related Substances	Tinidazole Imp:0.0067% Any Secondary Imp:0.0068% Total Impurity: 0.0015% 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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6.0	Particulate matter			IP Monograph (2.5.9)
	Particulate matter for ≤100 ml nominal volume.			IP Monograph (2.5.9)
	For ≥ 10µm	1.67 particles per container Confirms	Not more than 6000 particles per container	
	For ≥ 25µm	0.00 particles per container Confirms	Not more than 600 particles per container	
7.0	Assay of Sodium Chloride	0.7964% w/v 99.55% Confirms	Between 95.0% to 105.0% of the label claim. (Label claim:0.80%w/v)	IP Monograph
8.0	Assay of Metronidazole	0.4980% w/v 99.60% Confirms	Between 90.0% to 110.0% of the label claim. (Label claim:0.5%w/v)	IP Monograph (2.4.7)
9.0	Bacterial Endotoxins	<0.175 EU/mg Confirms	Not more than 0.35 EU/mg	IP Monograph (2.2.3)
10.0	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	JkPatel	[signature]	[signature]
Date	19/10/25	19/10/25	19/10/25
Name	Jinal Patel	Baldev Makwana	Kuldeep Nai
Designation	Q.C. Analyst	Q.C. ~~Officer~~/Executive	Q.C. ~~Officer~~/Executive