

**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 (INFECGYL IV) - AMERICAN - NH (W/O -C) | | |
| Batch No. | : AC2235001 | A.R. No. | : KAPL/FP/25/AC2235001 |
| Batch Size | : 3500 Ltr | Quantity sampled | : 25 Nos |
| Fill Volume | : 100 ML | Received Date | : 24/12/2025 |
| Mfg. Date | : 01/12/2025 | Testing Date | : 25/12/2025 |
| Exp. Date | : 30/11/2028 | Completion Date | : 08/01/2026 |

| 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 | 5.55 | Between 4.5 and 7.0. | IP Monograph (2.4.24) |
| 4.0 | Related Substances | Tinidazole Imp.: 0.0210 % any secondary Imp.: 0.0257% Total Imp.: 0.0044 % | 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 | 10.33 Particles per container 14.00 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 | 0.5059 %w/v 101.18 % | 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 | 0.7964 %w/v 99.55 % | 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) |

Revision No.: 2.00

Issue Date: 31/07/2025

Eff. Date: 01/08/2025

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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 | 08/01/2026 | 08/01/2026 | 08/01/2026 |
| Name | Jinal Patel | Baldev Makwana | Kirit Patel |
| Designation | QC Officer | ASST. MANAGER | QA Manager |

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