

Laboratory **ITL Labs Private Limited, 25 Gokuldas Compound, Industrial Estate, Indore, Madhya Pradesh**

Accreditation Standard **ISO/IEC 17025: 2017**

Certificate Number **TC-5638**

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Validity **23.08.2019 to 02.08.2020**

Last Amended on --

| Sl. | Product / Material of Test | Specific Test Performed | Test Method Specification against which tests are performed | Range of Testing / Limits of Detection |
|----------------------------------|--|----------------------------|---|--|
| <u>BIOLOGICAL TESTING</u> | | | | |
| I. | DRUGS & PHARMACEUTICALS | | | |
| A. | Antibiotics | | | |
| 1. | Amikacin Injection | Assay | Indian Pharmacopeia | 80% to 130% of Label Claim |
| 2. | Erythromycin Tablet | Assay | Indian Pharmacopeia | 80% to 120% of Label Claim |
| 3. | Erythromycin Stearate Tablet | Assay | Indian Pharmacopeia | 80% to 125% of Label Claim |
| 4. | Gentamycin Injection | Assay | Indian Pharmacopeia | 85% to 120% of Label Claim |
| 5. | Gentamycin Eye Drop | Assay | Indian Pharmacopeia | 80% to 130% of Label Claim |
| 6. | Neomycin Eye Drop | Assay | Indian Pharmacopeia | 80% to 125% of Label Claim |
| B. | Microbial Limit Test | | | |
| 1. | Non Sterile Pharmaceutical Products | Total viable aerobic count | Indian Pharmacopeia | ≤10 to 10 ⁵ CFU/g/ml |
| | | Escherichia coli | Indian Pharmacopeia | Absent/Present per g/ml |
| | | Salmonella | Indian Pharmacopeia | Absent/Present per 10g/10ml |
| | | Shigella | Indian Pharmacopeia | Absent/Present per 10g/10ml |
| C. | Parenteral preparation | | | |
| 1. | Parenteral | Bacterial Endotoxin Test | Indian Pharmacopeia | Qualitative |

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|-----|--|-------------------------|---|--|
| | Preparation | (Gel clot method) | | Complies/ Does not comply |
| IV. | Perantral, Ophthalmic, Preparation, Blood Bags, Surgical Dressings, Cotton & Medical Devices | Sterility | Indian Pharmacopeia | Complies/ Does not comply |

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CHEMICAL TESTING

| | | | | |
|-----------|--|---------------------------|---|-----------------|
| I. | DRUGS & PHARMACEUTICALS | | | |
| A. | Pharmaceuticals Raw Materials | | | |
| 1. | Amoxicillin Trihydrate | Assay | Indian Pharmacopeia | 70% to 130% |
| | | Sulphated ash | Indian Pharmacopeia | 0.01% to 15.0% |
| | | Specific optical rotation | Indian Pharmacopeia | ±0.05° to ±360° |
| 2. | Cloxacillin Sodium | Assay | Indian Pharmacopeia | 80% to 120% |
| | | Specific optical rotation | Indian Pharmacopeia | ±0.05° to ±360° |
| 3. | Calcium Carbonate | Assay | Indian Pharmacopeia | 80% to 120% |
| | | Loss on drying | Indian Pharmacopeia | 0.05% to 20.0% |
| 4. | Ibuprofen | Assay | Indian Pharmacopeia | 80% to 120% |
| | | Loss on drying | Indian Pharmacopeia | 0.05% to 20.0% |
| 5. | Ranitidine Hydrochloride | Assay | Indian Pharmacopeia | 80% to 120% |
| | | Loss on drying | Indian Pharmacopeia | 0.05% to 20.0% |
| | | Sulphated ash | Indian Pharmacopeia | 0.01% to 15.0% |
| 6. | Tinidazole | Assay | Indian Pharmacopeia | 80% to 120% |
| | | Loss on drying | Indian Pharmacopeia | 0.05% to 20.0% |
| 7. | Zinc Sulphate | Assay | Indian Pharmacopeia | 80% to 120% |
| B. | Pharmaceuticals Finish Products | | | |
| 1. | Aciclovir Tablet | Assay | Indian Pharmacopeia | 80% to 120% |
| 2. | Amoxicillin Capsule | Assay | Indian Pharmacopeia | 70% to 130% |
| 3. | Albendazole Tablet | Assay | Indian Pharmacopeia | 80% to 120% |
| 4. | Ascorbic Acid Tablet | Assay | Indian Pharmacopeia British Pharmacopeia | 80% to 120% |

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| 5. | Aspirin Tablet | Salicylic acid | Indian Pharmacopeia British Pharmacopeia | Qualitative |
| | | Assay | Indian Pharmacopeia British Pharmacopeia | 80% to 120% |
| 6. | Atenolol Tablet | Assay | Indian Pharmacopeia British Pharmacopeia | 80% to 120% |
| 7. | Calcium Gluconate Tablet | Assay | Indian Pharmacopeia | 80% to 120% |
| 8. | Cephalexin Capsule | Dissolution | Indian Pharmacopeia | 50% to 110% |
| 9. | Cetirizine Tablets | Dissolution | Indian Pharmacopeia | 50% to 110% |
| 10. | Chlropheniramine Tablet | Assay | Indian Pharmacopeia | 80% to 120% |
| 11. | Chlroquine Phosphate Tablet | Dissolution | Indian Pharmacopeia | 50% to 110% |
| 12. | Ciprofloxacin Tablet | Assay Dissolution | Indian Pharmacopeia Indian Pharmacopeia | 80% to 120% 50% to 110% |
| 13. | Cloxacillin Sodium Capsules | Assay | Indian Pharmacopeia | 80% to 120% |
| 14. | Cyanocobalamine Injection | Assay | Indian Pharmacopeia | 80% to 120% |
| 15. | Cyproheptadine Syrup | Assay | Indian Pharmacopeia | 80% to 120% |
| 16. | Cyproheptadine Tablets | Assay | Indian Pharmacopeia | 80% to 120% |
| 17. | Dextrose Injection | Identification | Indian Pharmacopeia | Qualitative |
| | | 5 HMF | Indian Pharmacopeia | Qualitative |
| | | Assay | Indian Pharmacopeia | 80% to 120% |
| 18. | Ferrous Sulphate Tablets | Assay | Indian Pharmacopeia | 80% to 120% |
| 19. | Frusemide Tablets | Assay | Indian Pharmacopeia | 80% to 120% |
| 20. | Furazolidone Tablets | Assay | Indian Pharmacopeia | 80% to 120% |

Pankaj Goyal
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| 21. | Glycin Irrigation Solution | Assay | Indian Pharmacopeia | 80% to 120% |
| 22. | Ibuprofen Tablets | Assay | Indian Pharmacopeia | 80% to 120% |
| | | Dissolution | Indian Pharmacopeia | 50% to 110% |
| 23. | Mebendazole Tablet | Assay | Indian Pharmacopeia | 80% to 120% |
| 24. | Metformin Tablets | Dissolution | Indian Pharmacopeia | 50% to 110% |
| | | Assay | Indian Pharmacopeia | 80% to 120% |
| 25. | Metronidazole Tablet | Assay | Indian Pharmacopeia | 80% to 120% |
| | | Dissolution | Indian Pharmacopeia | 50% to 110% |
| 26. | Norfloxacin Tablets | Dissolution | Indian Pharmacopeia | 50% to 110% |
| | | Assay | Indian Pharmacopeia | 80% to 120% |
| 27. | Paracetamol Syrup | Assay | Indian Pharmacopeia | 80% to 120% |
| 28. | Paracetamol Tablets | Dissolution | Indian Pharmacopeia | 50% to 110% |
| | | Assay | Indian Pharmacopeia | 80% to 120% |
| 29. | Povidone-Iodine Solution | Assay | Indian Pharmacopeia | 85% to 120% |
| 30. | Quinine Sulphate Tablets | Assay | Indian Pharmacopeia | 80% to 120% |
| 31. | Ranitidine Tablets | Assay | Indian Pharmacopeia | 80% to 120% |
| 32. | Riboflavin Tablets | Assay | Indian Pharmacopeia | 80% to 120% |
| 33. | Sodium Chloride Injection | Identification | Indian Pharmacopeia | Qualitative |
| | | Assay | Indian Pharmacopeia | 80% to 120% |
| 34. | Sodium Chloride & Dextrose Injection | Identification | Indian Pharmacopeia | Qualitative |
| | | 5 HMF | Indian Pharmacopeia | Qualitative |
| | | Assay | Indian Pharmacopeia | 80% to 120% |
| 35. | Tinidazole Tablets | Assay | Indian Pharmacopeia | 80% to 120% |

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| C. | Raw Materials | | | |
| 1. | Pharmaceuticals Raw Materials | | | |
| | | Identification (By IR) | Indian Pharmacopeia | Qualitative |
| | | pH | Indian Pharmacopeia British Pharmacopeia United States Pharmacopeia | 2.0 to12.0 |
| | | Acidity/ Alkalinity | Indian Pharmacopeia British Pharmacopeia United States Pharmacopeia | Qualitative |
| | | Weight | Indian Pharmacopeia | 0.2 g/ml to15.0 g/ml |
| | | Relative Density (Specific Gravity) | Indian Pharmacopeia | 0.70 to 2.050 |
| | | Limit test for Chloride | Indian Pharmacopeia | Qualitative |
| | | Limit test for Heavy Metals | Indian Pharmacopeia | Qualitative |
| | | Limit test for Iron | Indian Pharmacopeia | Qualitative |
| | | Limit test for Sulphate | Indian Pharmacopeia | Qualitative |
| D. | Pharmaceuticals Finish Products | | | |
| 1. | General Test | | | |
| | | Identification (By IR) | Indian Pharmacopeia | Qualitative |
| | | pH | Indian Pharmacopeia British Pharmacopeia United States Pharmacopeia | 2.0 to12.0 |
| | | Acidity / Alkalinity | Indian Pharmacopeia British Pharmacopeia United States Pharmacopeia | Qualitative |
| | | Weight | Indian Pharmacopeia | 0.2 g/ml to15.0 g/ml |

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| | | Relative Density (Specific Gravity) | Indian Pharmacopeia | 0.70 to 2.050 |
| | | Disintegration Test | Indian Pharmacopeia | Qualitative |
| | | Particulate Contamination | Indian Pharmacopeia | Qualitative |
| | | Uniformity of weight of Single dose preparation | Indian Pharmacopeia | 25 mg to 5250 mg |
| | | Contents of Packaged Dosage Forms | Indian Pharmacopeia | Not less than label claim |