

Laboratory **Pharmaffiliates Analytics & Synthetics (P) Ltd., Plot No. 225, Industrial Area, Phase-II, Panchkula, Haryana**

Accreditation Standard **ISO/IEC 17025: 2005**

Certificate Number **TC-7535**

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Validity **04.07.2018 to 03.07.2020**

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 |
|-----|----------------------------|-------------------------|---|--|
|-----|----------------------------|-------------------------|---|--|

BIOLOGICAL TESTING

| I. DRUGS AND PHARMACEUTICALS | | | | |
|-------------------------------------|---|--------------------------------------|----------------------|------------------------------------|
| 1. | Raw materials | | | |
| | Maize starch, Mannitol, Dibasic Calcium Phosphate, Microcrystalline Cellulose IP, Magnesium Stearate IP, Aciclovir | Total aerobic microbial count. | Indian Pharmacopoeia | 10 cfu/g 1cfu/ml |
| | | Total combined yeast and mould count | Indian Pharmacopoeia | 10 cfu/g 1cfu/ml |
| | | Staphylococcus aureus | Indian Pharmacopoeia | Absent/Present Per ml or g |
| | | Pseudomonas | Indian Pharmacopoeia | Absent/Present Per ml or g |
| | | E.coli | Indian Pharmacopoeia | Absent/Present Per ml or g |
| | | Salmonella | Indian Pharmacopoeia | Absent/Present Per 10ml or 10 g |
| | | Clostridia | Indian Pharmacopoeia | Absent/Present Per ml or g |
| | | Shigella | Indian Pharmacopoeia | Absent/Present Per ml or g |
| | | Candida | Indian Pharmacopoeia | Absent/Present Per ml or g |
| 2. | Finished Products (Solid oral dosages form) | | | |
| | Cifran OD Tablets, Glimepiride, Tablets, Atorvastatin Calcium Tablets IP Simvastatin Tablets IP, Riomet GF | Total aerobic microbial count. | Indian Pharmacopoeia | 10 cfu/g 1 cfu /ml |
| | | Total combined yeast and mould count | Indian Pharmacopoeia | 10 cfu/g 1cfu/ml |
| | | Staphylococcus aureus | Indian Pharmacopoeia | Absent/Present Per ml or g |
| | | Pseudomonas | Indian Pharmacopoeia | Absent/Present Per ml or g |

Nitin Gupta
Convenor

Alok Jain
Program Director

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|------------|---|-------------------------|---|--|
| | Tablets, Cephalexin Capsule IP | E.coli | Indian Pharmacopoeia | Absent/Present Per ml or g |
| | | Salmonella | Indian Pharmacopoeia | Absent/Present Per 10ml or 10 g |
| | | Clostridia | Indian Pharmacopoeia | Absent/Present Per ml or g |
| | | Shigella | Indian Pharmacopoeia | Absent/Present Per ml or g |
| | | Candid | Indian Pharmacopoeia | Absent/Present Per ml or g |
| II. | WATER | | | |
| | | Standard Plate count | IS 1622 | ≥ 1 cfu/ml |
| | | Coliform count by MPN | IS 1622 | 2MPN/100 ml |
| | | E.coli by MPN | IS 1622 | 2MPN/100ml |

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| <u>CHEMICAL TESTING</u> | | | | |
| I. DRUGS & PHARMACEUTICALS | | | | |
| 1. | Raw Materials | Identification Test | Indian Pharmacopoeia | Qualitative test |
| | | a. (by IR) | Indian Pharmacopoeia | Qualitative test |
| | | b. (by UV) | Indian Pharmacopoeia | Qualitative test |
| | | c. (by Chemical) | Indian Pharmacopoeia | Qualitative test |
| | | Arsenic | Indian Pharmacopoeia | Qualitative test |
| | | Iron | Indian Pharmacopoeia | Qualitative test |
| | | Chloride | Indian Pharmacopoeia | Qualitative test |
| | | Sulphate | Indian Pharmacopoeia | Qualitative test |
| | | Lead | Indian Pharmacopoeia | Qualitative test |
| | | Crystallinity | Indian Pharmacopoeia | Qualitative test |
| | | Heavy Metals | Indian Pharmacopoeia | Qualitative test |
| | | Clarity & colour of Solution | Indian Pharmacopoeia | Qualitative test |
| | | Acidity or Alkalinity | Indian Pharmacopoeia | Qualitative test |
| | | Unsaponifiable matter | Indian Pharmacopoeia | Qualitative test |
| | | Light Absorption | Indian Pharmacopoeia | Qualitative test |
| | | Solubility | Indian Pharmacopoeia | Qualitative test |
| B. Individual Raw Material | | | | |
| 1. | Aspartame | Assay (by non aqueous titration) | Indian Pharmacopoeia | 80% to 110% |
| 2. | Amoxicillin Trihydrate | Assay (by HPLC) | Indian Pharmacopoeia | 80% to 110% |
| 3. | Ampicillin Trihydrate | Assay (by HPLC) | Indian Pharmacopoeia | 80% to 110% |

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|-----|---------------------------------------|--|---|--|
| 4. | Ascorbic Acid | Assay (by Iodometric titration) | Indian Pharmacopoeia | 80% to 110% |
| 5. | Betamethasone Sodium Phosphate | Assay (by UV) Free Betamethasone & other derivatives (by TLC) | Indian Pharmacopoeia Indian Pharmacopoeia | 80% to 110% Qualitative test |
| 6. | Ammonium Chloride | Assay (by Titration) | Indian Pharmacopoeia | 80% to 110% |
| 7. | Boric Acid | Assay (by Titration) | Indian Pharmacopoeia | 80% to 110% |
| 8. | Calcium Carbonate | Assay (by Titration) | Indian Pharmacopoeia | 80% to 110% |
| 9. | Calcium Gluconate | Assay (by Titration) | Indian Pharmacopoeia | 80% to 110% |
| 10. | Bromhexine Hydrochloride | Assay (by Potentiometric titration) | Indian Pharmacopoeia | 80% to 110% |
| 11. | Dibasic Calcium Phosphate | Assay (by Titration) | Indian Pharmacopoeia | 80% to 110% |
| 12. | Clotrimazole | Assay (by Titration) | Indian Pharmacopoeia | 80% to 110% |
| 13. | Cetirizine Hydrochloride | Assay (by Potentiometric Titration) | Indian Pharmacopoeia | 80% to 110% |
| 14. | Chlorpheniramine Maleate | Assay (by HPLC) Related Substances (by TLC) | Indian Pharmacopoeia Indian Pharmacopoeia | 80% to 110% Qualitative test |
| 15. | Cephalexin | Assay (by HPLC) Related Substances (by HPLC) | Indian Pharmacopoeia Indian Pharmacopoeia | 80% to 110% Qualitative test |
| 16. | Cinnarizine | Assay (by non aqueous titration) | Indian Pharmacopoeia | 80% to 110% |
| 17. | Citric acid Monohydrate | Assay (by Titration) | Indian Pharmacopoeia | 80% to 110% |
| 18. | Cyproheptadine | Assay (by Titration) | Indian Pharmacopoeia | 80% to 110% |

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| | Hydrochloride | | | |
| 19. | Domperidone | Assay (by Titration) | Indian Pharmacopoeia | 80% to 110% |
| 20. | Dexamethasone Sodium phosphate | Assay (by HPLC) | Indian Pharmacopoeia | 80% to 110% |
| 21. | Dextromethorphan Hydrobromide | Assay (by Titration) Related Substances (by HPLC) | Indian Pharmacopoeia Indian Pharmacopoeia | 80% to 110% Qualitative |
| 22. | Diclofenac Sodium | Assay (by Potentiometric titration) Related substances (by HPLC) | Indian Pharmacopoeia Indian Pharmacopoeia | 80% to 110% Qualitative |
| 23. | Disodium Edetate | Assay (by Titration) | Indian Pharmacopoeia | 80% to 110% |
| 24. | Ferrous Fumarate | Assay (by Titration) | Indian Pharmacopoeia | 80% to 110% |
| 25. | Glycerin | Assay (by Titration) | Indian Pharmacopoeia | 80% to 110% |
| 26. | Ibuprofen | Assay (by Titration) | Indian Pharmacopoeia | 80% to 110% |
| 27. | Iodine | Assay (by Titration) | Indian Pharmacopoeia | 80% to 110% |
| 28. | Metronidazole Benzoate | Assay (by Potentiometric titration) | Indian Pharmacopoeia | 80% to 110% |
| 29. | Microcrystalline cellulose | Assay (by Titration) | Indian Pharmacopoeia | 80% to 110% |
| 30. | Nicotinamide | Assay (by HPLC) Related Substances (by TLC) | Indian Pharmacopoeia Indian Pharmacopoeia | 80% to 110% Qualitative test |
| 31. | Paracetamol | Assay (by Titration) | Indian Pharmacopoeia | 80% to 110% |
| 32. | Piroxicam | Assay (by HPLC) | Indian Pharmacopoeia | 80% to 110% |
| 33. | Povidone- Iodine | Assay (by Titration) | Indian Pharmacopoeia | 5% to 15% |
| 34. | Promethazine Hydrochloride | Assay (by Titration) | Indian Pharmacopoeia | 80% to 110% |
| 35. | Pseudoephedrine Hydrochloride | Assay (by Titration) | Indian Pharmacopoeia | 80% to 110% |
| 36. | Pyridoxine | Assay (by Titration) | Indian Pharmacopoeia | 80% to 110% |

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| 37. | Hydrochloride Riboflavine Sodium Phosphate | Assay (by UV) | Indian Pharmacopoeia | 60% to 90% |
| 38. | Riboflavine | Assay (by UV) | Indian Pharmacopoeia | 80% to 110% |
| 39. | Saccharin | Assay (by Titration) | Indian Pharmacopoeia | 80% to 110% |
| 40. | Saccharin Sodium | Assay (by Potentiometric Titration) | Indian Pharmacopoeia | 80% to 110% |
| 41. | Salbutamol | Assay (by Potentiometric Titration) | Indian Pharmacopoeia | 80% to 110% |
| 42. | Sodium benzoate | Assay (by Titration) | Indian Pharmacopoeia | 80% to 110% |
| 43. | Sodium citrate | Assay (by Titration) | Indian Pharmacopoeia | 80% to 110% |
| 44. | Sulphamethoxazole | Assay (by Titration) | Indian Pharmacopoeia | 80% to 110% |
| 45. | Thiamine Hydrochloride | Assay (by Potentiometric Titration) | Indian Pharmacopoeia | 80% to 110% |
| 46. | Tinidazole | Assay (by Titration) | Indian Pharmacopoeia | 80% to 110% |
| 47. | Trimethoprim | Assay (by Potentiometric Titration) | Indian Pharmacopoeia | 80% to 110% |
| 48. | Zinc Oxide | Assay (by Titration) | Indian Pharmacopoeia | 80% to 110% |
| 49. | Zinc Sulphate | Assay (by Titration) | Indian Pharmacopoeia | 80% to 110% |
| 50. | Estradiol Impurity | Chromatographic purity (By area normalization) By HPLC | British Pharmacopoeia | NLT 85% |
| 51. | Fusidic Acid Impurity | Chromatographic purity (By area normalization) By HPLC | British Pharmacopoeia | NLT 85% |
| 52. | Citalopram A Impurity | Chromatographic purity (By area normalization) By HPLC | British Pharmacopoeia | NLT 85% |

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| C. | Pharmaceutical Dosage Formulation | | | |
| 1. | Amoxicillin Trihydrate Dispersible (Tablet) | Assay (by HPLC) | Indian Pharmacopoeia | 70% to 150% |
| 2. | Cephalexin (Tablet) | Assay (by HPLC) | Indian Pharmacopoeia | 70% to 150% |
| 3. | Diclofenac Sodium (Tablet) | Assay (by HPLC) | Indian Pharmacopoeia | 70% to 150% |
| 4. | Folic Acid (Tablet) | Assay (by HPLC) | Indian Pharmacopoeia | 70% to 150% |
| 5. | Metronidazole (Tablet) | Assay (by Titration) | Indian Pharmacopoeia | 70% to 150% |
| 6. | Trimethoprim and sulphamethoxazole (Tablet) | Assay (by HPLC) | Indian Pharmacopoeia | 70% to 150% |
| 7. | Paracetamol (Tablet) | Assay (by UV) | Indian Pharmacopoeia | 70% to 150% |
| 8. | Amoxicillin (capsules) | Assay (by HPLC) | Indian Pharmacopoeia | 70% to 150% |
| 9. | Ampicillin (capsules) | Assay (by HPLC) | Indian Pharmacopoeia | 70% to 150% |
| 10. | Cephalexin (capsules) | Assay (by HPLC) | Indian Pharmacopoeia | 70% to 150% |
| 11. | Piroxicam (capsules) | Assay (by HPLC) | Indian Pharmacopoeia | 70% to 150% |
| 12. | Paracetamol (Syrup) | Assay (by HPLC) | Indian Pharmacopoeia | 70% to 150% |
| 13. | Sulphamethoxazole & trimethoprim (OS) | Assay (by HPLC) | Indian Pharmacopoeia | 70% to 150% |

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| II. | FOOD & AGRICULTURAL PRODUCTS | | | |
| 1. | Biscuit | Moisture Content | FSSAI Manual | 0.5 to 5.0 % (w/w) |
| | | Total Ash | FSSAI Manual | 0.5 to 2.0 % (w/w) |
| | | Acid Insoluble Ash | FSSAI Manual | 0.05 % to 0.15 % |
| 2. | Wheat Atta | Moisture Content | FSSAI Manual | 1.0% to 14.0 % (w/w) |
| | | Total Ash (On dried basis) | FSSAI Manual | 0.5 % to 2.0 % (w/w) |
| | | Acid Insoluble Ash (On dried basis) | FSSAI Manual | 0.05% to 0.15 % |
| 3. | Rice | Moisture Content | FSSAI Manual | 1 % to 16 % (w/w) |
| 4. | Sugar | Moisture Content | FSSAI Manual | 0.05% to 0.5% (w/w) |
| 5. | Moong Dal | Moisture Content | FSSAI Manual | 1% to 14 % (w/w) |
| 6. | Tea | Moisture Content | FSSAI Manual | 1% to 9% (w/w) |