

Analytical Research

Impurity Profile

- Identification and quantification of organic impurities using highly sensitive instruments like LC-MS/MS
- Separation and quantification of Isomers using Chiral HPLC
- Estimation of process impurities using gradient HPLC and GC systems
- Identification and quantification of polymorphs with the aid of XRD
- Identification of residual solvents using GC-MS with head space
- Inorganic impurities using ICP-MS and A.A.S with furnace & Hydride.
- Thermal analysis using DSC & TGA

Analytical Method Development & Validations

- Validation of Pharmacopoeial methods
- Validations for related substance, assay, residual solvents, dissolution profile, trace metals and particle size distribution

Equipments

LC-MS/MS, GC-MS/MS, GC-MS with Head Space, ICP – MS, Atomic Absorption Spectrophotometer, MPD X–RAY Diffractometer, T.G.A. & DSC, CHNSO Analyser, H.P.L.C. (with RID & PDA), FTIR , Polarimeter,

Particle Characterization

- Malvern Master size 'S' & 2000 (Air & Liquid)
- Hiac Royo Liquid Borne Particle Counter
- Micromeritics Surface area analyzer (BET method)
- Metone Air Borne Particle Counter

Accreditations

- USFDA registered cGMP control testing laboratory
- Department of Science & Technology approved R & D Centre
- Drugs Controller General of India (DCGI)
- NABL (ISO - 17025) accreditation for Chemical, Biological and Medical Testing
- CPCSEA registered animals facility
- Recognized by Bureau of Indian Standards
- ISO-9001:2000 Quality Management Systems
- Drugs Control Administration (A.P)
- Approved by Department of AYUSH.
- Department of Biotechnology approved Institutional Bio-Safety Committee (IBSC)
- SME 1 Credit Rating by CRISIL indicates Highest Level of Credit worthiness.

Sipra Labs Limited

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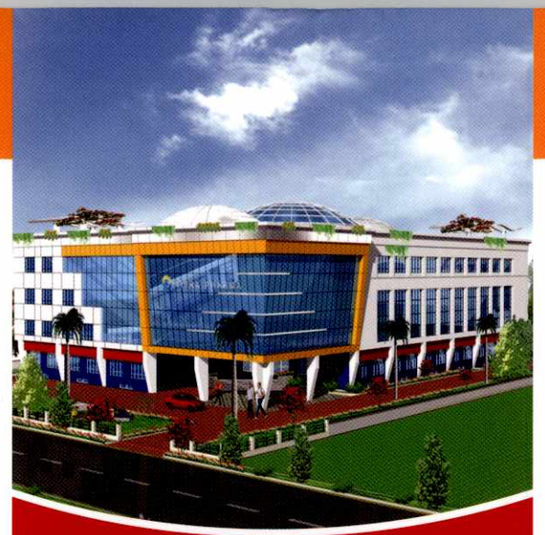

SIPRA LABS

One Stop solution
for **Pharmaceutical Research**

Sipra Labs Limited

Our Commitment

We are committed to delight customers by providing products & services that excel the expectations consistency in terms of quality speed to market, delivery and competitiveness.

The Leader With The Leaders



Formulation Research & Development

Formulation Research is a full fledged activity at Sipra and it includes formulation development, analytical method development & validation, stability studies and dossier preparation. Total solutions under one roof to pharmaceutical researchers to save their time and cost.

CAPABILITIES

We Develop:
- Tablets : Immediate Release, Sustained Release, Targeted Delivery
- Capsules: Immediate Release, Sustained Release
- Suspensions & syrups
- Injectables
- Ointments

We Conduct:
- Accelerated Stability Studies
- Long Term Stability Studies
- Photo Stability Studies
- Forced Degradation Studies

We Prepare:
- Dossier - As per CTD & MCC guidelines

Formulation Equipment:
- Fluid Bed Processor
- High Shear Mixer Granulator (HSMG)
- Sifter & Multimill
- Dryers & Blenders
- Multi Tooling Compression M/C
- Auto Coater
- Capsules MF 30
- Homogenizer & Colloid Mill

Development Equipment
- X-Ray Diffractometer
- Differential Scanning Calorimeter
- T.G.A.
- HPLCs(PDA, UV, Fluorescent & RI Detectors)
- Surface Area and Pore Size Analyzer
- Auto Dissolution Apparatus

Stability Equipment:
- PLC based Walk In Chambers

Bioequivalence / Bioavailability studies

DCGI approved facility meeting international standards, provides services for clinical pharmacology and bioequivalence studies

- PD/PK Studies
- Multi Dose Studies
- Multi Period Studies
- Drug-Food Interaction Studies
- Urinary drug elimination studies
- Cosmetic and safety evaluation studies
- Drug-Drug Interaction Studies

CAPABILITIES:

- Phase I to Phase IV studies
- 4 Clinics with a total of 120 beds
- 20 beds ICU with central online monitoring
- Central Nursing station with telemetric monitoring, data recording & data retrieval
- Web linking of ICU with medical experts
- Bio-metric system for retrieval of data.
- Over 15,000 volunteer database.
- ICCU is equipped with ADR monitoring and reporting.
- Recreational area for subjects.
- Adoption of GLP guidelines as per ICH standards.
- More than 100 Validated Methods
- SAS (Ver 8.2), Pharsight WinNonlin (Ver 5.2.1) Software for bio statistics.

Equipment:

LC-MS/MS (API- 4000, 3000, 2000), GC MS Clarus-500, HPLCs with UV Fluorescence Detectors & Deep Freezer (-80°C)

Fully Automated Immuno & Biochemistry Analyser, ELIZA Reader, X – Ray, Hematology Analyzer, Electrolyte Analyzer, Urine Chemistry Analyzer, E.C.G. & Deep Freezer – 25± 50C & -75± 50C

Microbiological Studies

Sipra lab's ultra modern Microbiology lab, meeting OECD GLP guidelines, has modular rooms and air handling systems as per USFDA requirements. Spread over 2000 sft, it has four numbers of state-of-the-art LAF rooms. It has capability to maintain eight different incubating conditions and is equipped to store samples at temperatures ranging from -80o C to above ambient. Laboratory cultures are well maintained with traceability and access controlled custody.

CAPABILITIES:

- Microbiological tests and assays as per USP, Ph.Eur, IP etc
- Screening of bacteria and virus
- Expertise in bacterial endotoxin tests (BET) and BET method validation
- Sterility testing using fully automated system eliminating any chance of contamination
- Validation of microbiological methods
- Validation of LAF, Autoclaves and incubators as per approved methods
- Environmental monitoring for bio-burden and air borne particulate matter with trend analysis
- Rapid microbiological techniques for faster and reliable results
- Water (process, raw and purified) analysis as per desired pharmacopoeias
- Preservative efficacy testing
- Antibiotic susceptibility and resistance studies
- Cleaning validation studies

Pre-Clinical Studies

Pre Clinical Toxicity center has the facility to monitor physical, physiological, clinical, biochemical, hematological parameters. It has sufficient number of animal rooms with individually ventilated cages, conforming to international standards, for housing and experimentation. studies are also conducted as per specified study plans of customers.

CAPABILITIES:

- Acute, Sub Acute & Chronic Toxicity Studies
- Genotoxicity Studies
  1. Ames Test
  2. Chromosomal Aberration Test
  3. DNA Effect Test
- Dermal Studies
- Cytotoxicity Studies
- Behavioural studies
- Maximum Tolerated Dose
- Assessment of Allergenicity
- Kinetic Studies on Rats & Beagle Dogs

Equipments

- Individually Ventilated Cages
- Facility designed as per GLP
- Independent facility for Rats, Mice
- Rabbits and Beagle Dogs
- Drug storage at specified conditions
- Safety alarms/call to scientists
- Online Recording of Observations
- Ultra modern Histopathology lab
- Regular IAEC meetings

Species

- Wistar rats
- Swiss Albino & BalC mice,
- Guinea pigs
- New Zealand white rabbits
- Beagle dogs

Food & Safety Analysis

Food & Safety laboratory is accredited by NABL and recognized by B.I.S. for testing of safety & quality measures for various products like Fruits, Vegetables, Nuts, Dairy products, packaged drinking water, packing materials and Beverages including fruit concentrates,

CAPABILITIES:

Safety Parameter

Aflatoxins & Mycotoxins

- Toxic Residue
  1. Pesticide Residue as per WHO & EPA
  2. Residual Solvents
- Heavy Metals
- Microbiological Evaluation

Packaged drinking water as per IS: 14543-2004

Packing Materials as per IS: 15410-2005 (Bottles, Jars, Pouches, Containers & Drums)

Quality measures - Nutritional facts

Equipments

- L.C-MS/MS
- G.C-MS/MS
- I.C.P. MS
- Atomic Absorption Spectrophotometer
- H.P.L.Cs with fluorescent detector
- FTIR Spectrometer
- Incubators
- Centrifuge
- Pouch Tester
- EZ tester
- Melt flow index
- Transparency Tester
- Nephalo Turbidity Meter
- Haze Meter
- Profile projector
- UV /VIS Spectro meter