

PRECLINICAL SERVICES



FACILITY

33,000 sft Animal House and 10,000 sft in-vitro facility

27 Animal Rooms with ante rooms

5 Procedure Rooms

48 Kennel Dog Facility

5, 10 & 12 Room Modules



SERVICES

- Pharmacology
- DMPK/ADME
- Safety Pharmacology
- Toxicology
- Bioanalytical



Drug discovery services to pharma and biotech companies

17 years of experience in safety evaluation on more than 200 drug molecules

Biocompatibility tests on medical devices and efficacy studies on new formulations

Screening of NCEs

- In vitro systems to facilitate lead optimization and identification
- In vivo models viz., mice, rats, guinea pigs, rabbits and beagle dogs through different routes for proof of principle, fast track kinetics and safety assessment with GLP compliance.



PRECLINICAL SERVICES

TOXICOLOGY - TRACK RECORD

Pre-clinical safety division started in 1992 at Cherlapally facility

Certified for GLP by Standard Australia Quality Assurance Services in 1997

Initial focus on agricultural & industrial chemicals. Shifted focus to pharma and biotech industries from 2000

State of the art new facility with full set of preclinical services was inaugurated in 2009



- TPA / Oxazolone induced ear edema in mice.
- Cotton-pellet & Air-pouch granuloma models in rats
- TNBS - induced colitis in rats & mice
- Thermal & mechanical pain models employing Tail Flick model, Hot Plate, Plantar Test, Randall-Selitto, Electronic von Frey in rats & mice
- COPD model in Guinea pig
- Metabolic Disorder Models



PHARMACOLOGY

Pain and Inflammatory models

- FCA / Capsaicin induced hyperalgesia in rats
- Carrageenan induced paw edema in rats & mice
- Acetic acid / Formalin induced writhing in mice



SAFETY PHARMACOLOGY

Respiratory system

- Whole body plethysmography in Guinea pigs & rats

Cardio-vascular system

- hERG cardio-vascular toxicity (Potassium ion channel)
- Radio telemetry in beagle dogs



DMPK/ADME

In Vitro

- PAMPA Permeability Assay
- CaCo-2/MDCK Absorption Assay
- CYP 450 Inhibition & Induction Assay
- S9 & microsomes metabolic stability assay
- Protein binding studies
- Plasma/whole blood stability studies
- Skin permeability studies (Franz diffusion)
- In Vivo (rat, rabbit and beagle dogs)
- Pharmacokinetics (fast track & regulatory)
- Bioavailability studies



Bio analytical Support

- 27 Mass specs covering technologies such as single quadrapole, triple quadrapole, ion trap, LC-MS/MS, GC-MS/TOF, HRGCMS, ICP-MS
- Multiple HPLCs with PDA and fluorescence detectors
- Different matrices tested include rat plasma; dog plasma; & monkey plasma
- Proprietary method development & validation on NCES & method transfer
- Metabolite identification, profiling & structure elucidation

TOXICOLOGY (Exploratory & Regulatory)

Exploratory toxicity screens

- MTD studies in mice, rats, rabbits & beagle dogs with TK
- 7-14 day DRF studies in mice, rats, rabbits & beagle dogs
- Ames test
- In Vitro genotoxicity studies in CHO & HL cell lines
- Target organ toxicity studies-Hepatotox, Bone marrow suppression
- Cytotoxicity studies (using target specific or battery of cell lines)



Regulatory toxicity studies

(IND-enabling & GLP Compliant)

- Acute, short & long term toxicity studies with toxicokinetics in rodents & Beagle dogs
- Reproductive
- Fertility & developmental toxicity in rats & rabbits
- Genetic Toxicology (In Vitro & In Vivo)
- Ames test
- In Vitro Chromosome aberration test in CHO & HL cell lines
- In Vivo Chromosome aberration test in rat
- In Vivo Micronucleus test in mice
- Other studies
- Biocompatibility studies on medical devices as per ISO 10993
- Skin/Eye irritancy, Sensitization studies