

Discovery Research

Bioanalysis Capabilities



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Infrastructure



- State of Art Bioanalysis Laboratories
- Located in Two Sites
 - Pashamylaram
 - Jeedimetla
- Eight Tandem Mass Spectrometers (Most sensitive, QqQ, Q-Trap)
 - API-6500 QTRAP, API-6500+ QqQ- UHPLC
 - API-4000 Q-Trap (1), API-4000 (2)
 - API-3000 (2), API-2000 (1)
- Automated Liquid Chromatography Systems
 - UV –Visible Detection
 - Fluorescence Detection
 - Electrochemical Detection

Infrastructure



LC-MS/MS, QTRAP6500 and QqQ6500+ with UHPLCs

Strengths



- Rapid method development, fit for purpose validation and sample analysis
- Developed & Validated more than 250 Bioanalytical Methods involving
 - Drug and Metabolite or Multiple Analytes from same Sample
 - Highly Sensitive Methods requiring as low as pg/mL quantitation
 - Can analyze even with low sample volume (0.05 to 0.1 mL)
 - High throughput semi-automated precipitation (96 well plate), LLE, SPE and PPTn.
 - Hard tissue sample processing by enzymatic pretreatment, bead lysis followed by homogenization
 - Successfully handled sample receipt from various locations within India, across US and Europe
 - 24-48 hr turnaround time for sample analysis

LC-MS/MS Based Quantitative Bioanalysis



Matrix

- Plasma
- Blood
- Brain homogenates
- Cerebro Spinal Fluid
- Urine, feces
- Hard tissue (skin, kidney, spleen etc)
- Microsomes
- Bile
- Isolated Brain Regions
- Assay Buffers
- Synovial fluid
- Aqueous and Vitreous Humor

Species

- Rat
- Mice
- Hamster
- Guinea Pig
- Rabbit
- Dog
- Monkey

**Can undertake simple
to complex design**

Clinical Pharmacokinetic Support



- First in Human (FIH) Clinical Trials
 - Single Ascending Dose (SAD)/ Multiple Ascending Dose Trial (MAD)
 - New Product/Formulation Development Studies
 - New Fixed Dose Combination Studies
- Human Bioequivalence /Relative Bioavailability Studies
- Pharmacokinetic Drug Drug Interaction Studies
- Therapeutic Drug Monitoring Studies
- Pilot and Pivotal US ANDA Studies
 - Parallel Design
 - Crossover Design
 - Controlled Population Studies
 - Fixed Dose Combination Studies

Preclinical Toxicokinetic Support



- Bioanalysis Support to Regulated Preclinical Toxicology Studies
- Repeat Dose Rodent Toxicology Studies (Rat, Mice & Hamster)
- Repeat Dose Non Rodent Toxicology Studies (Dog, Guinea Pig, Rabbit)
- Reproductive Toxicology Studies (Rodent and Non Rodent)
- Long Term Toxicology Studies
- Carcinogenicity, Mutagenicity and Genotoxic Potential Evaluation Studies

Bioanalysis Timelines



- Typically a Study gets initiated within 2 days of
 - Receipt of Test Article(s)
 - Signed Protocol
- Fit for purpose method validation within 2 days
- PK Study with 200-400 samples
 - Data within 3 days from sample receipt (UHPLC-MS/MS)
 - Data with report within 2 weeks
 - 48 hour turnaround, if needed



Quality Assurance System



- Accredited by ISO/IEC 17025:2005 Quality System since 2005
- Independent Quality Assurance Team
- SOPs for Operation, Calibration, Maintenance and Quality Systems
- Well Managed Reports/Data and Samples Storage & Retrieval
- Well Documented Biological and Formulation Sample Receipt & Handling
- Facility audited and approved by many global pharmaceutical companies and majority of Indian Pharma Companies

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