Discovery Research

Bioanalysis Capabilities

Discovery Research
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Overview

S. No	Title	Page No
1	Infrastructure	3-4
2	Strengths	5
3	LC-MS/MS based quantitative bioanalysis	6
4	Clinical Pharmacokinetic Support	7
5	Preclinical Toxicokinetic Support	8
6	Bioanalysis Timelines	9
7	Accreditation	10
8	Quality Assurance	11
9	Contacts	12

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

Accreditation

NABL

National Accreditation Board for Testing and Calibration Laboratories

(An Autonomous Body under Department of Science & Technology, Govt. of India)

CERTIFICATE OF ACCREDITATION

BIOPHARMACEUTICAL RESEARCH LABORATORY (A DIVISION OF SUVEN LIFE SCIENCES LIMITED)

has been assessed and accredited in accordance with the standard

ISO/IEC 17025:2005

"General Requirements for the Competence of Testing & Calibration Laboratories"

for its facilities at

IDA, Plot No. 265-268, Phase-II, Pashamylaram, Patancheru Mandal, Medak, Telangana

in the discipline of

CHEMICAL TESTING

(To see the scope of accreditation of this laboratory, you may also visit NABL website www.nabl-india.org)

Certificate Number T-1167

Issue Date 18/08/2016

Valid Until 17/08/2018

This certificate remains valid for the Scope of Accreditation as specified in the annexure subject to continued satisfactory compliance to the above standard & the additional requirements of NABL.

Signed for and on behalf of NABL

N. Venkateswaran
Program Manager

Anil Relia
Director

Prof. S. K. Joshi
Chairman

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

Contacts

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