# Discovery Research

## Bioanalysis Capabilities


Discovery Research
Suven Life Sciences Ltd
Serene Chambers, Road-5, Avenue-7, Banjara Hills,
Hyderabad-500034, India.
Contacts: lyf2@suven.com, nvsrk@suven.com

# Overview

# 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

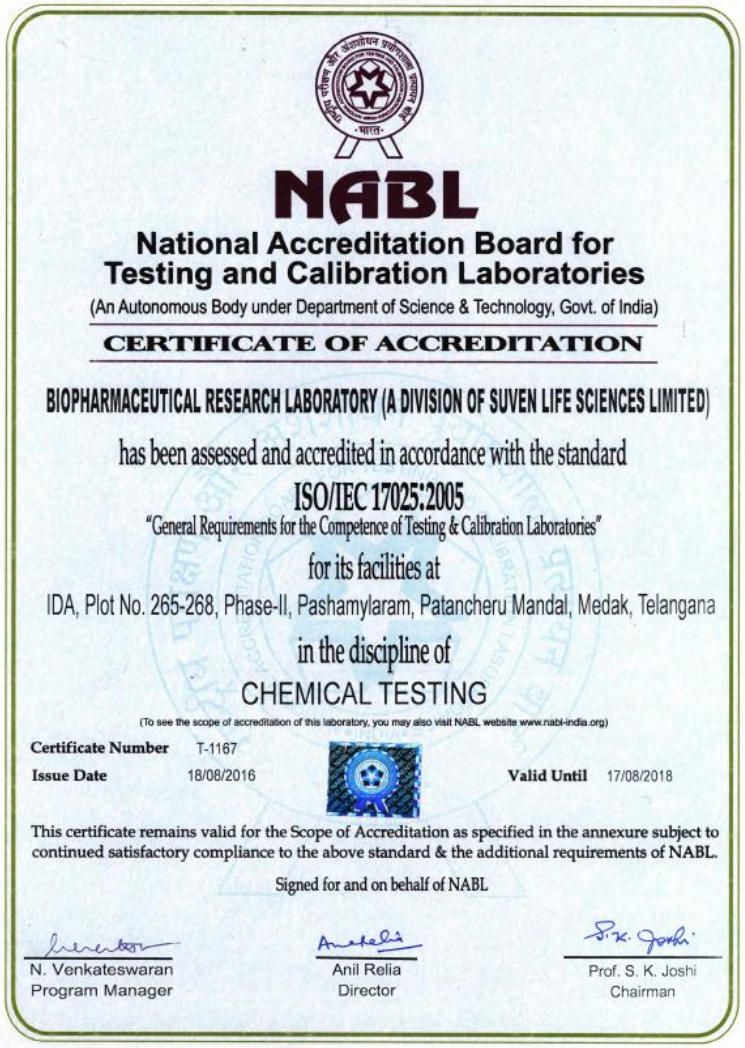
# Preclinical Toxicokinetic Support

- 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

Venkat Jasti

Chairman & CEO

E-mail: info@suven.com

Ramakrishna Nirogi

Vice President, Discovery Research

E-mail: nvsrk@suven.com