Regulated Bioanalysis Capabilities

Suven Life Sciences

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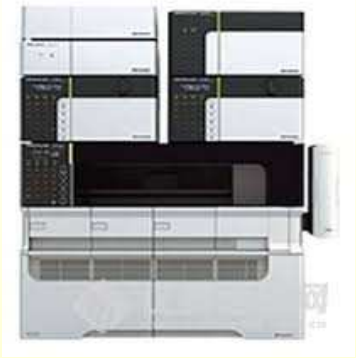
SUVEN
Life Sciences

Suven 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

Suven – Strengths

- Rapid method development, fit for purpose validation and sample analysis (ISR)
- Developed & Validated more than 150 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

Can undertake simple to complex design

Scope : As Per Study Design Requirement

- First in Human (FIH) Clinical Trials
  - Single Ascending Dose Trial (SAD)
  - Multiple Ascending Dose Trial (MAD)
  - New Product/Formulation Development Studies (*I.V., P.O, I.N.*, dermal, ocular, infusion)
  - New Fixed Dose Combination Studies

Scope : Clinical Pharmacokinetic Studies

- Human Bioequivalence Studies
- Human 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

Scope : 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

Suven Bioanalysis Scientists Qualifications / Experience

2016	Personnel				
	Ph.D.	Average Years Experience	MS / M.Pharm	Average Years Experience	Technician / Lab Support
Bioanalysis	02	6 - 12 Years	16	2 - 8 years	04
Quality Assurance	00	NA	05	2 - 6 years	01
Management	2 (more than 20 years of discovery experience)				
Office / Admin	04				

Senior and Core Group Leaders have pursued their education from reputed academic institutions like **IIT**, NIT and other reputed universities etc.

Results / Data Communication

- Results Review by Focused Scientific Team
- QA Audited Intermittent Reports to Customers
- Secured Tunnel for safe E-mail exchanges
- Weekly/Bi Weekly webex /Telecon for exchange and discussion of Project Progression
- Chromatograms and Raw data can be shared to Customer through secure Email system for remote Review
- Reports submitted to FDA in *eCTD* format
- Dedicated laboratory note book to individual client

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

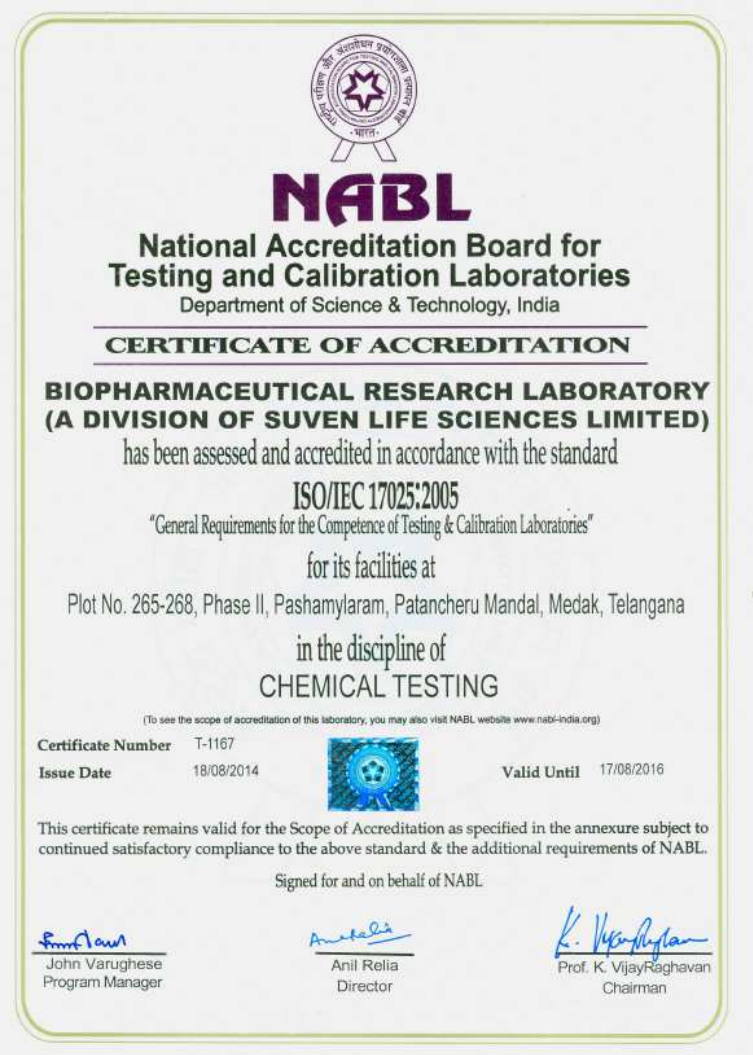
Study supervision

- Majority of the work contracted would be done in in-house
- Supervision - on methodologies and work-flows of study personnel
- Process and Project based audits by QA for each study
- Identification of 3 to 4 critical phases- audit reports for each phase
- Majority of Scientists working for more than 5 years
- Minimal turn around time for the projects
- Capacity; 6 x200 = 1200 samples/day of any four different studies, (3.6 lakh p.a)
- Type of preclinical samples; plasma, blood, serum and skin and skin layers, synovial fluid, hard tissue, assay buffers etc.

Policies

- Comprehensive SOPS for Equipments and Procedures
- Routine Instrument Qualification either by vendor or trained personnel
- Bioanalytical Method Validation as per SOP/Plan align to regulatory guidance
- Only Authorized individuals have access to system with well defined access levels

Accredited by NABL for Testing Competence for ISO/IEC 17025:2005



NABL

National Accreditation Board for Testing and Calibration Laboratories

Department of Science & Technology, 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

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 18/08/2014

Valid Until 17/08/2016

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

John Varughese
Program Manager

Anil Relia
Director

Prof. K. VijayRaghavan
Chairman