



## Bioanalytical Services



**Your Preferred Partner for  
Bioanalytical Services**

**Eurofins Advinus Biopharma Services India Private Limited**

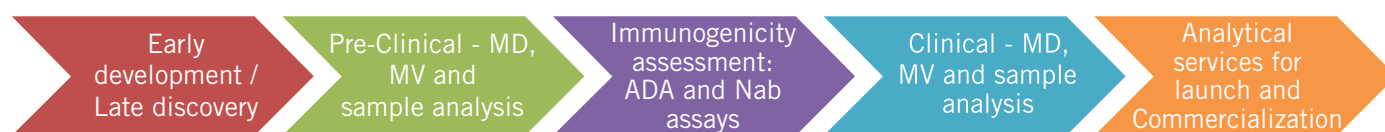


## About us

- Part of Eurofins Scientific Group - a Global leader in the pharmaceutical, food, environmental testing market
- India's most experienced GLP CRO with 30+ years of experience
- End-to-end services to support small molecules and biologics discovery and development
- Global acceptance of 200+ IND pharm tox packages by regulatory agencies
- Dedicated logistics team equipped to handle global shipment of samples (including import requirements)



## Bioanalytical services across the value chain



MD - Method development, MV - Method validation

- Expertise in bioanalysis of NCES, biologics, biosimilars including mAbs and vaccines
- Ability to develop assays across various platforms such as LC- MS/MS and ELISA, ICP-MS and MSD
- High understanding of global regulatory compliances
- Efficient turn-around time for sample analysis
- Have successfully completed multiple audits by US-FDA, GLP approving authorities, clients and third party auditors



## Our differentiators

- A trained and seasoned team of bioanalysts with vast experience in handling NCEs, generics, biologics and complex formulations
- State-of-the-art infrastructure for development of sensitive bioanalytical methods
- Specialized teams to handle logistics of samples, sample management and project management
- Quick turn-around time for clinical sample analysis
- Expertise in developing methods for specialized liposomal formulations and other complex molecules
- Support bioanalytical services for tissue matrix from rodents, non-rodents, non-human primates and human samples
- Laboratories are equipped with Watson LIMS 7.5 -a 21CFR Part 11 compliant data management system and Phoenix WinNonlin 8.0 software



## Bioanalytical services for small molecules

- Development of sensitive methods on multiple platforms for analysis of multi-analytes, metabolites, pro-drug and active drug, photo/temperature sensitive compounds, racemic compounds and ex-vivo unstable compounds
- Dedicated bioanalytical team which has executed 200+ IND pharm-tox packages
- Successful bioanalytical methods developed and validated for >650 compounds; several assays at pg/mL sensitivity level
- Experience in handling various biological matrices like blood, serum, plasma, CSF, urine, feces and other tissue homogenates



## Bioanalytical services for biologics

- Development, transfer, validation of PK/TK, ADA and NAb methods to support various stages of biologics/biosimilar development
- Use of sensitive assay platforms like LC-MS/MS, ELISA and MSD
- Experience in Cell-based efficacy assays, bioassays and biomarker assays
- Complimentary capabilities to generate assay specific polyclonal antibodies and labelled reagents



## Clinical sample bioanalysis

- Development and validation of methods for NCEs, generics and large molecules using LC-MS/MS, HPLC and ICP-MS
- Quantification of clinical trial samples for analyte and/or metabolite for Phase I through Phase II studies
- Experience in handling various clinical sample matrices such as blood, serum and plasma
- Data turn around within 72 hours of receipt of sample to support exposure guided dose escalations
- Dedicated logistics team equipped to handle global shipment of samples (including import requirements)





## LC-MS/MS method development expertise include

- Liquid/Liquid, solid phase extraction (SPE) and protein precipitation in 96-well and standard formats
- Simultaneous determination of pro-drug & active drug, parent compound and metabolites
- Chiral chromatographic separation and bioanalysis for racemic compounds
- Determination of free, liposome encapsulated, and total drug after administration of liposomal formulation
- Determination of free and protein bound drug from plasma after administration of complex formulation such as polymer-bound drug
- Derivatization approaches for poorly ionizable compounds
- Assays for endogenous compounds, nutraceuticals, plant extracts, photo/temperature sensitive compounds
- Experience in developing bioanalytical assays for drugs that are unstable ex-vivo in biological matrix
- Capability for analyzing 15,000+ samples per month on 10+ LC-MS/MS



## Equipment

### LC-MS/MS Systems (n=16)

- API 6500+ (2), API 6500+ with Q-Trap (1), API 5500 with Q-Trap (1), API 4500 (1) API 4000 (9)
- Shimadzu 8060 (1), Shimadzu 8060 Nx (1)
- ICP-MS (2) is also available for bioanalysis

### Freezers with centralized data logger

- -70°C Freezers (9)
- -20°C Freezers (6)
- 24x7 Power backup and alarm systems

### Sample preparation lab

- 6 Refrigerated centrifuges with various capacities
- Bullet Blender Gold (Tissue homogenizer)

- 96 well plate vacuum manifold and positive pressure SPE sample processors
- Nitrogen evaporator
- Milli-Q water system with Q-POD element

### IT Infrastructure

- Watson LIMS
- GPS synchronised clocks across labs for uniform time recording
- Phoenix WinNonlin
- Graphpad Prism
- Data transfer done via e-mail, client FTP, client e-rooms

### ELISA and MSD based Analysis

- Meso Scale Discovery QuickPlex SQ 120 (2)
- Multimode plate readers (3)
- Plate Washer (4)

### Biomarker Bioanalysis

- Flow Cytometry
- Q-PCR
- COBAS

### Protein Biochemistry

- Protein Simple Maurice
- SDS-PAGE
- Western Blot
- Chemidoc
- Nanodrop



The total area of the Bioanalytical lab is 6250 sq.ft.

**Eurofins Advinus Biopharma Services India Pvt. Ltd.**

Bengaluru : #21 & #22 Phase II, Peenya Industrial Area, Bengaluru - 560058

