

SMALL MOLECULE BIOANALYTICAL SERVICES

India: Capabilities

- 650+ bioanalytical methods in biological fluids
- Over 1 million samples analyzed annually
- 3 LCMS lab
 - 40 LC/MS/MS (28 API 4000, 8 API 5500, 2 API 5500+, 2 SCIEX 7500 equipped with UFLC & HPLCs)
- One ICP-MS (Thermo Scientific iCAP RQ)
- Separate LC-MS team and lab set up for dedicated method development and validation
- Experience in conducting bioanalytical assays for unstable compounds, compounds having metabolite back conversion, endogenous compounds, liposomal products, chiral compounds, elemental analysis
- Highly experienced team involved in MD and MV of simple to complex assays employing most sensitive LC-MS/MS

North America: Capabilities

- In 2014, established a Bioanalytical facility in Toronto Canada
- State-of-the-art 12,000 sq. ft. facility providing services in:
 - Sample Analysis to support Human BA/BE studies
 - GLP and Non-GLP non-Clinical Animal Studies (dogs, cats, horses, rats, etc.,)
 - IVRT & IVPT Bioequivalence studies for semisolids
- 8 LC-MS/MS systems including 6 API 4000 and 2 API 6500. 2 Shimadzu HPLC in the IVRT lab.
- Modern Sample Processing Laboratory having an isolated light sensitive lab
- Data acquisition with audit trail system
- Dedicated Sample Storage Room
- Scientific expertise and experience in developing bioanalytical methods for complex drugs and metabolites including endogenous substances:
Calcitriol, Tiotropium Bomide, Misoprostol, Lubiprostone, Estradiol & Estrone
- Expertise in conducting rapid sample analysis in support of First-To-File
- Excellent track record of regulatory history
- Last FDA inspection in 2021 on an IVRT study with no observations