

Bio-analytical Methods for challenging molecules :

Robust and reliable bioanalytical assays for complex molecules pose many challenges. Such challenging molecule for Quantitative Bioassay can be categorized as endogenous molecule, unstable molecule, chiral molecules, and requirement of Lower LLOQ etc.

Main challenges for Quantitative Bioassay of such type of molecules :

- Free drug is present in minute quantity in Endogenous molecule, thus selection of acceptable approach for selectivity and quantization.
- For chiral molecules, chromatographic resolution between the enantiomers
- Optimization of Run time to achieve high throughput
- Biological instability of the drug and metabolite(s) during sample collection, processing, storage, sample extraction and LC-MS/MS analysis
- Availability of high end sensitive equipments to achieve the required LLOQ
- Selective extraction from endogenous interferences requires extensive sample clean up.
- Sample handling to achieve the regulatory requirement and validation as per guidance.
- Method reproducibility and turnaround time for bioassay.

Our Capabilities :

- Experienced Method development team to handle complex chromatography and assay methodologies.
- Availability of high end sensitive equipments to achieve the required LLOQ
- Developed Suitable extraction methodology for the removal of endogenous moiety from biological matrix
- Optimized acceptable methodology for endogenous moieties, unstable drug & metabolite(s) and chiral separation
- Trained bio-analysts to handle complex methods in regulated environment
- Team having experience and validated methods are available for complex molecules and studies were conducted and submitted to regulatory.
- Incurred Sample Reanalysis evaluation for all analytes within the predefined criteria.

Veeda Advantage

- 100% data review by Bio-analytical Quality Monitors
- State of art Bio analytical Lab equipped with high end sensitive equipment's to achieve the required LLOQ.
- Trained Bio analysts to handle complex sample processing
- Proven regulatory track record with 11 USFDA, 5 European, 4 WHO & 5 ANVISA audits
- State of the art Bio-analytical Unit with more than 590 validated assays in its library of compounds including 36 NCE methods, 20 more under development.

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