meadowhawkbiolabs.com

DISCOVERY BIOANALYTICAL LC-MS

SMALL MOLECULE DISCOVERY ASSAYS DESIGNED TO DELIVER RAPID, RELIABLE BIOANALYTICAL STUDY DATA FOR NON-REGULATED STUDIES.

Meadowhawk's teams are deeply experienced in developing and applying fit-for-purpose LC-MS assays. Diagnostic tools and proven fail-safes are included in each experiment to identify potential liabilities in the bioanalytical results and to minimize the need for sample reanalysis. Our small molecule phamacokinetics assays consistently meet or exceed scientific and quality requirements at all points along the drug discovery continuum.

Our tiered approach allows fit-for-purpose assay range, rigor, complexity and cost-effectiveness across your exploratory to pre-IND studies.

Exploratory Tier

Standardized processes designed to produce data for support of preliminary screening programs or to group compounds with similar PK characteristics.

Optimization Tier

Tailored approaches to generate results for identification and progression of lead candidates or to rank compounds based on PK parameters.

Pre-IND Tier

Customized assays developed and qualified to provide definitive data for use in designing regulated studies and to support IND submissions.

The data quality indicators embedded into every assay test for common, often hidden, small molecule bioanalytical issues including experimental and analytical reproducibility, compound stability, and potential matrix effects.

These diagnostic evaluations provide valuable insight into the robustness and reliability of your discovery bioanalytical study data.

Meadowhawk's facilities feature state-of-the-art research platforms, including API7500 triple quad mass spectrometers, to ensure ease of execution and virtually infinite flexibility.

Count on Meadowhawk for rapid turnaround times, judicious use of your precious compounds, and data of identifiable quality.

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Discovery Bioanalysis Small Molecule Assay Tiering				
Attribute		**Exploratory**	**Optimization**	**Pre-IND**
Research Objective		To provide data which supports preliminary evaluations and/or binary decision making	To provide data which supports more granular and precise evaluations for decision making and candidate selection	To provide definitive data derived from focused studies to support the design and execution of IND-enabling studies
Turnaround Time		+	+	++
Experimental Rigor		++	+++	++++
Cost		+	++	+++
Bioanalysis Assay Parameters				
Precision/Accuracy Criteria		±25% (±30% LLOQ)	±20% (±25% LLOQ)	±15% (±20% LLOQ)
Analytical Reference Material	**Molecular Structure**	Not required	Not required	Preferred
	Salt Form	Required	Required	Required
	Purity Information	Not required, assume 100% in absence	Not required, assume 100% in absence	Required
	Quantity Required	Pre-weighed or ≥ 2 mg	Pre-weighed or ≥ 2 mg	Pre-weighed or ≥ 5 mg
	Weighings	Single	Single	Triplicate
	Stock Solution Checks	No	No	Yes (equivalency within 5%)
Method Qualification		No	No	Required
Calibration Standards		Target range: 0.500-10,000 ng/mL	Target range: 0.500-10,000 ng/mL	Custom range for compound/study
Quality Control Samples		No	Independently prepared at 3-4 concentration levels (extracted in triplicate)	Independently prepared at 3-4 concentration levels (extracted in triplicate)
Linearity of Dilution		Highest calibration standard serves as dilution QC - processed and analyzed at highest dilution factor used in batch	Independent dilution QC (2-3X ULOQ) processed & analyzed at highest dilution factor used in batch	Independent dilution QC (≥3X ULOQ) qualified at highest dilution factor utilized during sample processing
Internal Standard		Cocktail Internal Standard	Cocktail Internal Standard	Analog or Stable Isotope Label (Sponsor provided)
Sample Dilutions		Performed according to predefined guidelines for applicable dose routes	Based on historical data (if available) or general predefined guidelines for applicable dose routes	Based on historical PK results (In-house data or sponsor provided)
Samples Above Quantitation Limit		Fit for purpose data extrapolation (linear regression at ULOQ) or post-extraction dilution with reanalysis		Sample reprocessing with required dilution for quantification
Meadowhawk Diagnostics		Assay Robustness (Triplicate Extraction, Triplicate Analysis) Compound Properties (Analyte Stability, Blood/Plasma Ratio) Matrix Effects (Dilution Equivalency, Vehicle QC)		Matrix Effects (Dilution Equivalency, Vehicle QC)
Data Deliverable		Standard Excel Tabular Summary Additional options: PK calculations and Bioanalytical Word Report		

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