



Bioanalytical & Biomarker Services

## Discovery Services through Pre-IND (non-GLP)

Assay Parameters	Screening*	Research	Qualified
Method Development	No	2-3 days	3-5 days
Method Qualification	No	Optional	Preferred
Reference Material	1-2 mg (pre-weigh); or $\geq 5$ mg or 1 mg/mL	2x1-2 mg (pre-weighed), or $\geq 10$ mg	3x1-2 mg (pre-weighed), or $\geq 10$ mg
Analyte Information	free base MW, Bioratio, % Purity	free base MW, Bioratio, % Purity	free base MW, Bioratio, % Purity, Moisture; formal CoA preferred
Internal Standard	Generis IS	Generic IS, close analogue preferred	Close analogue or SIL preferred
Dynamic Range	Minimum 3 orders magnitude	Minimum 3 orders magnitude	Assay Dependent
Sample Extraction Volume	10-25 uL of Biofluid/fit-for-purpose	10-25uL of Biofluid/fit-for-purpose	Assay Dependent
Calibration Standards	$\geq 5$ standards	$\geq 6$ standards	$\geq 6$ standards
QC Samples	No	Min 3 levels	Min 3 levels
Accuracy and Precision	$\geq 75\%$ Standards within $\pm 25\%$ (LLoQ $\pm 30\%$ )	$\geq 75\%$ STD's within $\pm 20\%$ (LLoQ $\pm 25\%$ )	$\geq 75\%$ STD's within $\pm 15\%$ (LLoQ $\pm 20\%$ )
	-	$\geq 67\%$ QC samples within + 20%	$\geq 67\%$ QC samples within +15%
	-	$\geq 50\%$ QC samples at each level passing	$\geq 50\%$ QC samples at each level passing
Reportable AQL's	Extrapolated	Extrapolated	-
Data Deliverables	Excel File Summary	Excel File Summary	Excel File Summary with Methodology Tab

### Bioanalytical Probes

Cocktail IS	Yes	Yes	No
Sample Dilution	No	As requested	As Required
Specificity	Evaluated	Evaluated	Evaluated
Carry-Over	Evaluated	Evaluated	Evaluated

### Additional Tests Available by Request

Matrix FT Stability, Matrix RT Stability, Matrix LTS Stability, Process Sample Stability, Stock Solution Stability, Protein Binding, Targeted Met. ID and Quant, Additional Method Development and Qualification, PK Parameter Calculations and Interpretive Reporting, Expanded Word Reports

### Additional Matrices for Analysis

Biofluids: Serum, Whole Blood, CSF, Urine, BAL Fluid, Aqueous Humour, Vitreous Humor, Dose Formulation, Saliva, et al

Tissues: Liver, Brain, Kidney, Lung, Various Muscles, Feces, et al

Hard Tissues: Whole Skin, Eye: Lens, Retina, Choroid, et al

\*assumes single small molecule, single matrix biofluid, utilizing protein precipitation extraction, followed by standardized reverse phase chromatography, with run times < 5 min, minimum batch may apply