

Overview and Specifications of Non-GLP, Research Grade Assays

Attribute	Parameter	RGA1	RGA2	RGA3
Application	Assay Type	Screening	Lead Optimization	Candidate Selection & Pre-IND Enabling Studies
Analytical Reference Materials	Method Qualified	No	No	Yes
	Analyte Information Req'd	Correction factor, molecular weight	% Purity, salt content, M.W.	% Purity, salt content, moisture, M.W.; formal CofA preferred
	Internal Standard (ISTD)	Generic internal standard	Generic internal standard	Close chemotype, structural analog or stable label preferred
	Chemical Structure (Analyte & ISTD)	Structure preferred (not required) functional groups useful w/o structure elemental comp.	Structure preferred (not required) functional groups useful w/o structure elemental comp.	Structure preferred minimum functional groups, elemental comp.
	Minimum Quantity (Analyte & ISTD)	1–2 mg (pre-weigh) or ≥ 5 mg bulk or stock sol'n 1 mg/mL	1–2 mg (pre-weigh) or ≥ 5 mg bulk or stock sol'n 1 mg/mL	3x 1–2 mg (pre-weigh) or ≥ 10 mg bulk
Calibration Standards	Sample Extraction Volume	Default 10 μ L of biofluid/fit-for-purpose	Default 10 μ L of biofluid/fit-for-purpose	Assay dependent
	Concentration Range Default	Minimum 3 orders of magnitude	Minimum 3 orders of magnitude	Client/assay defined
	Number of Standards	≥ 6	≥ 6	≥ 6
	Accuracy	≥ 75% STDs within \pm 25% (\pm 30% LLOQ)	≥ 75% STDs within \pm 20% (\pm 25% LLOQ)	≥ 75% STDs within \pm 15% (\pm 20% LLOQ)
QC Samples	Concentrations	-	Minimum of 3 levels	Minimum of 3 levels
	Preparation	-	-	≥ 2 weighings or stock sol'n equiv.
	Precision (%CV)	-	≤ 20% all levels	≤ 15% (≤ 20% LLOQ)
	Accuracy	-	≥ 67% all QCs within \pm 20%, ≥ 50% at each level pass	≥ 67% all QCs within \pm 15% (\pm 20% LLOQ), ≥ 50% at each level pass
Bioanalytical Probes	Cocktail IS	Yes	Yes	No
	Sample Dilution	-	As requested	As required
Other Test Parameters	Specificity	Evaluated	Evaluated	Evaluated
	Carryover	Evaluated	Evaluated	Evaluated
	Matrix FT Stability	-	-	As requested
	Matrix RT Stability	-	-	As requested
	Matrix LT Storage Stability	-	-	As requested
	Processed Sample Stability	-	-	As requested
Data Extrapolation	Reportable AQLs	Yes	Yes	-
Deliverable	Report & Data	Excel file summary	Excel file summary	Excel file summary with methodology tab