

TIER 2 LC/MS/MS BIOANALYSIS

ANALYTICAL SYSTEMS

- SCIEX 4000 TRIPLE QUAD MASS SPECTROMETER
- AGILENT 1100 HPLC
- AGILENT DIODE ARRAY
- CTC PAL AUTOSAMPLER
- MP BIO HOMOGENIZER
- SOLID PHASE EXTRACTION
- REFRIGERATED CENTRIFUGES



TIER 2: SMALL MOLECULE BIOANALYSIS

Scenarios: In vivo pharmacokinetic studies for compounds and formulations under preliminary pharmacological and pharmacokinetic evaluation.

Typical number of molecules: 1-3

Method Development Cost Range (number of compounds dependent): \$2250/day typically 1-2 days/molecule/matrix

EXAMPLE ANALYSIS

LC/MS/MS Method Development: Compound infusion, MS autotune or manual tune. Ionization parameters optimization, HPLC column and mobile phase selection for acceptable peak shape, injection of compound at 5 ng/mL in water and acetonitrile to assess peak shape.

Sample Extraction: Direct 5:1 acetonitrile precipitation of 25-50uL plasma/serum, centrifugation, dry down under heated nitrogen and reconstitution in initial mobile phase.

Sample Extraction Sensitivity and Linearity: Assessment of a single standard curve for linearity and sensitivity.

Standard Curve in species matrix: 5000, 2500, 1000, 500, 250, 100, 50, 25, 10, 5, 2.5, 1 ng/mL, Blank, Double Blank

Extracted once and injected twice

Minimum Acceptance criteria: +/- 22.5% center of range, +/-30% LLOQ

Quality Controls: 1000, 100, 10 ng/mL in duplicate from second working stock solution

Acceptance criteria: +/- 22.5%

Sample Batch Analysis: One standard curve at the beginning of run, interspersed QCs through samples, and second standard curve at the end of the batch of up to 70 samples.

Sample Analysis Cost Range: minimum batch cost of \$2000 for fluids and \$2600 for tissues; additional \$50/fluid sample or \$65/tissue sample above 40 samples for a single compound.

Results Reporting: Excel file (additional charge for standard report format)

Standards: Reporting of Used/Excluded, Nominal, Back Calculated, % Nominal

QCs: Reporting of Used/Excluded, Nominal, Back Calculated, % Nominal

Samples: Calculated concentration in tabular format.



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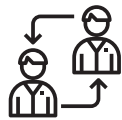
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