

Bioanalytical PK/TK Support Services

Intertek's pharmacokinetic (PK) and toxicokinetic (TK) services are capable of supporting both large and small molecule research and development programs from investigational studies in discovery through clinical first-in-man and drug-drug interaction studies:

- Non-compartmental and compartmental pharmacokinetic analysis
- Bioavailability and bioequivalence studies
- Preclinical toxicokinetic analysis
- Phase I and II clinical pharmacokinetic analysis
- Integration of pharmacokinetic and anti-drug antibody (immunogenicity) results in animals and humans
- Biomarker assessment and pharmacokinetic/ pharmacodynamic (PK/PD) analysis and modeling
- PK/TK study design, protocol development and drug disposition consultancy
- Guidance on scaling from animals to humans
- Integrated program/project support, including pre-IND and IND PK/TK packages

Data analysis and modeling are conducted with WinNonlin® Phoenix™ version 6.1.

Intertek provides seamless integration of PK/TK data analysis with Intertek's bioanalytical laboratories to help evaluate and understand a drug's disposition, immunogenicity (if applicable) and pharmacokinetic characteristics.

Method Development & Validation

High Throughput GLP Sample Analysis

- Preclinical
- Clinical Phase I-III
- Bioequivalence
- Bioavailability
- Tissue Residue Studies for Veterinary Medicines

Non-GLP Rapid Proof of Concept Bioanalysis

- Early Pharmacokinetic (PK) Studies
- Lead Optimization Studies
- Tissue Bioanalysis

Bioanalysis in Tissues & Fluids

Bioanalytical PK/TK Support Services

Sample Handling & Management

Pre-Clinical and Clinical Study Management

Intertek

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Intertek Pharmaceutical Services

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GLP Bioanalytical LC-MS/MS Services



Intertek BioClin is experienced in:

- Development and validation of quantitative LC-MS/MS methods for novel drugs and metabolites according to regulatory guidance and industry standards
- Transfers and validations of existing methods
- All phases of regulated preclinical and clinical bioanalysis
- High-throughput sample analysis
- Data management and reporting for regulatory compliance

Projects are assigned to and managed by experienced Principal Investigators with support from teams of Project Coordinators, senior scientists and analysts. The teams ensure your methods are developed, validated, and that study samples are accessioned, analyzed and reported in a timely and cost-efficient manner.

- Liquid/liquid, solid-phase extraction (SPE) and protein precipitation
- High-throughput, semi-automated sample processing
- Analysis of peptides
- Novel analyses of pegylated drugs
- Tissue bioanalysis and residue studies
- Chiral analysis
- Hydrophilic interaction and ion exchange chromatography

Non-GLP Rapid Proof of Concept Bioanalysis



Intertek BioClin offers a low cost, non-GLP, rapid proof of concept bioanalysis service in support of:

- Early pharmacokinetic (PK) studies
- Lead optimization
- Tissue bioanalysis

Projects are assigned to a dedicated team of bioanalytical scientists with in-depth experience in many classes of compounds and different matrices. Methods are rapidly developed and samples quickly analyzed. Data is typically delivered within 5-days of receipt of samples.

Rapid Discovery Bioanalysis

Includes LC-MS/MS instrument optimization with direct analysis of your samples employing a generic protein precipitation method with a broad range of calibration standards.

Lead Optimization / Early PK

Includes a more rigorous evaluation of assay performance and calibration curve range prior to analysis of your samples. Samples are analyzed under more stringent guidelines using freshly prepared calibration curves and QC samples.

- A range of established and proven generic discovery-phase methods developed for broad screening applications and quick turnaround times
- Rapid method transfer and adaptation
- Experienced method development scientists
- Plasma, blood, urine, all tissue types and unusual matrices
- Highly optimized program that is flexible, fast and cost-effective

GLP, Non-GLP and Clinical Analysis of Tissues

Intertek BioClin has a decade of experience in developing, validating (highly optimizing) and conducting regulated LC-MS/MS bioanalysis for a wide variety of compounds in multiple tissue matrices of different species.

A diverse platform of homogenization techniques is available for processing tissues to ensure optimal extraction of analytes from tissue homogenates or intact tissues and fluids. Technologies such as multi-tube bead homogenization and high energy ultrasonication are often employed individually, or in conjunction with more traditional processing techniques.

Non-GLP studies are also routinely conducted to support discovery, lead optimization and proof of concept programs.

Tissue matrices for bioanalysis include:

- Muscle
- Kidney
- Liver
- Fat
- Bone
- Bone marrow
- Synovial fluid
- Cardiac tissue