

Pharmacokinetic/Toxicokinetic Services

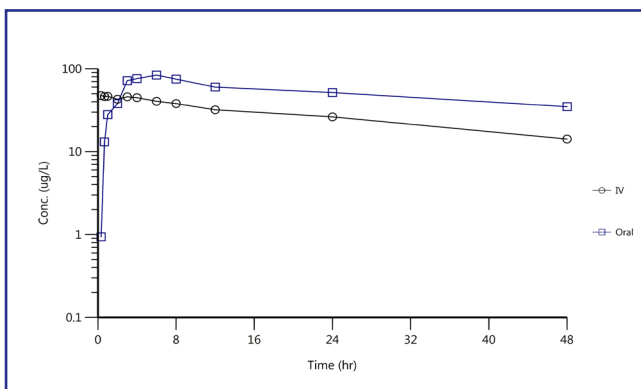
Pharmacokinetic studies are a critical component in evaluating the safety and efficacy of a drug from discovery through post-marketing clinical trials. Quality and reliability of the bioanalytical assay are vital to the pharmacokinetic analysis which help to elucidate decisions management of clinical studies. At Alturas Analytics, our PK expertise complements our bioanalytical services to provide a comprehensive and GLP compliant analytical package of the highest integrity.

PK/TK Services

- ▶ Non-compartmental analysis
- ▶ Validated WinNonlin®
- ▶ Single/Multi-dose
- ▶ Co-administered drug parent/metabolite
- ▶ Submission Ready Reports
 - ▶ Customized Reporting
 - ▶ eCTD Compliant

Bioanalytical Package

- ▶ GLP Compliant
- ▶ Method Development and Validation
- ▶ Pre-clinical and clinical studies
- ▶ Bioanalytical Sample Analysis



Concentration versus time profile following a single IV or oral dose.

“...Providing comprehensive GLP compliant analytical packages of the highest integrity.”



Focused on MS/MS Bioanalysis and PK Services

Known as the technology leader of MS/MS bioanalysis, Alturas Analytics delivers results on time with scientific integrity that exceeds industry standards. Privately owned and client focused, in our 20 years of operation Alturas Analytics has earned a reputation for personalized service and innovative MS/MS solutions.

BIOANALYTICAL SERVICES

- ▶ Methods Development, Transfer and Validation
- ▶ GLP and Non-GLP Sample Analysis
- ▶ Antibody Drug Conjugate (ADC) and Other Macromolecule Analysis
- ▶ Protein Binding Determination
- ▶ Dried Blood Spot (DBS) and Matrix Spot Analysis
- ▶ PK and TK Analysis and Reporting

QUALITY SYSTEMS

- ▶ Compliant to GLP and FDA, EMA and Crystal City Guidelines
- ▶ Onsite QA and IT Departments
- ▶ Thermo-Watson LIMS
- ▶ 21 CFR Part 11 Compliant
- ▶ GLP Validated Analyst Software
- ▶ Validated WinNonlin®
- ▶ Rush and Next Business Day Data Delivery Available

RESEARCH

- ▶ 15% of Capacity Reserved for Research
- ▶ New Bioanalytical Techniques Including:
 - ▶▶ Microflow LC-MS/MS
 - ▶▶ Immunocapture
 - ▶▶ Picofuze™
 - ▶▶ Creation of Novel Dye to Analyze Translucent Matrices Such As:
 - ◆ Tears, Cerebrospinal Fluid, Synovial Fluid

FACILITIES AND EQUIPMENT

- ▶ 15,000 Sq. Ft. Purpose-Built Facility
- ▶ Sciex 4000, 5500 and 6500 Mass Spectrometers
- ▶ Shimadzu UPLCs
- ▶ Waters M-Class Microflow UPLCs
- ▶ Watson LIMS system
- ▶ HTDialysis Micro-Equilibrium Devices