

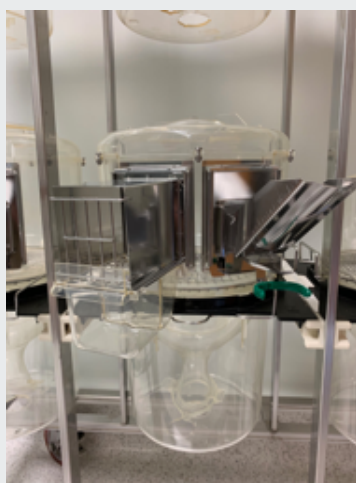
NONCLINICAL NONGLP PK & GLP TK

PHARMACOKINETICS

- Validated Phoenix PK Platform
- Experience in tissue and fluid analysis
- Compartmental Modeling
- Dose Simulation
- Allometric Scaling
- Noncompartmental PK Analysis
 - Sparse Sampling
 - Full Profile

TOXICOKINETICS

- GLP compliance
- Company SOPs
- QC/QA Process
- PP and PC Domain SEND generation and validation with Pinnacle21



NONCLINICAL PHARMACOKINETICS & TOXICOKINETICS

In-house Dosing Capabilities: IV, PO, IP, SC, Intraplantar, IM, Intranasal capabilities and additional cannulated routes

In-house Formulation: Solution and suspension formulation development and stability analysis.

In-house Rodent Vivarium: Capable of housing rodents (mice and rats) for single dose and repeat dose studies.

Drug Metabolism and Excretion Studies: Drug metabolism cages available for collection of excreta.

Collaborate with Client in Design of Studies: Cassette dosing, Drug-drug interaction, etc.

Collaborations with third party vendors for large animal dosing and sample collection.

Sample collection: Microsample collection in rodents for full PK profiles; tissue sample collection for understanding of organ specific uptake (i.e. brain, etc.)

Noncompartmental Analysis: Analysis of analytes by industry accepted noncompartmental methods following internal SOPs.

Compartmental Analysis: Evaluation of compartmental models to describe the concentration data for future dose modeling and simulation.

TOXICOKINETICS

Protocol Development: Experience working with toxicologists and bioanalysts to design toxicokinetic analyses to support IND and NDA submissions.

Quality Assured Analyses and Reports: Xyzagen follows internal SOPs to ensure analysis and reports are consistent and meet current regulations and guidance.

PP SEND Domain Generation: Software and processes to generate PP SEND Domains and submit to client's toxicology lab for incorporation into the final report. Validation of SEND file supported by Pinnacle21 software.



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