FIRST-IN-RODENT™ PK

Understanding your drug's in vivo pharmacokinetics early will help inform decisions regarding pharmacology, candidate selection and toxicology design.

COST: STUDIES CAN RANGE FROM $8000, FOR A SIMPLE CROSS OVER DESIGN IN RATS, AND UP, DEPENDING ON COMPLEXITY.

WHEN TO RUN AN IN VIVO STUDY & SPECIES SELECTION

- If your small molecule drug candidate has in vitro activity on your biological target then you should consider a PK study.
- Conducting the study will help inform on where resources should be applied in order to optimize your candidate or chemical series.
- If there is no other information available then select the industry standard Sprague Dawley Rat.
- If your company is working with a mouse transgenic model to assess pharmacology then consider the wild type strain.

STUDY DESING AND FORMULATION

- Determine your primary objective and secondary objectives before considering the design.
- If the objective is to gather general knowledge then consider a rat IV & PO cross over study with urine excretion collection.
- Consider drug analysis in plasma, blood and urine.
- Consider micro-sampling for full time course profiles and animal minimization.
- Xyzagen can develop a solution or suspension formulation for your early development API.

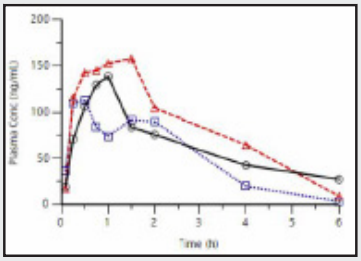
PK ANALYSIS

- If your drug is poorly soluble then an oral suspension and solution cross over design can be more informative than a CaCo-2 in vitro permeability study.
- Evaluating the IV and PO PK of your molecule can provide insights into potential metabolism liabilities or absorption liabilities
- Evaluating blood and urine exposure in addition to plasma can be informative on whether your drug is highly extracted (cleared) by liver and/or kidneys

FUTURE DEVELOPMENT

- Compartmental modeling can be employed to evaluate future dosing scenarios prior to initiating additional studies
- With mouse and rat PK, allometric scaling can be evaluated to support large animal PK study design.
- If poorly soluble (BSA Class 2) with good in vitro potency or poor half life for target product profile then can assess different formulation for improved kinetics.
- Model Based Drug Design can be applied with a well designed, data rich, initial study.

Experienced scientists in pharmacokinetic study design, implementation, analysis, and reporting.



- Formulation
- Study Design
- Microsample Collection
- Incorporating PK/PD Endpoints
- Organ Collection
- Bioanalytical Method Development
- Sample Analysis
- PK Interpretation
- Report writing with optional IND CTD written and tabulated summaries
- PK modeling and stimulation

XYZAGEN
LABORATORY AND RESEARCH SERVICES

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ABOUT US

We help advance your R&D programs through rational, decision-based, focused projects.

OUR SERVICES

BIOANALYSIS

STRATEGIC CONSULTING & SCIENTIFIC WRITING

STUDY MONITORING

PHARMACOLOGY

NONCLINICAL PHARMACOKINETICS

CLINICAL PHARMACOLOGY & PK

GLP TOKICOKINETICS

LABORATORY ANALYSIS

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