Axcelead DMPK Services

Accelerate your projects move on to the next step

Delivering customized solutions in alignment with your development strategy — as a trusted partner.

Modeling & Simulation

Comprehensive support from non-clinical to clinical stages (in collaboration with Prof. Yusuke Tanigawara)

- Estimation of clinical effective dose
- Optimization and streamlining of clinical study design
- Support for practical translational research (Translational modeling)

Drug–Drug Interactions

Support leveraging global development experience

- Proposals and execution of efficient *in vitro* studies aligned with clinical strategy
- Support from non-clinical to clinical using PBPK modeling
- Prediction and mechanistic understanding through *in vitro* studies and M&S

Metabolites

Leveraging development capability to resolve metabolite issues

- Comprehensive development strategy advisory
- *In vitro/in vivo* metabolite identification
- Synthesis of reference and stable isotope-labeled compounds, and efficacy and safety evaluation of metabolites
- Addressing issues related to human metabolites

Standard turnaround is Just 3.5 Days!

Reliable data using state-of-the-art liquid handlers and assay conditions optimized by experienced scientists

HT-ADME

Physicochemistry studies
- Purity
- Kinetic solubility (JP1st/JP2nd)
- logD HPLC method
- ePSA

Permeability
- PAMPA pH7.4/5.0
- MDR1 substrate screening
- BCRP substrate screening
- Caco-2 permeability (3W culture)
- Caco-2 permeability (10-11d culture)
- Caco-2 permeability (10-11d culture, 24h incubation)

Metabolism
- Metabolic stability
- Glucuronidation (UGT)
- Hepatocyte Clearance

Drug-Drug interactions
- CYP competitive inhibition (6 isomers)
- CYP competitive inhibition (3A4 testosterone)
- CYP time dependent inhibition (3A4)
- CYP inhibition shift method (DI/TDI)
- Transporter substrate (MDR1/BCRP)
- Transporter inhibition (various transporters)
- CYP induction (human hepatocyte)
- CYP induction (HepaRG)

Reactive metabolite
- dGSH trapping
- CN trapping

Pharmacokinetic evaluation
- Cassette dosing PK (rat/mouse)
- Brain Kp (rat/mouse)
- Plasma protein binding
- Brain tissue binding

In addition, new assay systems can be developed to evaluate your modalities.

Discovery DMPK

Bioanalysis (including method development)

In vitro **DMPK studies**
- CYP phenotyping
- Metabolite structure analysis (*in vitro / in vivo*)
- Blood / plasma concentration ratio

Pharmacokinetic studies
- Tissue distribution, urinary / biliary excretion
- Parenteral administration (transdermal, intranasal, pulmonary, sublingual, intrarectal, etc.)

Compound optimization / translational research
- Structure property relationship
- DDI risk evaluation
- Human PK, effective concentration and effective dose prediction
- PK/PD/E analysis, TK/TD analysis, modeling & simulation (Business partnership with Leiden Advanced PK/PD)

Physicochemistry and Preformulation

Physicochemical property profiling
- Purity
- Crystal form / crystallinity
- Thermal property
- Hygroscopicity
- Particle size
- Thermodynamic solubility
- pKa

Development form selection

Formulation for animal experiments

Stability

(solid, solution, administration formulation)

Axcelead Drug Discovery Partners, Inc.
https://www.axcelead-us.com/

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