Integrated DMPK Services from HIT to Lead Optimization and IND Filing

Aragen's uniqueness comes from its ability to provide comprehensive DMPK expertise and technologies from the early drug discovery (High-throughput profiling/rank order) to lead optimization and IND filing for all modalities of small and large molecules in rodents and non-rodents. We work for customer delight, using biomatrices from certified vendors and animals from CRL subsidiaries. Our two mirror image facilities at Hyderabad and Bangalore have 2.5 dozen of high-end LC-MS/MS and HRMS, to eradicate bottlenecks in bioanalyses and produce quality data in best timelines.

TIER 1 ASSAYS

- Solubility (Kinetic and Thermodynamic, SIF, SGF)
- *Log P* and *Log D*
- PAMPA (GIT, BBB and Skin)
- Metabolic stability in microsomes and hepatocytes (2 time points, Multispecies)
- Protein binding (Single concentration)
- Cocktail CYP inhibition, HLM (Single concentration, 5 CYPs)
- Cassette IV PK
- Cassette PO PK

TIER 2 ASSAYS

- Plasma protein binding (3 concentrations, 3-5 species)
- Metabolic stability (Intrinsic Clearance)
- Plasma/blood stability
- CYP Inhibition (IC50, Ki)
- Met ID (soft spot), species comparison
- Blood / plasma Partitioning
- Time dependent inhibition / Mechanism based inactivation
- Reactive metabolites
- MDCK and Caco-2 permeability
- Rat IV PO PK
- Mouse IV PO PK
- Dog IV PO PK
- Blood brain barrier penetration studies (Brain and CSF) in rodents

TIER 3 ASSAYS

- Reaction Phenotyping
- Single raising dose in rat
- Single raising dose in mouse
- Single raising dose in dog
- CYP Induction
- Tissue distribution studies
- MTD studies in rat and mouse
- Mechanistic PK studies (Biliary excretion, First pass metabolism, BAL study)
- Metabolic Characterization and Identification of *In vivo* samples

IND PACKAGE

- Bioanalytical method validation in rodent and non-rodents
- Single and multiple dose pharmacokinetics
- Dose proportionality and absolute bioavailability in mouse, rat, and dog
- Plasma protein binding in mouse, rat, dog, and human plasma
- *In vitro* CYP450 inhibition (1A2, 2B6, 2C8, 2C9, 2C19, 2D6, 3A4/5) in human liver microsomes
- CYP induction in human hepatocytes
- *In vitro* metabolism in, mouse, dog, and human hepatic preparations
- Reaction phenotyping in recombinant CYPs or UGTs or other enzyme systems
- Mini Ames
- Contribution of P-glycoprotein (P-gp) and breast cancer resistant protein (BCRP) in limiting drug absorption or flux

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