CHEMPARTNER
DEDICATED TO LIFESCIENCE

DMPK AND EXPLORATORY TOXICOLOGY

Our team draws on their experience at world-renowned pharmaceutical companies, emphasizes a science-based culture and executes quality drug metabolism pharmacokinetic (DMPK) and exploratory toxicology studies and integrates DMPK/toxicology data into our biopharmaceutical clients' discovery programs as well as support of their regulatory filings.

OVERVIEW

EXPERTISE

- Founded in 2007
- 300+ scientists, 50% with MS/MD/PhD
- 10,000+ PK/PD/tox and 100,000+ ADME case studies
- 10+ years experience in IND filling (FDA and NMPA)

EQUIPMENT

- 48+ LC/MS/MS instruments (Thermo Q Exactive, SCIEX Triple Quad™ 7500/6500/5500, Waters QTOF, X500R QTOF)
- 3 MSD
- 4 ELISA plate readers

IN VITRO SERVICES

ABSORPTION

- Caco-2
- MDCK-MDRI

DISTRIBUTION

- Protein binding
- Kbb
- RBC

CLEARANCE

- CLint in different matrix
- Phenotyping

DRUG-DRUG INTERACTION

- IC50
- IC50 shift
- Ki
- Induction

METABOLITE ID

- GSH trapping
- Metabolite ID

IN VITRO GENOTOXICITY

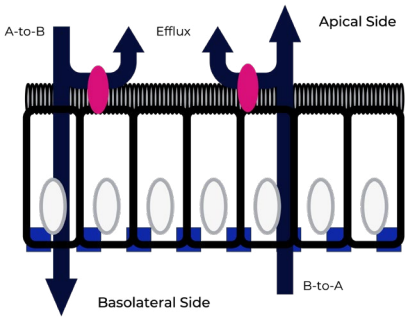
- Mini Ames

PHYSICAL-CHEMICAL PROPERTY

- Solubility and stability
- LogD, LogP, pKa
- PLM, DSC, TGA, XRPD
- Particle size distribution
- Dissolution test

CUSTOMIZED ASSAYS

IN VITRO PERMEATION MODEL



IN VITRO CYP INDUCTION MODEL

AAALAC AND OLAW ACCREDITED ANIMAL VIVARIUM

SPECIES	STRAIN/TYPE	ANIMAL CAPACITY
Mouse	C57/BL-6, CD-1, Balb/C nude, SCID, etc.	33,000
Rat	SD, Wistar Han, L ewis, nude, etc.	3,000
Guinea pig	Hartley	120

SPECIES	STRAIN	ANIMAL CAPACITY
Dog	Beagle	360
Non-human Primate	Cynomolgus and Rhesus	400
Mini-pig	Bana or Bama	56
Rabbit	New Zealand	56

IN VIVO SERVICES

PHARMACOKINETICS

- Screening single or cassette PK study
- Tissue distribution study
- Excretion and mass balance study
- BE, DDI, Ocular PK, etc.

GENERAL TOXICOLOGY

- MTD and DRF study
- Single dose study with 4-7 days observation
- Repeated dose study: 4-28 days

FORMULATION SUPPORT

- Formulation preparation and screening for PK , toxicology and pharmacology
- Solubility and stability in selected formulation
- Formulation evaluation for oral exposure
- Salt screening and polymorph screening
- Solid dispersion screening and spray drying

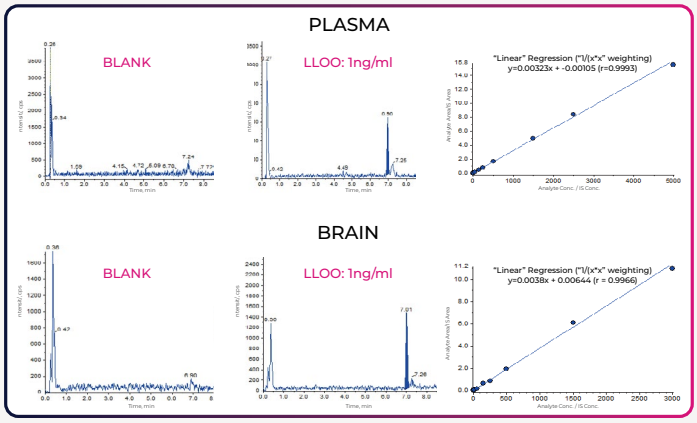
BIOANALYTICAL SERVICES

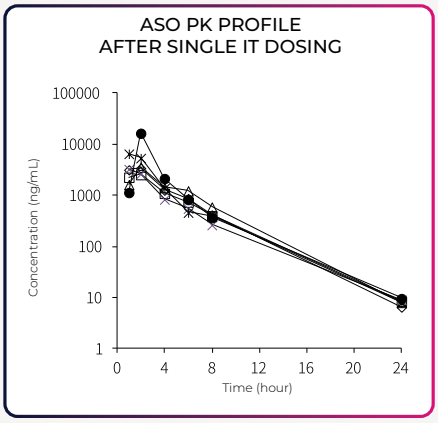
- Comprehensive discovery, preclinical and clinical bioanalysis

CASE STUDY

ASO PK STUDY IN MALE SD RAT

- Purpose: determine tissue distribution and PK profile of antisense oligonucleotide (lOkDa) in male SD rats
- Study design:
  - Intrathecal (IT) 1 mg/rat, single dose and repeated dose
  - Sampling of plasma, brain, spinal cord, and CSF
  - Bioanalytical method: LC-MS/MS (SPE coupled with Triple Quad 7500+)





LEARN MORE AT CHEMPARTNER.COM/SERVICES/DMPK-EXPLORATORY-TOXICOLOGY/