BIODURO-SUNDIA
保 诺 - 桑 迪 亚

# Drug Metabolism and Pharmacokinetics

## Providing World Class Quality Data

### The BioDuro-Sundia Advantage

BioDuro-Sundia provides insightful DMPK services through its unique position as a drug discovery and development organization. With strong credentials and experience, our DMPK team performs studies with a wide variety of animal models in an AAALAC accredited and GLP-like environment. Quality data is ensured by methodical protocols and best practices implemented by a group of expert leaders.

### Equipment and Facilities

We take great pride in adhering to strict regulatory standards and work in a professional GLP-like environment. We maintain a high quality AAALAC accredited vivarium and run our studies on quality controlled instruments.

### Instruments

**8 LC-MS/MS systems**

- 2 API-5500
- 1 API-4000 QTRAP
- 1 API-4500 QTRAP
- 4 API-4000 typical LOQ: 1 nM or lower

**2 UPLC systems**

- 1 Shimadzu LC-30AD
- 1 Waters H-Class

### Vivarium

- AAALAC accredited 15,000 sq. ft. (1,500 sqm)
- Small animal rooms
- SDF
- Dog animal rooms
- Conventional

In pursuit of your success.

www.bioduro-sundia.com

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## In vivo PK – Small Animals

- Mice (CD-1, C57BL-6 and more); Rat (SD, Wistar, Wistar Hanover, and more)
- Admin. Route: PO, IC, SC, IP, IN;IV/PO cassette dosing (5 in 1); IV infusion (30 min to days), osmotic pump (SC)
- Surgical rats: jugular vein cannulation; dual cannulation: jugular and portal; site-specific absorption: colon and duodenum
- Distribution in tissues, such as Blood Brain Barrier (BBB) and others: lung, liver, kidney, fat, spinal cord, muscle and more
- Serial bleeds for mouse PK study (three animals per route)
- Formulation development (~1,000 compounds/year)
- Capacity: 40 IV/PO PK studies/week; Turnaround time: 5-10 working days

## In vivo PK – Large Animals

- Beagles and Cyno Monkeys
- Monkey PK: BioDuro: Formulation prep., Monitoring for dosing and sampling, Bioanalysis and report writing; Partner: Dosing and Sampling
- Crossover or non-crossover; fast/fed (food effect); PK/PD evaluation
- Various routes of administration (IV, PO and IV infusion; IV cassette dosing- 5 in 1)
- Turnaround Time: 10 working days after receiving compounds (non-naïve animals)

## In vitro ADMET

**Physicochemical properties**

- Solubility (kinetic & thermodynamic at different pH values)
- LogD determination
- pKa determination
- Chemical stability
- Plasma stability; RBC partition
- Plasma and brain homogenate protein binding (RED)

**In vitro Drug Metabolism**

- Stability in liver microsomes / hepatocytes - half life and Clint
- CYP phenotyping
- Metabolite ID (phase I and II metabolism)

**Drug-drug Interactions**

- CYP inhibition assay IC50 determination
- Time dependent inhibition; GSH trapping assay

**Permeability**

- Caco-2 (21-day culture, A-B & B-A, as well as Pgp efflux)
- Parallel artificial membrane permeability assay (PAMPA)

## Bioanalytical Services (LC-MS/MS based)

Sample Analysis for PK, PK/PD, and TK Studies

Biomarker Quantification for PD Studies

Biologics (Peptide) Determination in Biosamples

Bioanalysis for CFDA Filing

**For more info please call: 858.529.6600 x509** **hello@bioduro-sundia.com** **www.bioduro-sundia.com**