



## PK Services

### Animal Facility

GVK BIO vivarium is AAALAC certified and registered with CPCSEA (Committee for the Purpose of Control and Supervision of Experiments on Animals), Government of India. In our rodent facilities, animals are housed in Individual Ventilated Cages (IVC) in controlled temperature (22° -25°C) & relative humidity (30%-70%) maintained at 12 h/12 h light/dark cycle.

### In Vivo Pharmacokinetics

- Rats of different strains- Sprague Dawley(SD), Wistar, Wistar Han and Lewis
- Mice of different strains - Swiss albino, BALB/c, C57BL/6, CD-1, Nude mice, etc.
- Hamster and Guinea pigs
- Discrete/Serial/Drug- Drug Interaction
- Rapid PK/Snapshot PK/Cassette PK
- Absolute Bioavailability
- Capabilities to conduct PK/PD relationship studies
- Blood sample collection techniques – retro-orbital / cardiac puncture/tail vein and jugular vein
- *In Vivo* Blood Brain Barrier(BBB) study
- Tissue Distribution studies
- Specialized studies for enterohepatic/first pass effect
- *Ex vivo* protein binding studies to measure free/bound drug and unbound drug in plasma, brain and CSF
- *Ex vivo* tissue permeability studies -Franz Diffusion assay (PermeGear)
- Biliary excretion studies
- Toxicokinetic studies
- Perfusion capabilities

### Cannulation/Surgical Procedures

- Jugular vein cannulation
- Portal vein cannulation
- Bile duct cannulation
- Femoral vein cannulation
- Double cannulation (jugular and femoral)
- Double cannulation (jugular and portal, jugular and bile duct)
- Carotid artery cannulation
- Ovariectomy
- Adrenalectomy

### Routes of Administration

- Oral - Solution, Suspension, Solids (pellets, capsules)
- Intravenous - Bolus, Infusion
- Intraperitoneal
- Subcutaneous
- Intramuscular
- Dermal
- Intratracheal
- Buccal/Sublingual
- Intraduodenal
- Intracolonic
- Intranasal

### Type of PK Studies

- Single Dose
- Multiple Dose
- Dose Linearity
- Tissue Distribution
- Alternate Dosing
- Drug-Drug Interaction Studies
- Fed/Fast PK
- BBB
- BBB & CSF
- Topical PK
- Infusion Studies
- Cassette PK

### Biological Fluid/Organ Collection

- Blood
- Urine
- CSF (Rat)
- BAL
- Bile
- All organs (brain, lungs, heart, lymphnode, salivary gland, ovary, spleen, skin, muscle, adrenals, kidney, fat tissue, thymus etc.)

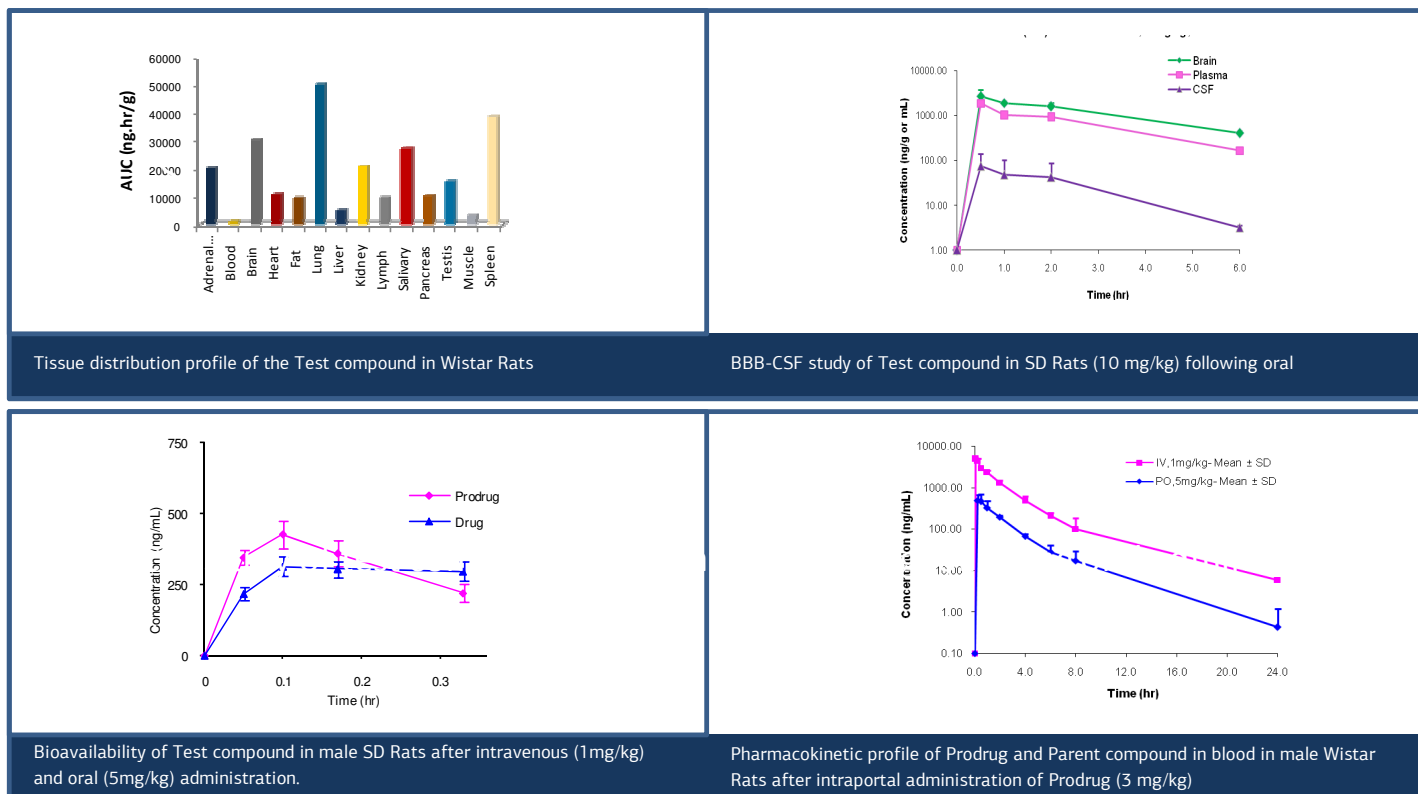
## Bio-analysis

- Analysis by LC-MS/MS/HPLC-UV/PDA/ Fluorimetry/ Spectrophotometer
- Method Development and Validation in Biological Matrices such as Blood, Plasma/Serum, CSF and Tissue homogenates
- PK analysis by Watson LIMS
- Quantification of Parent and Metabolites, Cassette Analysis, Cell Culture
- Measurement of Parent and Prodrug

### Typical study design for *In Vivo* PK/Bio-analysis

Report delivery within seven working days

Animal	Administration Route	Protocol	Parameters	Data Analysis
Mice/Rats (N=3/group)	p.o., i.v., i.p., s.c., i.m. infusion	Blood/Tissue samples collected at scheduled time points post dosing, plasma separated and analyzed for test item concentration	$C_{max}$ , $T_{max}$ , AUC, clearance, terminal elimination half life, bioavailability and volume of distribution	WinNonlin Software



## About GVK BIO

GVK Biosciences (GVK BIO) is Asia's leading Discovery Research and Development organization.

GVK BIO provides a broad spectrum of services, stand-alone and integrated, across the R&D value chain.

Chemistry Services ▪ Process R&D and Custom Synthesis ▪ Biology ▪ Informatics ▪ Clinical Research ▪ Clinical Pharmacology

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