



In Vivo Pharmacokinetics (PK)

TCGLS offers *in vivo* pharmacokinetic (PK) studies in rodents and higher species through network partners to determine the absorption, distribution, metabolism, and excretion (ADME) properties of drug candidates. We provide protocol design, formulation preparation, dosing, sample collection, bioanalysis, and PK parameter estimation. Studies are conducted in AAALAC-accredited facilities with adherence to animal welfare guidelines.

Our rodent PK services support early-stage drug development in mice, rats, and hamsters, covering study design, dose formulation, sample collection, bioanalysis, and PK data interpretation. We utilise advanced analytical techniques such as LC-MS/MS to quantify drug concentrations and generate detailed pharmacokinetic profiles. Our expertise ensures accurate assessment of ADME properties with rapid turnaround time, enabling decision-making for lead optimisation.

Overview of Services

Rodent PK Services

Exploratory PK Studies

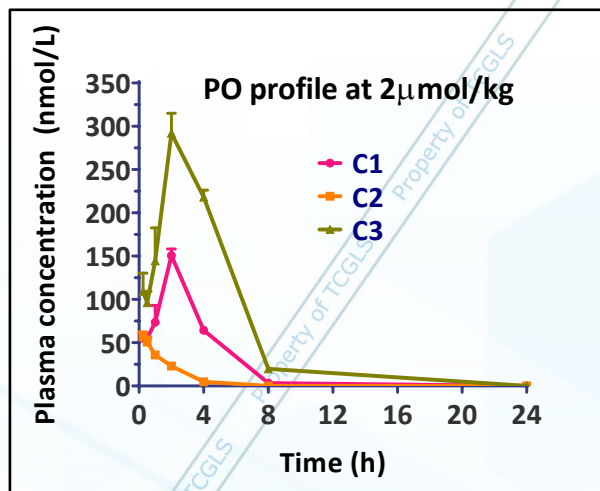
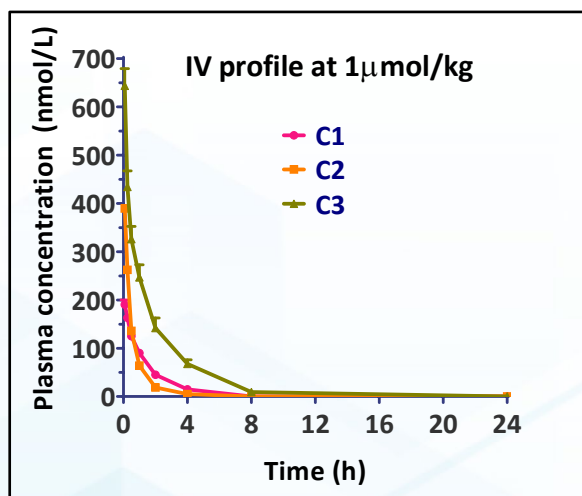
- **Discrete / Cassette Dose PK Screening**

Cassette Dose Pharmacokinetic Study

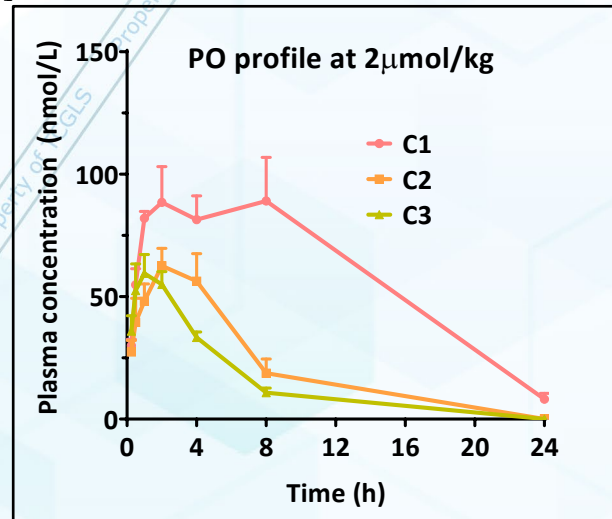
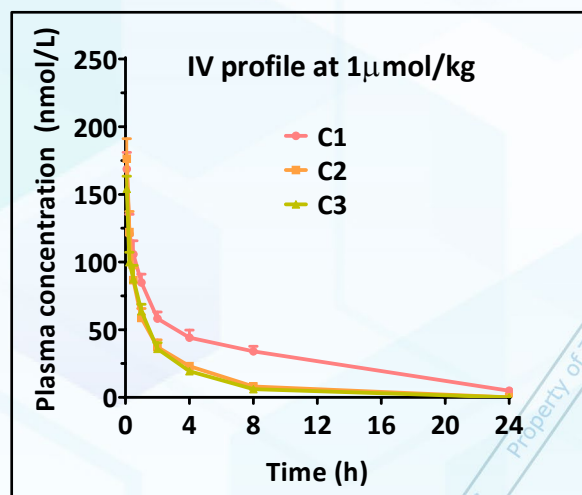
A cassette dose pharmacokinetic study involves administering a cocktail of multiple compounds to a single animal to assess their pharmacokinetics simultaneously. This approach is commonly used in early drug discovery to rapidly screen and compare compounds under identical conditions.

Case Studies

Rat study results



Mouse study results



- Multi-Dose (QD, BID, etc.) & Dose Escalation PK
- Serial / Group Blood Sampling
- Exposure Assessment in Various Biological Matrices
- Formulation Screening
- Bioavailability Assessment (Parallel or Crossover)
- PK Parameter Estimation by WinNonLin

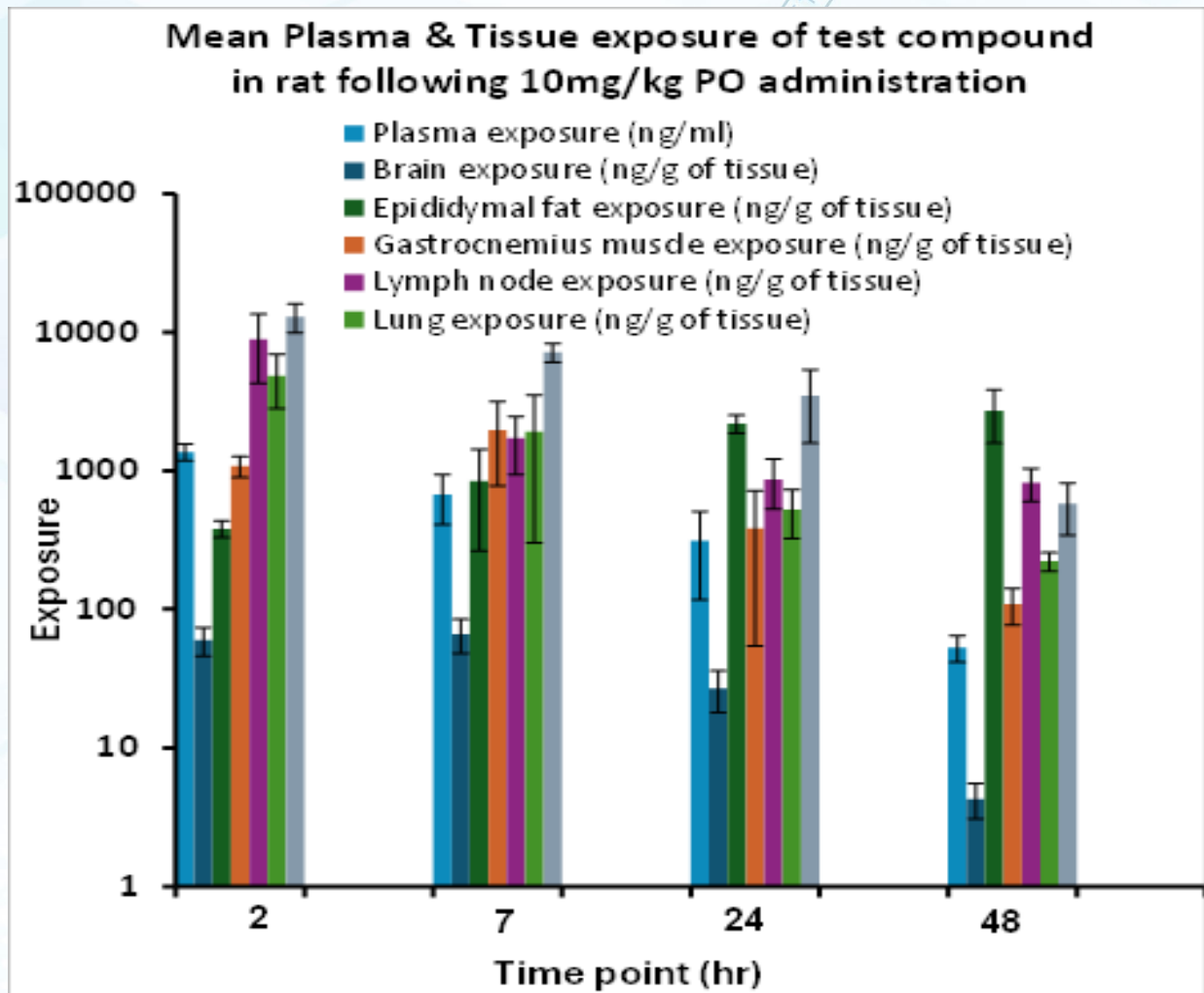
Specialised Services

• Tissue Distribution Study

The purpose of a tissue distribution study in rodents is to determine the distribution of a drug or test compound across tissues and organs following administration. This study provides critical information on the extent, rate, and pattern of distribution, which helps in evaluating target site exposure, identifying potential sites of efficacy or toxicity, and understanding the pharmacokinetic profile of the compound.

Case study

Rat tissue distribution



- **CNS Penetration / NeuroPK**

CNS Penetration Studies

The primary purpose of a central nervous system (CNS) penetration study in rats is to assess how well a drug or other substance can pass from the bloodstream into the brain and spinal cord, which together comprise the CNS. This is crucial for developing drugs targeting neurological conditions, as it helps determine if a drug can reach its intended site of action in sufficient concentrations to be effective.

CNS Penetration Following Infusion After Bolus Administration

Brief Design

Animal: Sprague Dawley Rats

Dose & route: 30 mg/kg; PO

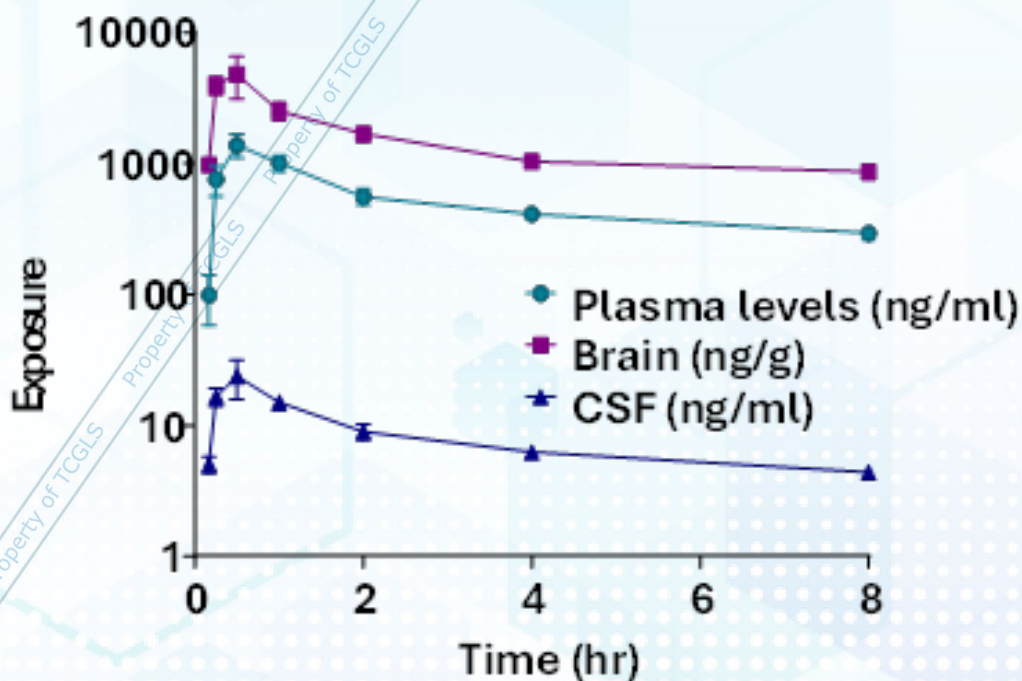
Sampling timepoints: 0.167, 0.25, 0.5, 1, 2, 4, 8 hours

Number of animals: Group sampling; n = 3/ time point

Biological Matrices: Plasma, Brain & CSF



Exposure in plasma, brain & CSF (Dose: 30mg/kg; po)



CNS Penetration Following Infusion in Conscious Rats

The variation in measured blood–brain partitioning for a given compound depends on sampling time. Ideally, in a steady-state infusion setup, the effects of variable blood–brain equilibration rates are eliminated. The use of a loading dose followed by constant infusion helps to achieve steady-state plasma drug concentration more rapidly, which is attained after 4 hours of infusion in cannulated rats. Following 4 hours of infusion via an infusion pump through a tethered assembly in conscious rats, plasma, CSF, and brain samples are collected, and drug concentration is measured.

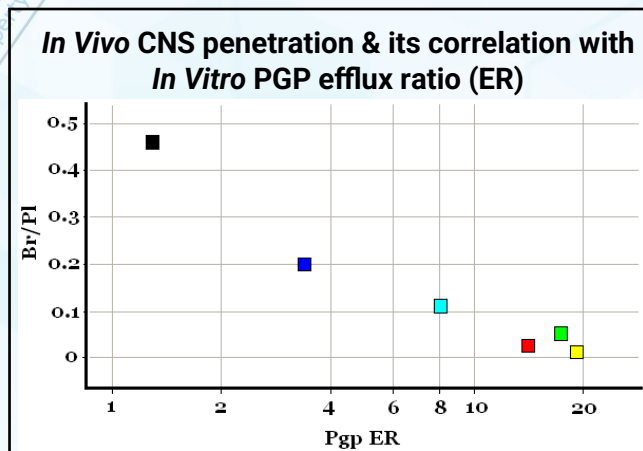
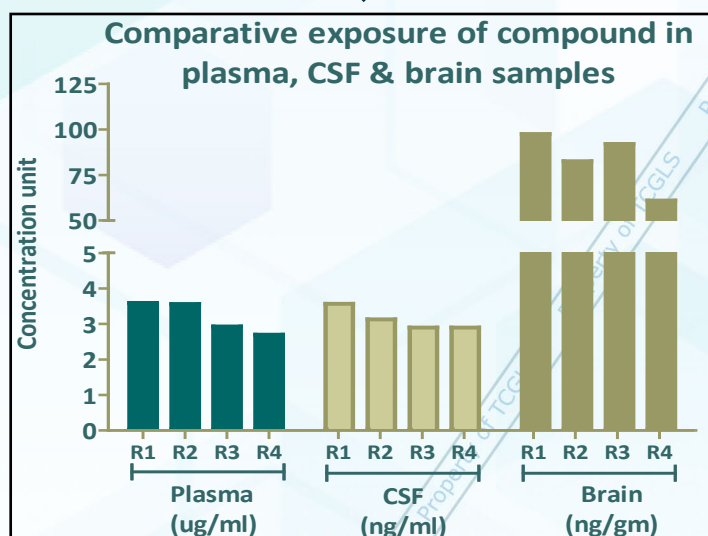
Brief Design

Animal: Jugular vein cannulated Sprague Dawley rats

Dosing regimen: IV bolus followed by IV infusion

Infusion technique: Through jugular vein by tethered infusion system

Biological matrices: Plasma, CSF & brain after 4 h of infusion



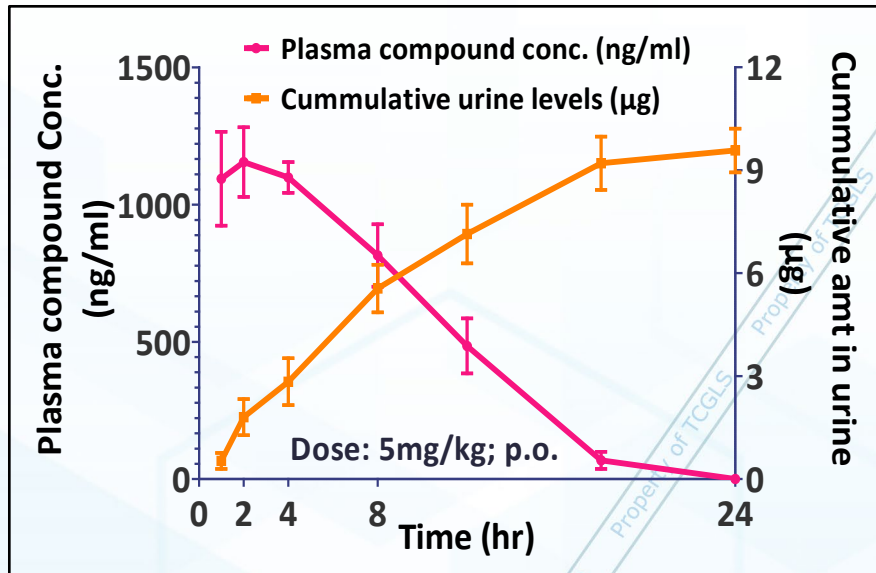
- Continuous Infusion via Tethered Assembly or Osmotic Pumps
- Juvenile PK Study
- Excretion Study (Urine & Faeces)

Rat Urinary Excretion

Urinary excretion studies in rodents are essential for understanding the elimination pathways of a drug. They help quantify the amount of parent compound and metabolites excreted via urine, providing insight into renal clearance, metabolism, and potential accumulation.

Case study

Rat Urinary excretion



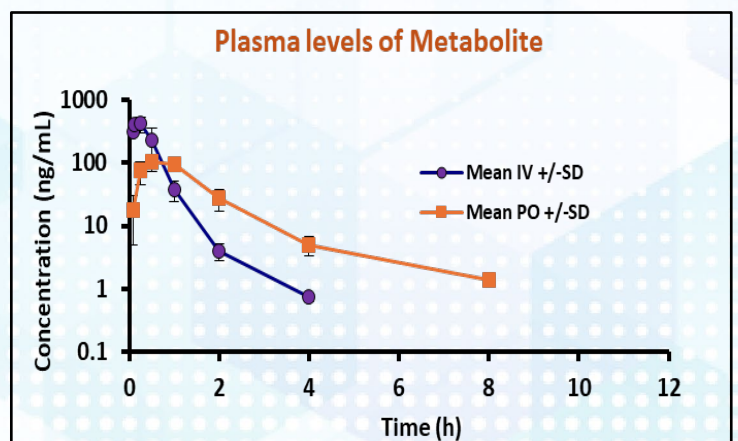
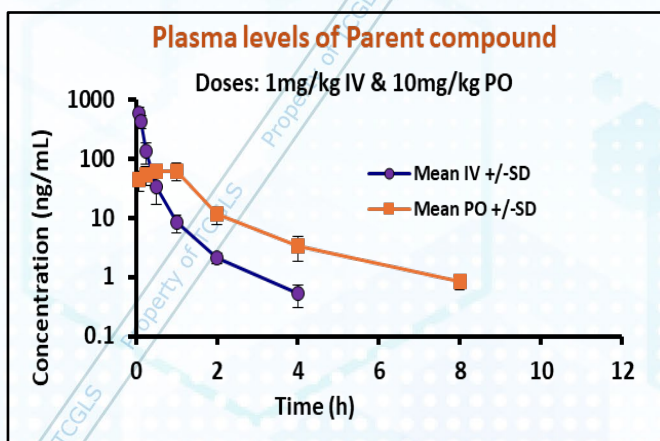
- PK-PD / Biomarker Quantification
- Metabolite Kinetics Study Post-Drug / Prodrug Dose

Parent-Metabolite PK

Parent-metabolite pharmacokinetic studies are crucial for understanding the complete drug profile. They help determine the extent of metabolism, the efficacy and safety of metabolites, and their contribution to overall therapeutic or toxic effects.

Case study

Mouse Parent-Metabolite PK



- **Toxicokinetics With Cage-Side Observation**
- **Customised PK To Meet Client-Specific Needs**

Routine Species & Strains

- Rat: Sprague Dawley, Wistar
- Mouse: CD-1, C57BL/6, BALB/c
- Hamster: Golden Syrian
- Special strains available via direct import

Routes of Administration

- Oral
- Intravenous
- Intraperitoneal
- Subcutaneous
- Intramuscular
- Intratracheal
- Intrathecal

Blood Sampling Methods

- Saphenous Vein Puncture
- Cannulated Jugular Vein

Biological Matrices for Exposure Assessment

- Plasma
- Blood
- CSF
- Tissues
- Urine
- Faeces

Rodent Facility, Accreditation & Compliance

- State-of-the-Art Facility with AAALAC Accreditation
- ISO Class 8 Clean Room Facility
- Registered with CCSEA (Govt. of India), Governed by IAEC
- Individually Ventilated Cages (IVC) for Animal Housing
- Animal Sourcing from CRL, Envigo & Jackson Registered Suppliers
- Dedicated PK Study Suites
- Occupational Health & Safety Compliance

Equipment & Instrumentation

- Metabolic Cages (Taconic)
- Tethered Infusion Systems (Sai Infusion Technologies)
- Infusion Pumps (Harvard Apparatus)
- Osmotic Pumps (Alzet)
- Individually Ventilated Cages (IVC) for Animal Housing
- Anaesthesia Machine (VetEquip Inc.)

Higher Species PK (through Network Partners)

- Rabbit
- Beagle dog
- Minipig
- Cattle
- Primate