康龙化成 PHARMARON

Biosciences

DMPK – Discovery through Clinical

Pharmaron's DMPK services support the needs for preclinical candidate (PCC) identification and nomination, Investigational New Drug (IND) enabling and New Drug Application (NDA) packaging for regulatory submission.

Capabilities

- Discovery *in vitro* ADMET for compound screening, PCC identification and nomination, including *in vitro* toxicity assays
- Discovery *in vivo* PK (in rodent and large animals) for compound screening, PCC identification and nomination
- PK/PD correlation
- GLP-like *in vitro* ADME for IND enabling
- GLP-like *in vivo* ADME for IND enabling
- GLP-compliant bioanalysis of samples from GLP safety assessment
- GCP-compliant bioanalysis of clinical samples
- Clinical metabolism for NDA submission
- Clinical absolute bioavailability using ^{14}C-microtracer/AMS platform
- ^{14}C and ^{3}H radiolabelling of small molecule compounds and biologics

Specialties

- Microdialysis for measurement of unbound compound concentration
- Comprehensive transporter studies including P-gp, BCRP, BSEP, MRP2, OATP1B1, OATP1B3, OAT1, OAT3, OCT1, OCT2, MATE1, MATE2K
- *in vitro* toxicity: Liver toxicity package (general and mechanistic toxicity evaluation), cardiotoxicity, genotoxicity, etc.
- BCS-based classification and biowaiver support
- Clinical absolute bioavailability using ^{14}C-microtracer/AMS platform
  - ^{14}C-labelled material synthesis - ^{14}C-microtracer
  - ^{14}C-microtracer dosed IV to human subject
  - Corresponding 'cold' compound dosed orally to same human subjects
  - AMS analysis of 'hot' compound and LC/MS/MS of the 'cold' compound in same samples
- AMS analysis of very low level of ^{14}C-labelled compounds in various bio-matrices
- Integration of DMPK functions across discovery, preclinical and clinical development phases

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Laboratory Services

Chemistry, Manufacturing and Control

Clinical Development

Biologics & CGT