Integrated Radiolabelled Drug Metabolism & PK

Pharmaron is uniquely positioned to help our partners plan and execute a complete metabolism strategy from radiosynthesis to human ADME studies required for drug approval. We offer both macrotracer (high ^{14}C dose) and microtracer (low ^{14}C dose) studies in human. The combination of ultra-sensitive Accelerator Mass Spectrometry (AMS) with High Resolution Mass Spectrometry (HRMS) analytical technologies provides unparalleled analytical capabilities and flexibility for complex metabolite profiling and structure elucidation.

Microtracer Option

Typically Start to CSR Times in 6-9 months

- Re-purify non-GMP ^{14}C API to clinical-grade specifications
- Utilize low radioactive dose - microtracer (~1-15 µCi)
- No dosimetry report required
- Hybrid LSC/AMS total [^{14}C] analysis for mass balance
- LC-AMS and HRMS for metabolite profiling/met ID
- Coordinate clinical with preclinical ADME/QWBA studies
- Human ADME and/or Absolute Bioavailability
- Clinical study report

Services

Radiosynthesis

- $^{14}C/^{3}H$ radiolabelled compounds for use in metabolism and PK studies
- GMP and non-GMP, small molecules and biologics
- Clinical-grade re-purification of ^{14}C-APIs for microtracer studies (non-GMP)

Human Metabolism

Clinical Pharmacology Center (CPC) – 90+ beds, Phase I/IIa (Maryland, US)

- ^{14}C ADME studies in human – Metabolism and PK
- ^{14}C AMS-enabled microtracers – Metabolism and absolute bioavailability
- Metabolite profiling, metabolite identification, metabolite safety
- Combination ^{14}C Phase I studies with SAD/MAD/FE/QT
- Clinical drug-drug interaction (DDI) studies

in vivo Metabolism

- PK, excretion balance, metabolite profiling, metabolite identification
- QWBA (dosimetry, if required), mARG
- Rodents and non-rodents
- Bile duct cannulated animal models

in vitro Metabolism

- *in vitro* cross-species comparative metabolism studies in liver hepatocytes/microsomes
- *in vitro* Metabolism DDI assays
- *in vitro* Transporter-mediated DDI assays

Bioanalysis

- LC-MS/MS, LC-AMS, LC-LSC
- Ligand-binding assays
- Small molecules, biologics, biomarkers

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