

Accelerator Mass Spectrometry (AMS) Services

¹⁴C Analysis by AMS for Clinical & Non-clinical Drug Metabolism

Accelerator Mass Spectrometry (AMS) is an ultra-sensitive analytical technique that detects and quantifies ¹⁴C atoms at trace levels that are 500 – 10,000 fold more sensitive than traditional LSC or LC-MS/MS methods. Originally used for radiocarbon dating, AMS was introduced for biomedical applications in the early 2000's and now plays a routine and pivotal role in pharmaceutical R&D. With no matrix interference or ionization issues, AMS is applicable to low-dose, long half-life, and low systemic drug exposure analysis.



Capabilities:

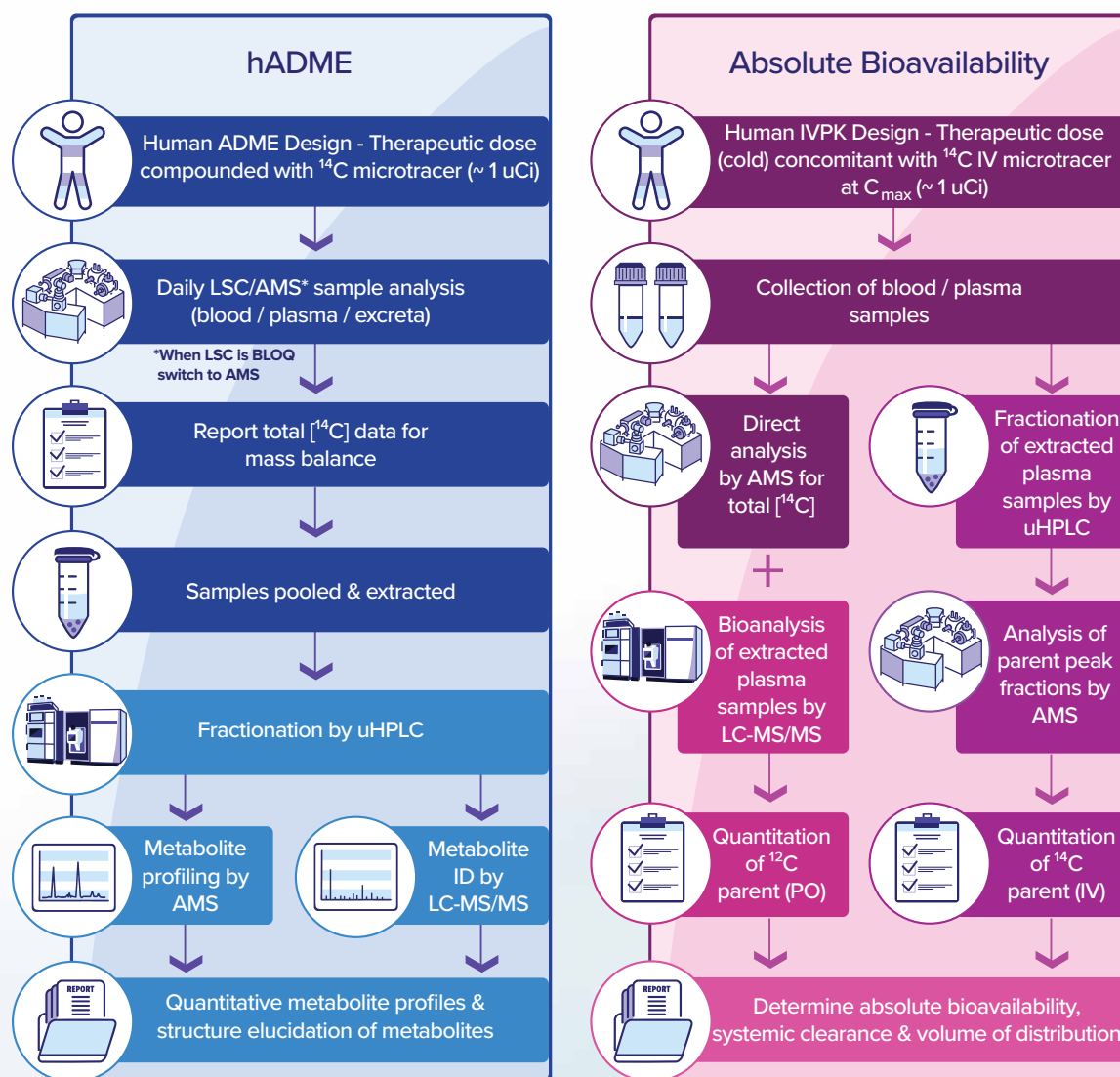
- **Clinical & Non-clinical Support:** ADME, absolute bioavailability, PK, TK, metabolite safety (MIST)
- **Sample Types:** Plasma, blood, urine, faeces, bile, CSF, expired air, tissues, PBMCs
- **Instrumentation:**
 - ▣ **Ionplus 50kV LEA** – Low energy, gaseous (¹⁴CO₂) AMS for rapid sample analysis
 - ▣ **NEC 250kV SS-AMS** – Ultra-sensitive, graphite (¹⁴C) with dual ion sources, for high volume sample analysis (>2,000 samples/week)
- **Software:** 21 CFR Part 11 compliant, audit trail, automated workflows (Ionplus AMS only)
- **Mass Balance Metabolite Profiling Studies** In toxicology species
- **Microtracer hADME Studies:** Provides complete metabolism data with minimal ¹⁴C dose in human
- **Absolute Bioavailability IVPK Studies:** Concomitant oral/¹⁴C IV dosing for absolute bioavailability in human
- **Metabolite Profiling:** LC+AMS for high resolution profiling including quantitation of ultra-low level metabolites

Advantages of AMS at Pharmaron:

- **Recognized Global Leader:** >25 years' experience with world-class AMS facilities in the US, UK and China
- **Accelerated Timelines:** End-to-end integrated ¹⁴C metabolism programs including radiosynthesis, non-clinical and clinical
- **Cost Efficiency:** Minimal GMP and human dosimetry requirements
- **Regulatory Acceptance:** GCP-compliant for FDA/EMA/MHRA/JMHW/TSA submissions
- **High Quality Data:** Rich, quantitative datasets for confident decision-making and de-risking

AMS Workflow

A fundamental and foundational workflow helps illustrate how ^{14}C AMS-enabled strategies can integrate both the full characterization of drug metabolism in human (ADME) together with determining absolute bioavailability, systemic clearance and volume of distribution (IV Pharmacokinetics) for your compound. These complementary approaches can be run in parallel in the clinic and generate a deep data-driven understanding of drug metabolism, systemic PK and biotransformation.



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