

## Small Molecule Bioanalytical Services

Discovery and Regulated Bioanalysis to support PK, TK, PD, Biodistribution, BA/BE and Biomarker Assays

### Discovery Phase

- Rapid method development for discovery bioanalysis
- Fast throughput sample analysis

### Preclinical Phase

- GLP compliant method transfer, validation and sample analysis
- IND-enabling programs per ICH/FDA/EMA/NMPA regulatory guidance
- Data packages and reports for IND submissions

### Clinical Phase

- Support for Phase I-III clinical trials
- GCLP-compliant method transfer, validation and sample analysis
- Clinical protocol development
- Clinical trial support for sample acquisition, shipment and logistics

Heterocyclic Molecules & Steroids

Peptides

ADCs and DAR

Oligonucleotides, Nucleotides & Nucleosides

Carbohydrates

Lipids

Pharmaron is a global life science service provider that offers a broad spectrum of research, development and manufacturing service capabilities throughout the entire drug discovery, preclinical and clinical development process across multiple therapeutic modalities, including small molecules, biologics and CGT products.



Laboratory Services



Chemistry, Manufacturing & Control



Clinical Development



Biologics & CGT

# Driven by Science to Help our Partners Succeed

Discovery

Preclinical

Clinical

Market

## › Regulatory Support

20 years of experience with global regulatory authorities to meet international regulatory guidelines

## › Successful Audits

Pharmaron's bioanalytical laboratories were successfully inspected by FDA, MHRA, OECD, NMPA and EMA

## › Experience

Hundreds of individual projects executed and 30+ IND-enabling small molecule bioanalytical packages submitted per year

## › Partnering with Your Team

Regular and direct communication with our scientific teams and project managers

## Capabilities

- Quantitative analysis of molecules with a wide range of structures and polarities
- Single-analyte, multi-analyte and chiral methods to separate enantiomers
- Metabolite profiling and metabolite identification
- Ultra-sensitive detection of radiolabelled compounds employing AMS
- Development of customized and generic biomarker assays

## Instrumentation

- 220+ LC-MS/MS (Thermo LTQ Orbitrap-X<sup>®</sup>, Thermo Q-Exactive, OE 120<sup>®</sup>, OE 240<sup>®</sup>, and Waters Q-ToF Vion<sup>®</sup>, Sciex 4000, 5500, 6500, 7500<sup>®</sup> systems)
- HPLC/UV
- HPLC/fluorescence
- ICP-MS
- Accelerated Mass Spectrometry
- Automated liquid handling (Hamilton Vantage<sup>®</sup>, Tomtec Quadra 4<sup>®</sup>, Tecan, Beckman, Agilent Bravo<sup>®</sup>)
- Watson-LIMS<sup>®</sup> data management

**Talk to our scientists about your drug development program today**

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