Q² Solutions®

Assays and services to accelerate the development of your pharmaceutical product

In vitro ADME, LC-MS/MS bioanalysis and metabolite identification service list

Q² Solutions provides services designed to help you get the data you need and to drive informed development decisions for your pharmaceutical product. Our integrated drug metabolism solutions include high-throughput screening assays, human clearance predictions, drug-drug interaction risk assessments and metabolite profiling to support clinical safety. In addition to the services listed below, we can also provide bundled services for discovery and regulatory-phase packages to enable decision-making in early discovery through IND and beyond.

Bioanalytical/Pharmacokinetic Services	
Discovery Bioanalysis by LC-MS/MS	**Details**
Tiered bioanalysis services from rapid, fit for purpose to method qualification	Dedicated team with scientific expertise and state-of-the-art instrumentation. Cassette dosed and multi analyte (parent and metabolites) analysis
Bioanalytical with optional Pharmacokinetic Analysis: Biological fluids and tissues	Species selectable, non-compartmental PK summary
Bioanalytical with optional Pharmacokinetic Analysis: Dried Blood Spot	Species selectable, non-compartmental PK summary
***In Vitro* ADME Services**	
High-Throughput Screening Assays	**Details**
Solubility/Permeability Assays:	
Solubility: Turbidmetric	10μM to 100μM in buffer
Permeability: MDCK	MDCK (wild type), MDCK-II cell lines
Metabolic Stability Assays:	
Metabolic Stability: Single Point	Hepatocytes or microsomes: Species selectable
Metabolic Stability: Intrinsic Clearance	Hepatocytes or microsomes: Species selectable
Metabolic Stability: Plasma of S9	Species selectable
Inhibition Assays (enzyme):	
P450 Inhibition: Reversible Single Point	Single concentration, P450 selectable (up to seven)
P450 Inhibition: Reversible IC_{50}	Multiple concentration, P450 selectable (up to seven)
Time Dependent P450 Inhibition: Single Point	Single concentration, CYP3A
Time Dependent P450 Inhibition: Multiple Point	CYP3A, CYP2B6, CYP2C8, CYP2C9, CYP2C19
Time Dependent P450 Inhibition: IC_{50} Shift	CYP3A or CYP3Q, 2D6 and 2C9 cocktail assays
Inhibition Assays (transporter):	
Transporter Inhibition: Bile Salt Export Pump (BSEP) Inhibition	Vesicles
Reaction Phenotyping Assays:	
P450 Reaction Phenotyping: Substrate Depletion	Microsomes with inhibitors for CYP2C9, CYP2D6, CYP3A
Other Assays:	
Protein Binding: Plasma, Microsomes, Brain Homogenate, HAS, AAG	Equilibrium dialysis HTDialysis or RED devise; Species selectable
Blood to Plasma Ratio	Species selectable
Bundled Tier 1 Screening Assays:	
Metabolic stability, permeability, CYP inhibition	Human liver microsomes, MDCK, CYPs2C9, 2D6, 3A in cocktail
Late-Stage Discovery to Regulatory Phase Assays	**Details**
Metabolic Stability Assays:	
Metabolic Stability: Intrinsic Clearance	Hepatocytes and microsomes: Species selectable (±ABT optional)
Metabolic Stability: Glucuronidation (UGT) Clearance	Microsomes (liver, intestine, kidney); Species selectable (±BSA)
Metabolic Stability: Low Turnover Drugs	Hepatocyte coculture systems (HμREL), Species selectable

In Vitro ADME Services (continued)	
Inhibition Assays (enzyme):	
P450 Inhibition: Hepatocytes Suspended in Plasma	CYP2C9, CYP2D6, CYP3A, combined reversible and TDI inhibition model
P450 Inhibition: Reversible IC_{50}	Definitive IC_{50} for up to 7 P450s/8 assays
P450 Inhibition: Reversible K_i	Definitive K_i for selected P450s
Time Dependent P450 Inhibition: IC_{50} Shift	IC_{50} shift following 30 min pre-incubation (part of reversible inhibition IC_{50} assay)
Time Dependent P450 Inhibition: Kinetics	CYPs 1A2, 2B6, 2C8, 2C9, 2C19, 2D6 and 3A; k_{inact}/K_I and CL_{inact}
Time Dependent P450 Inhibition: Mechanism	Metabolic intermediate (MI) complex formation, CYP3A4
UGT Inhibition: Reversible IC_{50}	UGT1A1, 1A3, 1A4, 1A6, 1A9, 2B7; Definitive IC_{50} using human liver microsomes
Induction Assays:	
P450 Induction: mRNA discovery screen in human hepatocytes	CYP1A2, CYP2B6, CYP3A4, message RNA assay following 24 hour treatment
P450 Induction: mRNA	CYP3A4, CYP2B6, CYP1A2, CYP2CB, CYP2C9, CYP2C19 mRNA, 48 to 72 hour treatment with basic DDI modeling (± CYP activity evaluation)
Reaction Phenotyping Assays:	
Hepatocytes with pan-CYP inhibitor (ABT)	Estimate CYP vs. non-CYP mediated fraction of metabolism
P450 Reaction Phenotyping: Substrate Depletion	Combination of rCYPs to predict $HLMf_{m,CYP}$ using RAF and/or chemical inhibitors
P450 Reaction Phenotyping: Metabolite Formation	Combination of rCYPs and/or chemical inhibitors
Estimation of Fraction Metabolized by CYP3A4 and CYP3A5	Combination of rCYPs and/or chemical inhibitors (ketoconazole and CYP3cide)
Aldehyde Oxidase (AO) Reaction Phenotyping: Human	Human cytosol or hepatocytes ±Hydralazine (AO inhibitor)
Other Assays:	
Protein Binding: Equilibrium Dialysis by HTDialysis Method	Plasma, microsomes, HAS, AAG, Species selectable; human clinical plasma
Blood to Plasma Ratio	Species selectable
Bundled IND-Enabling Assays:	
In Vitro DDI: CYP inhibition, time-dependent inhibition (TDI) and induction	HLMs and human hepatocytes; Assays meet regulatory guidelines for IND
Metabolite Profiling and Identification Discovery and Development Services	
Discovery to Regulatory Phase Assays	LC-MS analysis using high resolution mass spectroscopy (Waters Synapt G2-S and Thermo Q-Exactive HF and Exploris 240 HRMS)
Metabolite Profiling and Identification: *In vitro* incubations with subcellular fractions (Microsomes, Hepatocytes, cytosol, S9, co-cultured hepatocytes, such as HμREL or HeptoPac)	Species selectable: mouse, rat, dog, monkey, human and others commercially available
P450 Reaction Phenotyping: Metabolite Formation	Microsomes with inhibitors for CYP1A2, CYP2B6, CYP2C8, CYP2C9, CYP2D6, CYP3A
Metabolite Profiling and Identification: *In vivo* Services	Plasma, urine, bile, feces, tissues and/or dried blood spot (DBS, species selectable)
Metabolite Profiling and Identification: Exploratory Profiling	Exploratory assessment using unlabeled drug; Preclinical or clinical samples
Metabolite Profiling and Identification: Radioprofiling and Metabolite Identification	Preclinical or clinical samples; plasma, urine, bile, feces, tissues
Reactive Intermediate Screen	Microsomes; Species selectable trapping reagents: glutathione, cyanide, semicarbazid, methoxyamine
Reactive Intermediate Screen: Covalent Binding	Radiolabel covalent binding in microsomes or hepatocytes, species selectable
Large Molecules Discovery and Development Services	
Large Molecules-Identification/Quantification e.g., proteins, peptides, ADCs, polynucleotides, etc.	LC-MS using high resolution mass spectroscopy (Thermo Q-Exactive HF and Exploris 240) Bottom-up and Top-down approaches
Large Molecules stability assays in various applicable biological matrices	SPE coupled with various applicable LC-MS approaches
Hybrid assays	Affinity purification LC-MS approaches to complement ligand binding assays with specificity
Global proteomics and Phosphoproteomics	ThermoScientific tandem mass tags (TMT) based LC-MS using high resolution mass spectroscopy (Thermo Q-Exactive HF and Exploris 240)
Ionizable lipids-stability assays	LC-MS using high resolution mass spectroscopy (Thermo Q-Exactive HF and Exploris 240)

A full range of bioanalytical and ADME services

Q^2 Solutions operates on of the world's largest and most respected bioanalytical and ADME laboratory networks. From our global locations, we serve many of the largest pharmaceutical, specialty pharmaceutical and biotechnology companies in North America, South America, Europe and Asia. Our highly trained scientists utilize a range of leading-edge technology, automation and state-of-the-art techniques.

- ***In Vitro* ADME Assays and Metabolite Identification Services** in support of rapid drug discover ADME properly optimization and regulatory filings
- **Bioanalytical Liquid Chromatography Tandem Mass Spectrometry (LC/MS/MS) Services** for the quantitative determination of small molecule drugs and macromolecule therapeutics in support of pharmacokinetic (PK) studies
- **Immunoassay Services** for Enzyme-Linked ImmunoSorbant Assays (ELISA), mesoscale (MSD), electrochemiluminescence (ECL), and neutralizing antibody assays (NAB) in support of PK and immunogenicity studies
- **Biomarker Services** for LC-MS and ligan-binding assays for the quantitative determination of bioanalytical biomarkers

Scan to learn more

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