

Inotiv Standard IND-Enabling *In Vitro* DMPK Package for Small Molecules



BIOANALYTICAL METHOD DEVELOPMENT AND QUALIFICATION FOR *IN VITRO* PACKAGE STUDIES

Method Development (One-time charge, matrix agnostic, 8 hours)

**Not needed if a part of a larger toxicology package that includes Bioanalytical Method Development*

Method Qualification (Plasma and blood matrices, single species, 8 hours)



ABSORPTION

Bi-Directional Permeability - Human Caco-2 Cells



DISTRIBUTION

Plasma Protein Binding - Rapid Equilibrium Device - Rat, Dog and Human

Red Blood Cell Partitioning - Human Blood

**Additional species available upon request*



METABOLISM/DRUG-DRUG INTERACTION

Metabolic Stability / Intrinsic Clearance in Liver S9 Fraction - Rat, Dog and Human

**Liver Microsomes, Hepatocytes and Hepatocyte Co-Culture models available upon request*

Metabolite Profiling in Liver S9 Fraction - Rat, Dog and Human

**Liver Microsomes, Hepatocytes and Hepatocyte Co-Culture models available upon request*

CYP Inhibition in Human Liver Microsomes (IC₅₀ Shift Design, 7 CYPs)

CYP Reaction Phenotyping - Recombinant Human P450 Enzymes

CYP Induction in Pre-Qualified Plated Human Hepatocytes (3 donors, 3 CYPs, mRNA)

Transporter Inhibition for ABC and SLC Transporters

Transporter Substrate Assessment for ABC Transporters (P-gp and BCRP)

**Substrate Assessment for SLC Transporters available upon request.*



EXCRETION

Single Dose Biliary and Urinary Excretion Pharmacokinetic Study in Sprague Dawley Rats to Assess Clearance Mechanisms (With Optional Metabolite ID)

