

DMPK Services

PharmaLegacy Models and Research Tools

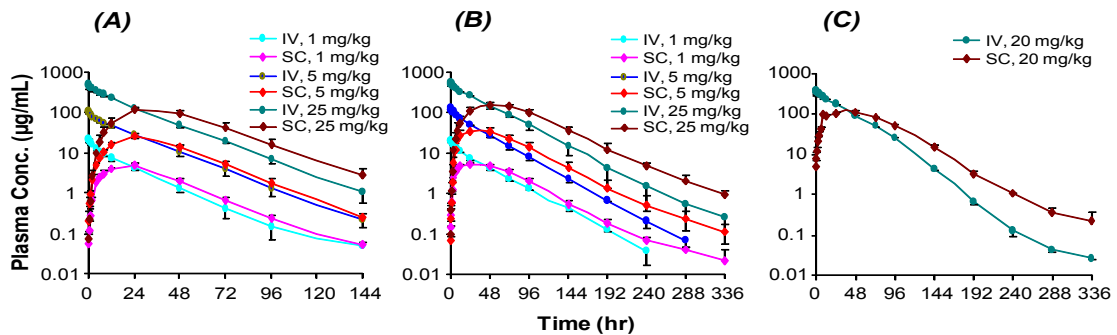
PharmaLegacy can provide a complete complementary PK/ADME service. Our team of DMPK scientists are dedicated to both discovery and development. This coupled with state-of-the-art instrumentation and supported by an AAALAC accredited vivarium, assists our clients from lead candidate selection through development and ensures a high quality of DMPK studies with cost-efficiency and fast turnaround.

Bioanalysis	In Vivo Pharmacokinetics	In Vitro ADME Profiling
Method	In Vivo Dosing	Assay Types
- LC-MS/MS (small molecules, peptides, and protein)	- Intravenous (bolus/infusion)	- Metabolic stability
- HPLC (small molecules and oligonucleotides)	- Oral, subcutaneous, intramuscular, dermal plus other routes	• Test system (microsomes, S9, and hepatocytes)
- ELISA (antibody)	- Intra-duodenal, intra-portal	• Species (rodent, canine, non-human primate and human)
Biological Matrix	Species	- Drug-drug interaction
- Plasma, serum and blood	- Rodent	• CYP inhibition (human liver microsomes)
- Urine, feces and bile	- Canine	• CYP inhibition (recombinant CYP450)
- Tissues and tumor specimens	- Non-human primate	• Phenotyping
- Cerebrospinal fluid	- Rabbit	- Metabolite identification
Services	Outputs	• Test system (microsomes and hepatocytes)
- Method transfer	- Sample concentrations	• Species (rodent, canine, non-human primate and human)
- Method development	- PK parameters (WinNonLin)	- Stability study
- Method validation	Services	• pH buffers
- Sample analysis	- Bioavailability	• Plasma/blood
- Data transformation	- Single and multiple dose PK	- Protein binding
	- Dose ranging and proportionality	• Ultra-filtration
	- Cassette PK for compound screening	• Equilibrium dialysis
	- Drug distribution in tissues	
	- PK study for formulation/ form development	
	- Exploratory non-GLP TK studies	
	- PK/PD study in animal disease models	
	- DMPK study for IND filing	



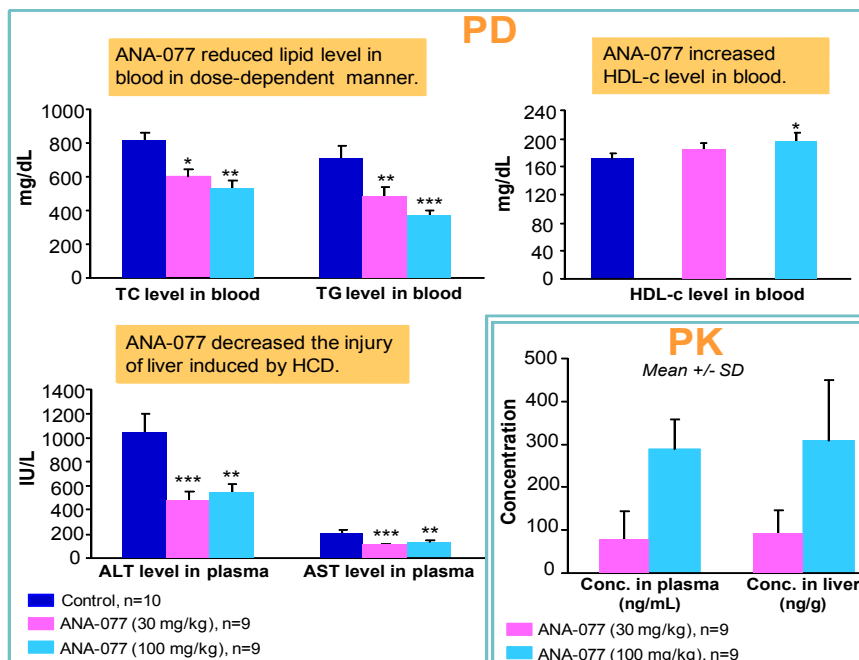
Case Study 1 - PK Profiling in Rodent, Non-human Primate and Canine

PK profiling of ANA-088 in SD rats (n=5, A), cynomolgus monkeys (n=3, B) and beagle dogs (n=3, C) after a single dose



Case Study 2 - PK-PD Study in Hamster

PK-PD study of ANA-077 on high cholesterol diet-induced hyperlipidemia in hamsters



Note:

All values in PD: Mean +/- SEM; HCD, high cholesterol diet; TC, total cholesterol; TG, triglyceride; HDL-c, HDL-bound cholesterol.

About PharmaLegacy Services

- World-class quality with increased speed and output at competitive cost.
- International GLP and QA-based operation.
- Electronic data management system (BioBook) for quality execution and maximum IP protection.
- AAALAC accredited large capacity to house over 10,000 animals under SPF and conventional conditions.
- Availability of 4,000 non-human primates for research use.