



Preclinical Technologies

FACTSHEET



ADME Studies

Aptuit provides drug development services to pharmaceutical and biotechnology companies worldwide. Our development services are based upon state-of-the-art facilities and timely delivery of quality data. A wealth of experience allows Aptuit to help you define the best strategy for the development of your compound. All of this is driven by your ultimate goal – getting to market faster.

Aptuit In Vivo Metabolism group offers a comprehensive range of studies to support regulatory submissions. Our Study Directors can use their expertise and experience to help you understand the in vivo characteristics and metabolic fate of your compound.

Our service portfolio includes:

Excretion Mass Balance Studies

Studies in rodent, rabbit, dog and primate with total radioactivity levels measured in urine, feces, bile, plasma, whole blood, carcass, expired air and in the milk of lactating animals.

Pharmacokinetics

Studies in rodent, rabbit, dog and primate following radiolabelled (and non-radiolabelled) dose administration. Comparison of plasma parent drug and radioactivity concentration time profiles provide information on drug absorption, bioavailability, elimination and in conjunction with metabolite profiling, the degree of drug metabolism.

Tissue Distribution

Conventional QTD and QWBPI.

Surgical Models

Our surgical expertise allows Aptuit to offer validated models for Hepatic Portal Vein Cannulation (rat only), Bile Duct Cannulation, Vascular Cannulation (rat and dog), Brain Perfusion (rat and mouse), Enterohepatic Recirculation and Intestinal Access Model (rat, mouse and dog).

New surgical models can also be transferred in, or developed in response to specific requests.

Routes of Administration

PO, IV, SC, IP, IM, ICV, Intrathecal, Intratracheal and Intrapulmonary routes of administration.

Radio-Isotopes

Studies carried out with a range of radiolabelled test compounds including ^{14}C , ^3H , ^{125}I , ^{35}S .

Human Radiolabelled Trials

Carried out in collaboration with a Phase I unit, including the provision of dosimetry data and full ARSAC submission.

Metabolite Profiling and ID

Samples from excretion balance and pharmacokinetic studies (animal and human) may be used for metabolite profiling and identification.

Additional Aptuit Capabilities

Aptuit offers a comprehensive suite of drug development services that range from candidate selection through to market, including consultancy services, API development and manufacture, preclinical and clinical technologies, pharmaceutical services, large and small scale manufacturing, IVRS, and clinical packaging and logistics, across a wide range of compounds, dosage forms and delivery systems.

For information about Aptuit's services, please call or email:

+1 816 767 3900 North America

+44 131 451 2451 Europe

email: info@aptuit.com

or visit our website: www.aptuit.com

Engineering a better drug development process.