



Preclinical Technologies

FACTSHEET



Radioanalysis Support of Clinical Mass Balance ADME Studies

A vital component to the understanding of safety and efficacy results in clinical development is the analysis of metabolism in human subjects. Although small in scope, a human metabolism study yields vital information which can assist in the interpretation of pharmacokinetic and pharmacodynamic data, provide insight into drug-drug interaction likelihood, as well as to help identify potentially toxic metabolites formed.

Aptuit's Radioanalysis Group provides the core services required for clinical mass balance ADME studies.

- Integrated with analytics group to provide drug content determination of Dosing Solutions or Tablets
- Validation of analyte recovery and sensitivity measurements for all matrices
- FDA inspection in August 2003
- 24 hour turnaround times for analysis of samples (clinical subject release within 24-48 hours of specimen collection)
- Watson® LIMS tracking of all specimens; samples remain within one facility for all analyses
- Validated data capture and concentration calculation system (DEBRA® Interface)
- Integrated with metabolite profiling and identification group
- Radioactive dose confirmation analysis

Aptuit offers a full service approach for the conduct of human metabolism studies in order to avoid delays and issues encountered when multiple vendors are involved.

- Nonclinical ADME studies and dosimetry calculations
- Regulatory support
- Formulation development
- Preparation and packaging of clinical dosage form
- Drug product analysis
- Bioanalysis of clinical pharmacokinetic samples
- Metabolite profiling and identification
- Pharmacokinetic analysis and report writing

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.

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Engineering a better drug development process.