

QPS

helps you navigate

Have all of your
Radiolabelled ADME studies
performed at QPS

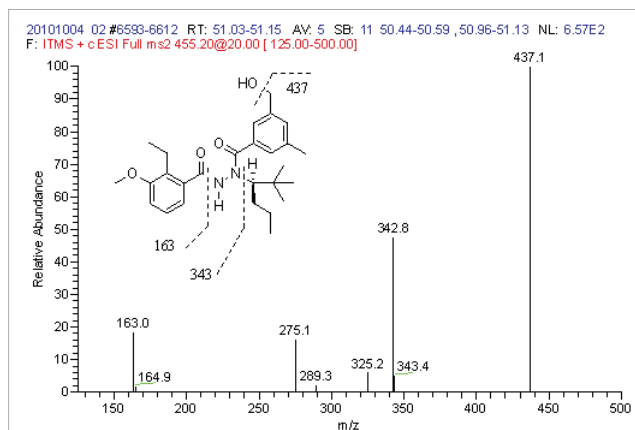
*Saves you time.
Saves you money.
Saves you resources.*



A well-conceived and executed preclinical and clinical radiolabelled ADME program will provide you with a detailed assessment of the total fate (mass balance, route and rate of excretion, tissue distribution, metabolic pathways, and identity and quantity of metabolites) of your drug candidate to support regulatory submissions.

Preclinical Radiolabelled ADME studies:

- ❑ Mass Balance/Routes of Excretion
- ❑ Placental/Milk Transfer
- ❑ Quantitative Whole-Body Autoradiography (QWBA)
- ❑ Microautoradiography (MARG)
- ❑ Plasma Protein Binding; RBC/Plasma Distribution
- ❑ Assessment of Covalent Binding
- ❑ In vitro Species Comparison of Metabolism
- ❑ Metabolic Reaction Phenotyping
- ❑ Metabolite Profiling, Identification & Radioquantification



Human Radiolabelled ADME studies:

- ❑ Consultation and Preparation of Clinical Study Protocol; including determination of human radiation dosimetry estimates on the basis of recommendations by MIRD, ICRP and/or the Sponsor

- ❑ Ethics Committee & Competent Authority Submission
- ❑ Preparation and Release of Radiolabelled IMP According to GMP Annex 13 by a Licensed Radio-pharmacy; including homogeneity and assessment of radio-Purity of the IMP in formulation by HPLC-radio flow-through detection prior to dispensing
- ❑ Drug Administration of Radiolabelled IMP by a Designated and Radio-licensed Research Physician
- ❑ Flawless Execution of Study According to Protocol
- ❑ Collection, Processing, and Analysis of Radioactive Human Blood, Plasma, and Excreta (urine, feces, and expired air.)
- ❑ Metabolite Profiling, Identification & Radio quantification
- ❑ Preparation and Submission of an Integrated Clinical Study Report(CSR)

QPS is a True Turnkey ADME Study Provider that Effectively Execute Your Radiolabelled Studies

- ❑ By Placing your studies with QPS, you will benefit from peer-to-peer communication with our expert ADME scientists who have extensive industry and CRO experience enabling optimal planning and execution of your studies.
- ❑ A senior technical professional will be assigned to facilitate the rapid development of your drug candidate by shepherding the compound through the various preclinical studies to your clinical ADME studies
- ❑ Any compound specific and/or sample handling procedures will be seamlessly transferred between QPS preclinical and clinical teams to minimize delays at the different stages of drug development which ensures rapid generation and rigorous analysis of preclinical and clinical ADME data resulting in high quality regulatory-filing ready study reports