

Radiolabelled Services for Animal Health Products

Pharmaron provides industry leading GLP radiolabelled services to our animal health partners. We offer a comprehensive range of *in vivo* metabolism studies in both food-producing and laboratory animals and *in vitro* species comparison.

We provide a full environmental risk assessment service offering all studies required for Phase I, IIa and IIb assessments together with regulatory consultancy and program management, if required. Our metabolism and environmental fate studies can be integrated with the radiosynthesis of test materials.

Capabilities

- Custom Radiosynthesis of ^{14}C and ^3H Compounds
- GLP Certificates of Analysis
- Food-producing Animal Metabolism
- Laboratory Animal Metabolism
- Dermal Penetration
- Cross-species Comparative Metabolism
 - $^{14}\text{C}/^3\text{H}$
 - Non-labelled
- Environmental Risk Assessment (ERA)
- Metabolite Profiling and Identification
- Chiral Analysis
- Program Management

Services

in vivo Animal Metabolism

- VICH GL46 - Nature of Residue in Food-producing Animals
- VICH GL47 - Comparative Metabolism in Laboratory Animals
- VICH GL48 - Marker Residue Depletion
- VICH GL49 - Validation of Analytical Method

in vitro Comparative Metabolism

- VICH GL47 - Comparative Metabolism in Laboratory Animals

Dermal Penetration

- OECD 427 - Skin Absorption: *in vivo* Model
- OECD 428 - Skin Absorption: *in vitro* Method

Environmental Risk Assessment Tier I, IIa & IIb

- EMEA 2009: EMEA/CVMP/ERA/418282/2005-Rev.1
- CVM 21 CFR*25.40 (a)
 - Environmental Fate (OECD 106, 307, 308)
 - Physical Chemistry (OECD 107, 117, 121, 123, 112)
 - Aquatic Ecotoxicology (OECD 201, 202, 203)
 - Terrestrial Ecotoxicology (OECD 208, 222, 232)
 - Biodegradation (OECD 216)
 - Regulatory Consultancy