eurofins | BioPharma Product Testing

Custom and cGMP Radiolabeling

Tracking how drugs are metabolized in the body is a challenging yet crucial aspect of developing a new drug. One of the most reliable and accepted ways is to create a "radiolabeled" version of the drug. This process involved replacing one of the atoms of the drug with a radioactive form of the atom. The radioactive atom essentially then functions like a GPS tag, allowing scientists to track not only where in the body does the drug go but how it behaves.

Custom Radiolabeling Syntheses

Whether you need radiolabeled compounds for use in pre-clinical and clinical metabolism studies, for environmental fate studies, or to support your R&D research program, Eurofins BioPharma Product Testing offers world-class services combined with a proven 30+ year track record. Our synthesis team brings unparalleled expertise to custom radiolabeling synthesis for the production of research grade, GLP certified, or cGMP material for your specific needs. We have extensive experience with multi-step/complex synthetic reaction schemes and a dedicated radiolabeled analytical testing team, which ensure on-time delivery of your material.

cGMP Radiolabeling

Few contract research laboratories maintain the rigorous cGMP-compliant environment required to manufacture certified radiolabeled APIs suitable for human clinical trials. We maintain four cGMP synthesis suites, a dedicated Quality Assurance staff, and a group of analytical chemists with decades of experience supporting cGMP programs. We are able to provide 14C or 3H labeling (or radio-isotopes available upon request) and are licensed to handle DEA scheduled II-V material.

Effective, timely, and quality production of radiolabeled CTMs requires radiochemistry expertise and rigorous cGMP-compliant facilities, processes and systems. Once synthesized, radiolabeled drugs often exhibit different stability and impurity profiles, and to ensure the validity of studies, these variances must be understood. These and other issues present special challenges related to cGMP compliance and patient safety during the clinical trial. Our expert team will work with you to understand your needs and expectations and design the custom program appropriate to your specific requirements.

Let us show you how to expedite the path to your next development milestone using expertly radiolabeled compounds.

Why Choose Eurofins BioPharma Product Testing?

We have decades of proven experience delivering high quality materials on time.

We work with you to design the program to meet your companies' specific needs and expectations.

We have a dedicated analytical team who specialize in method development, transfer, validation, stability testing and release testing of radiolabeled materials.

We have four dedicated cGMP synthesis suites with capacity to meet your project needs.

Our cGMP radiolabeling facility and systems have been audited by the FDA for cGMP compliance.

We have a world-class staff who have produced hundreds of cGMP radiolabeled materials.

Additional Services:

GLP Certification: Don't require cGMP? Do you need GLP certified radiolabeled materials to support pre-clinical studies or environmental fate studies? Then Eurofins BPT has a solution for you.

Stable Labeled Materials/Standards: Do you need a 13C or 2H labeled material or reference standard with GLP certification? We are able to help.

Comprehensive GMP Testing Services

Method Development & Validation • Release Testing • Raw Materials Testing
Cell Banking Services • Virology Services • Facility & Process Validation
Chemistry • Biochemistry • Molecular & Cell Biology • Microbiology
Stability Testing & Storage • Primary & Secondary Package Testing

Flexible Service Models

Fee For Service (FFS)
Full-Time-Equivalent (FTE)
PSS Insourcing Solutions®

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