

Radiosynthesis

Ricerca Biosciences' Radiosynthesis group has experience in labeling compounds to support your *in vitro* and *in vivo* DMPK studies, as well as your bioanalytical needs. We have the experience necessary to label your molecules, whether with ^{14}C , ^{13}H or stable isotopes (^2H , ^{13}C , ^{15}N), where you need it to best support the development of your lead compounds.

Our specific capabilities

- Non-GMP and cGMP radiosynthesis
- Gas transfer manifold for isotopic labeling using volatile radiochemicals (^{14}CO , $^{14}\text{CH}_3\text{I}$, ^{14}C phosgene, etc.)
- Four dedicated analytical HPLCs with radiodetection capabilities
- GLP characterization with Certificate of Analysis
- Dedicated prep HPLC for obtaining high level purity on radiolabeled materials
- Purification of radiolabeled compounds
- Stable isotope labeled synthesis
- Two dedicated cGMP manufacturing suites for manufacturing ^{14}C GMP APIs with full analytical, QA and QC support
- Separate and dedicated facilities for Pharmaceutical and AgChem projects
- Small scale ^{14}C polymer synthesis
- Seven radiochemists (5 Ph.D.s.) each with more than 5 years of experience in labeled compound synthesis
- Storage stability studies and Global Distribution



Gas transfer manifold



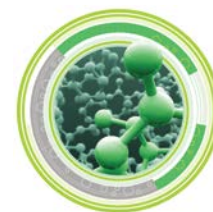
Prep HPLC

Core chemistry services

- Analytical chemistry
- Process chemistry
- Process development & engineering
- API manufacturing

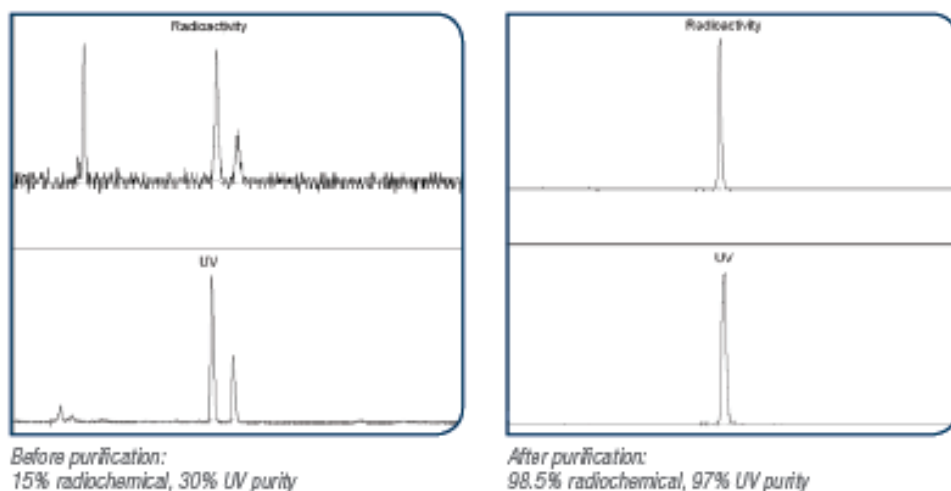
Related services

- Analytical method development and validation
- In-process support
- Dissolution testing
- Microbiology
- DMPK
- Degradant & impurity identification
- Toxicology & pharmacology
- Regulatory support



Radiosynthesis

Example of the high purity achievable through a successful prep HPLC purification



Ricerca Biosciences: Your research partner of choice

Ricerca Biosciences, a contract drug development organization, provides science-based services to the pharmaceutical, biotech, and specialty chemical industries for the development and commercialization of new innovative products. Ricerca's 260,000 ft² complex is located on a 43-acre site in Concord, Ohio. The facility is equipped with a full complement of well-maintained instrumentation and processing equipment operated in rigorous regulatory compliance to the highest quality standards.

Metabolic stability

- LC-MS/MS method development
- Metabolite profiling
- Metabolite identification
- Mass balance
- Tissue distribution
- Pharmacokinetic studies

Other Ricerca services

- IND-enabling drug safety studies
- CMC development programs
 - Synthesis and production of lead molecules
 - Pilot synthesis
 - Process improvement
 - Stability studies
 - Forced degradation
 - Polymorph characterizations