

Manufacture of ^{14}C Radiolabelled Drug Substances and Drug Products for Clinical Studies

Pharmaron provides unparalleled expertise in the manufacture of ^{14}C radiolabelled clinical trial materials, both ^{14}C -APIs (drug substance) and ^{14}C -IMPs (drug product). Our state-of-the-art radiosynthesis facilities has GMP-compliant laboratories for the preparation, analysis and release of radiolabelled compounds for use in clinical studies.

Capabilities

- ^{14}C Small Molecules
- ^{14}C Intermediates/Reagents
- ^{14}C Peptides/Proteins
- ^{14}C Oligonucleotides
- ^{14}C Polymers
- GMP ^{14}C Drug Substance/ QA Release
- GMP ^{14}C Drug Product/ QP Release
- GMP ^{14}C Re-purification
- Clinical-grade Re-purification (non-GMP)
- Covalent ^{14}C Radio-tagging
- GMP ^{14}C Oral Drug Formulations: Solutions, Suspensions, Solids for Reconstitution, Hard Shell Capsules, Formulations with Radiolabelled, Stable-labelled or Non-labelled

Services

- Consultation on synthesis routes, label position, specific activity and product specification
- Dedicated project team of chemists
- Dedicated GMP compliant QC analytical laboratories
- Capacity to manufacture seven ^{14}C -APIs and/or ^{14}C -IMPs in parallel
- Comprehensive analytical capabilities: LC-MS/MS, HRMS, HP(UP)LC, NMR, GC, FT-IR, DSC, TGA, KF
- Regulatory documentation
- Controlled procedures, verified cleaning of manufacturing suites, environmental monitoring
- Quarantine and identity testing of raw materials for GMP manufacture
- Full QA audit and project sign-off prior to release of ^{14}C -API and/or ^{14}C -IMP
- Re-purification of ^{14}C radiolabelled API to provide clinical-grade material for use in human ^{14}C microtracer studies
- Successful UK MHRA GMP audits (^{14}C -APIs / ^{14}C -IMPs)
- Worldwide shipping

Specialties

- Complex ^{14}C molecules including volatile compounds, aromatics, heterocyclics, chiral compounds
- ^{14}C peptides (via solution chemistry and/or auto-synthesizer)
- ^{14}C proteins (including fermentations)
- ^{14}C biomolecules via fermentation (Class 2 containment/Class 1 GMOs)
- ^{14}C covalent radiolabeling methods for macromolecules (RadioTag)