ALMAC

Partnering to Advance Human Health

^{14}C RADIOLABELLING

- non-GMP & GMP stable & radiolabelling expertise
- ^{14}C labelling of drug substance and drug product for human ADME studies
- Stable & radiolabelled metabolite synthesis
- Specialist expertise in peptide, ADC and bioconjugate ^{14}C labelling
- QC, Analytical and QP integration
- MHRA regulatory approved for ^{14}C GMP manufacture of drug substance and drug product

^{14}C **RADIOLABELLING**

OUR ESTABLISHED TRACK RECORD, COUPLED WITH OUR STRONG QUALITY CULTURE, ENSURES OUR INDUSTRY-LEADING ^{14}C LABELLED DRUG SUBSTANCE & DRUG PRODUCT SERVICES WILL MEET YOUR QUALITY, COST AND DELIVERY EXPECTATIONS

Trust Almac with your ^{14}C radiolabelling requirements and we will offer advice on the most appropriate label position for your molecule, including synthetic feasibility and metabolic stability.

Isotopic labelling imposes many synthetic challenges beyond those found in normal chemical synthesis due to the lack of available labelled starting materials. When the isotope is radioactive, this becomes even more demanding.

By working with us, you will have access to expertise in non-GMP and GMP stable and radiolabelling of your **small molecule, peptide, fermentation product, bioconjugate or Antibody Drug Conjugate (ADC).**

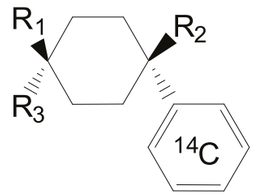
With our expertise in synthesis and purification, and efficient analytical and Quality Control (QC) integration, your labelled product will be manufactured with the correct chemical and isotopic purity and robustly qualified using validated equipment.

OVERVIEW OF CAPABILITIES

- non-GMP and GMP stable labelling
- non-GMP and GMP ^{14}C radiolabelling
- Labelled metabolite synthesis
- Repurification services
- Drug product manufacture (powder/liquid in bottle and capsule formulations)
- Peptide, ADC & bioconjugate labelling
  - non-GMP & GMP synthesis
  - Purification and isolation expertise
- QC & analytical integration
  - Method development
  - Method validation
  - Method transfer
  - Stability studies
  - Storage facilities
- Regulatory approval
  - Onsite Qualified Person (QP) approval
  - ^{14}C Investigational Medicinal Product (IMP) license
  - Medicine & Healthcare products Regulatory Agency (MHRA) issued GMP compliance certificate

CASE STUDIES

CASE STUDY 1 – ^{14}C GMP SMALL MOLECULE MANUFACTURE

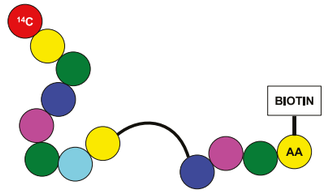


- Our client required kitsets to be used by patients in a trial of ^{14}C drug product

The Almac Solution involved:

- GMP manufacture of the API, release and study completed.
- Drug product manufacture including boxes with inserts, labels, dosing apparatus and QP release

CASE STUDY 2 – ^{14}C SYNTHESIS OF BIOTINYLATED 84MER PEPTIDE

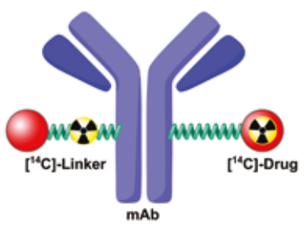


- Our client required 2 mg of ^{14}C labelled peptide

The Almac Solution involved:

- Integration of peptide and radiolabelling teams
- Redesign of the coupling step to minimise loss of expensive labelled amino acid

CASE STUDY 3 – ^{14}C LABELLED ADC MANUFACTURE



- Our client required ^{14}C labelling of the linker technology followed by formation of the ADC

The Almac Solution involved:

- Integration of biology, purification and radiolabelling teams
- Prep-HPLC, HIC chromatography and ultrafiltration purification expertise

CASE STUDY 4 – ^{13}C LABELLED METABOLITE SYNTHESIS

- Our client required 10g of ^{13}C labelled metabolite

The Almac Solution involved:

- Integration of biocatalysis and radiolabelling teams
- Identification, cloning and expression of an active P450 enzyme for selective oxidation of the ^{13}C-API to yield the ^{13}C-metabolite

SUPPORTING CAPABILITIES

OUR REPUTATION PRECEDES US IN **OFFERING CLIENTS SAVINGS IN BOTH TIME AND COST** THROUGH OUR INTEGRATED OFFERING

PHYSICAL SCIENCES

Our colleagues in Almac's Physical Sciences team provide us with a comprehensive physical characterisation service for stable and radio-labelled materials, as well as providing expertise on crystallisation and formulation issues when required.

CLINICAL TRIAL SUPPLY

Almac are market leaders in the supply of clinical trial materials, and we draw on this extensive experience for the manufacture, packaging and labelling of stable and radiolabelled drug products.

VALIDATED SHIPPING

Labelled materials are valuable and shipments are frequently sensitive to both time and temperature. Almac's dedicated dispatch department are experienced in working with couriers, brokers and receiving companies to ensure your material arrives on time and in the same quality it left our doors.

All our clients have unique needs.
That's why we develop unique solutions.

This is the ALMAC TOUCH™

GET IN TOUCH

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