ALMAC

Partnering to Advance Human Health

Brochure

# Think Almac...
# $^{14}$C Radiolabelling

- Non-GMP & GMP stable & radiolabelling expertise
- $^{14}$C labelling of drug substance for human AME studies
- Stable & radiolabelled metabolite synthesis
- Specialist expertise in peptide & bioconjugate $^{14}$C labelling
- QC, Analytical & QA integration
- MHRA regulatory approved for $^{14}$C GMP manufacture of drug substance

# Radiochemical highlights

- Radiochemical purity
- Chemical purity / assay
- Water content by KF
- XRPD analysis
- Peptide synthesis
- HIC chromatography
- Freeze drying
- Ultrafiltration & diafiltration
- Radionuclide purity
- Specific activity radioactive concentration by gravimetric determination
- Concentration by gravimetric determination
- Polymorph control
- Particle size analysis
- Residual solvent by GC
- Identity testing by MS / NMR
- Semi preparative HPLC
- Isotopic purity by MS

# $^{14}C$ Radiolabelling

Our established track record coupled with our strong quality culture, ensures our industry leading $^{14}C$ labelled drug substance provision will meet your quality, cost and delivery expectations.

Think Almac for 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.

Working with us provides access to a wide range of expertise allowing the successful synthesis of your small molecule, peptide, fermentation product or bioconjugate with a stable or $^{14}C$ radiolabel incorporated.

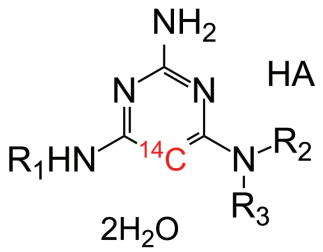
With our expertise in synthesis and purification, and efficient analytical and Quality Control (QC ) integration, your labelled product will be manufactured with the correct chemical and isotopic purity and robustly qualified using validated equipment.

## Overview of capabilities

- Non-GMP & GMP stable labelling
- Non-GMP & GMP $^{14}C$ radiolabelling
- Labelled metabolite synthesis
- Peptide, Peptide Drug Conjugate (PDC) & bioconjugate labelling
  - Non-GMP & GMP synthesis
  - Purification & isolation expertise
- QC & analytical integration
  - Method development
  - Method validation
  - Method transfer
  - Stability studies
  - Storage facilities
- Regulatory approval
  - Onsite Qualified Person (QP) approval
  - Medicine & Healthcare products Regulatory Agency (MHRA) issued GMP compliance certificate

# Case Studies

## Case Study 1 – $^{14}C$ GMP small molecule manufacture



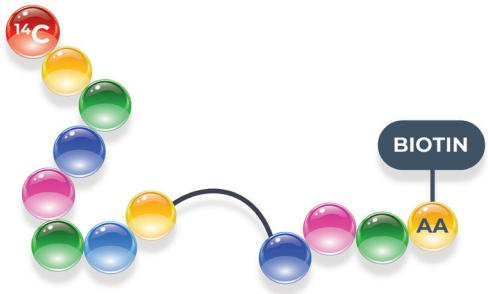

Form A dihydrate

Our client required 3 mCi [$^{14}C$]-Drug substance as Form A (dihydrate)

### The Almac Solution involved:

- GMP manufacture of the API, release analysis and completion of a stability study
- Desired polymorph was isolated via controlled crystallisation, drying, milling and controlled hydration
- Physical form of drug substance was confirmed by X-ray powder diffraction (XRPD)

## Case Study 2 – $^{14}C$ synthesis of biotinylated 84mer peptide

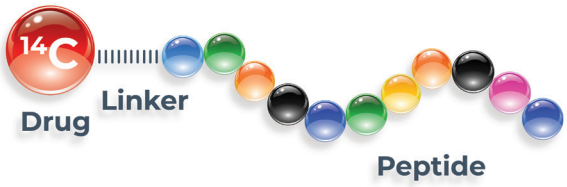



Our client required 2 mg of $^{14}C$ labelled peptide

### 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 PDC manufacture

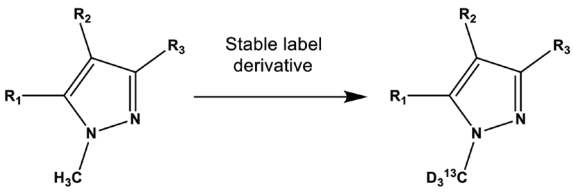



Our client required $^{14}C$ labelling of the linker technology followed by formation of the PDC

### The Almac Solution involved:

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

## Case Study 4 – $^{13}CD_3$ labelling




Our client required 250 mg of $^{13}CD_3$ labelled material

### The Almac Solution involved:

- Non-GMP synthesis of stable labelled product
- Prep HPLC purification expertise
- Isotopic purity determination by Mass Spectrometry to determine levels of isotopomers / unlabelled material

# Think Almac for supporting services

Our reputation for offering clients savings in both time and cost through our integrated offering precedes us.

## Physical Sciences

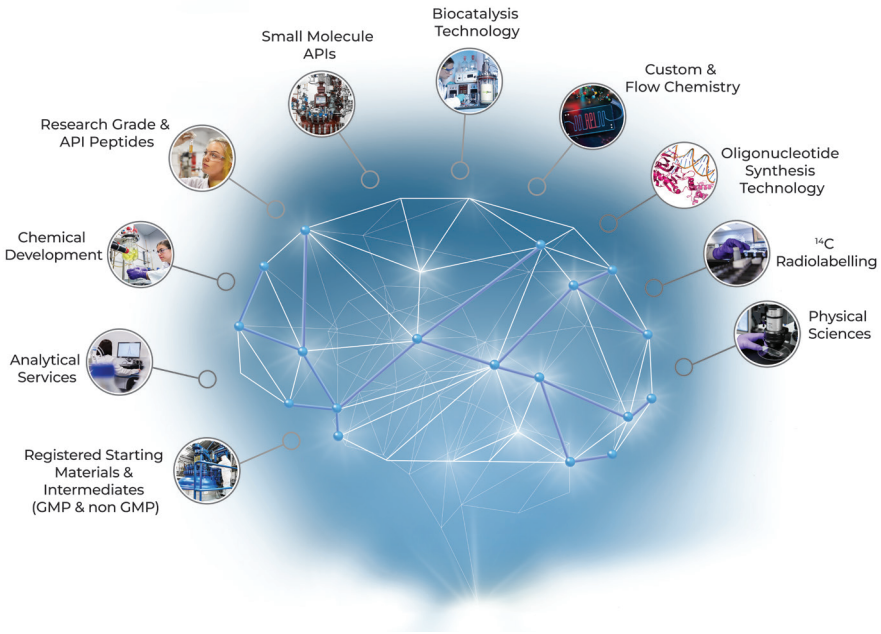
Our colleagues in Almac's Physical Sciences team provide us with a comprehensive physical characterisation service for stable and radio-labelled materials, as well as providing expertise on crystallisation issues, when required.

## Clinical Trial Supply

Almac is a market leader 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 substance.

## Validated Shipping

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




## Supporting Services

Almac's supporting services have the added advantage of working closely with a number of other teams to give our client access to a wide range of expertise to aid the successful deployment of supporting programs

almacgroup.com

## Get in touch


**Global HQ**
+44 28 3833 2200

**US HQ**
+1 215 660 8500

**Athlone, Ireland**
+353 90 646 0200

sciences@almacgroup.com


© Almac Group Ltd. All rights reserved AM2145