Think Almac...
Global Analytical Services

- Highly skilled analysts working in cGMP environments
- Fully cGMP certified facilities in EU, UK & US
- Supporting drug substance & drug product analytics across all phases, from early phase pre-clinical / clinical development to commercial release
- Offering a full suite of analytical testing for a range of product types including small molecules, peptides, biologics, conjugates, potent & controlled substances

Analytical services

Drawing upon our vast pool of scientific knowledge, we greatly reduce the analytical challenges that typically arise during drug development.

Method Development & Validation

Almac develops >750 analytical methods each year in our chromatographic, spectroscopic and microbiology teams. Providing analytical development services from first principles, pharmacopoeial, or client suppled methods, we deliver efficient efficient, accurate, reliable and robust analytical methods.

Our validation team has extensive experience across all clinical phases and offers a bespoke approach to ensure methods meet regulatory requirements. We follow relevant ICH guidelines such as ICH Q2(R1) or compendial guidance in combination with client-specific protocols, and provide comprehensive validation reports.

Analytical methods are routinely transferred into and out of our labs. Our team facilitates both comparative testing and limited validation exercises for a range of test methods.

Release testing

Almac supports the commercial release of drug product from our 3 global sites and can leverage efficiencies between the sites to allow for local release into a number of markets.

Almac routinely works on filed methods and is named as the commercial release lab on a number of licences.

We also support reference standard management for a library of standards and impurities across a catalogue of drug products. *(figure. 1)*

Reference Standard Management

figure 1.

Management of analytical methods

Method development / optimisation

Our dedicated team supervises ~2,000 stability programmes. From early phase material to validation and commercial batches, all conditions are continually monitored and employ back-up systems to ensure a secure and controlled environment.

Our European and US state-of-the-art, walk-in stability chambers provide 300m^3 of ICH-compliant, climatic storage facilities for all of your requirements ***(figure 2).***

-80°C & -20°C freezers	5°C refrigerated storage
25°C/60%RH long term stability storage	30°C/65%RH intermediate stability storage
30°C/75%RH climate zone IV	40°C/75%RH accelerated stability storage
Photo-stability	

figure 2.

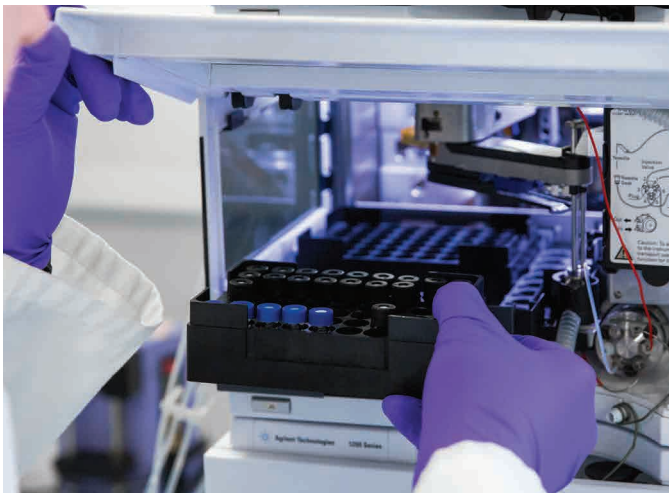
Spectroscopy services

With a wide range of sophisticated MS and NMR instruments, Almac routinely supports identification of unknowns, genotoxic impurities, elemental impurities and other requirements, often with expediated turnaround. Almac's specialist team has over 20 years' experience in solving clients' problems.

Our scientists are highly experienced in the development of high quality assays using state-of-the-art LC-MS/MS technology – including an Orbitrap Q-exactive high resolution instrument with applications across a range of molecular weight compounds.

This specialist analyst software is compliant with FDA 21 CFR Part 11.

Almac has two fully cGMP 500 MHz instruments equipped with state-of-the-art cryoprobe technology for interrogation of a range of nuclei. These instruments also offer the additional option of assay by NMR as a powerful alternative to HPLC.



Analytical support for clinical trial supplies

With >15 years' experience in providing analytical support to clinical packaging operations, our services include:

- Comparative dissolution testing
- Stability studies
- Identity testing
- Absence of active testing (placebo)

Clients who use Almac to release drug substance and drug product in the EU & US benefit from shortened transfer time, cost savings and minimised disruption thanks to scientific and procedural continuity. We are unmatched in our ability to manufacture clinical trial supplies, and provide analytical support.

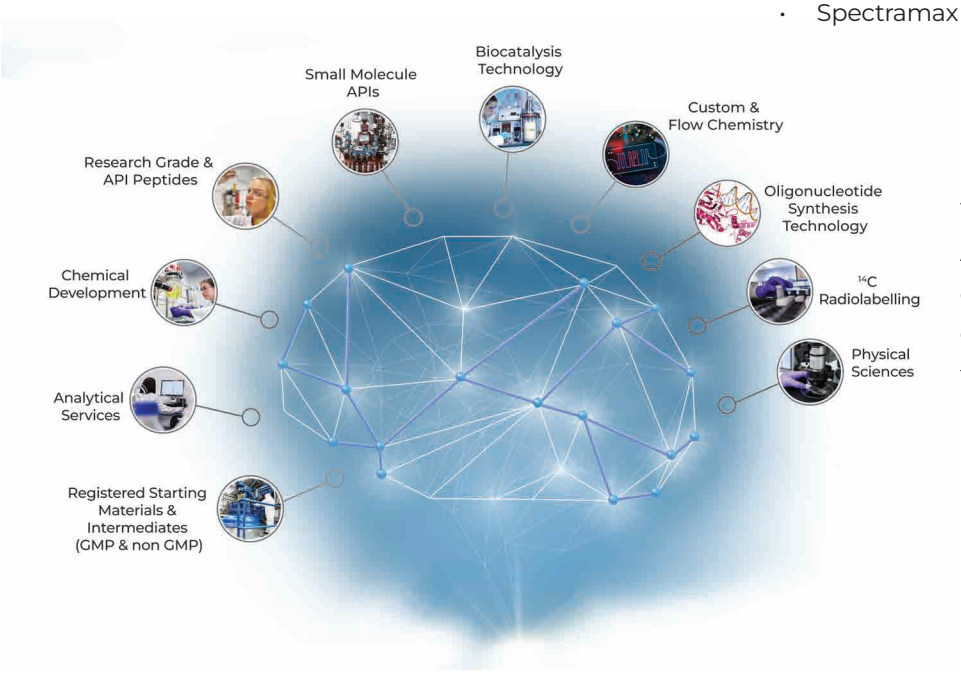
Think Almac for analytical services

Communication and scientific continuity are key, whether your analytical requirments are stand-alone or form part of a drug development or commercial manufacture project.

Our analytical scientists work with drug substance and drug product formulation scientists forming an integral part of the project team. This means they can share data, easily coordinate planning and scheduling to deliver maximum efficiency.

Equipment Capabilities

- Chromatography (HPLC, U(H)PLC)
- Dissolution (USP apparatus 1 & 2)
- Gas chromatography (headspace & direct injection)
- Gas chromatography – mass spectrometry
- Liquid chromatography – mass spectrometry (high resolution, ToF, QQQ & tandem)
- Inductively coupled plasma – mass spectrometry (ICP-MS)
- Ion chromatography
- Nuclear magnetic resonance (H, C, F & P probes)
- Optical microscopy
- Particle size analysis (wet & dry dispersion)
- X-ray powder diffraction
- Water content
- Ultraviolet-visible spectroscopy
- Thermo gravimetric analysis
- Differential scanning calorimetry
- Polarimetry
- Atomic absorption spectroscopy
- Autotitrator
- Capillary electrophoresis
- Dynamic vapour sorption
- Fourier transform infrared spectroscopy
- Hyper differential scanning calorimetry
- Biorad - gel electrophoresis
- Spectramax - bioassay, wallac, gamma counter



Analytical Services

Almac's analytical labs 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 analytical programmes

almacgroup.com

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