ALMAC

Partnering to Advance Human Health

Analytical Services

- Highly skilled analysts working in GMP / GLP environments
- Fully cGMP certified facilities in UK, Europe & US, including Ireland's only accredited GLP lab
- Supporting drug substance & drug product analytics across all phases, from clinical development into commercial release
- Offering a full suite of analytical testing for a range of product types including small molecules, peptides, biologics, conjugates, potent and controlled substances

Analytical Services

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

Chemistry testing

Almac provide a range of GMP chemical testing on drug substance (API) and excipients. We have an extensive team focused on the development, validation and execution of advanced cGMP analytical methods that range from routine tests to highly complex programmes.

Our in-depth technical expertise combined with our most advanced analytical instrumentation delivers fast and reliable results. Our testing is in line with ICH Q6A & ICH Q6B guidelines.

Chemistry testing services

- Pharmacopoeial / raw material analysis
- Drug product release testing
- Method development & validation
- Residual solvent analysis
- Validation of cleaning products
- Elemental impurities analysis
- Comparative testing
- Drug product dissolution testing
- Stability testing and storage
- Investigative analysis
- Physicochemical characterisation techniques (mass spectrometry, NMR, XRPD, particle size, TGA, DSC, DVS)
- Medical device support

Microbiology testing services

- USP, EP, BP methods
- Microbial limits testing and validation
- Disinfectant efficacy testing
- Preservative efficacy testing
- Endotoxin testing gel clot method
- Growth promotion testing of cultured media
- Incubation of environmental monitoring samples
- Bioburden validation and analysis
- Specialist microbiology services for medical device industry
- Identification of bacterial cultures using phenotypic method
- Sterility testing on biological indicator strips ampoules
- Testing of purified, potable and in-process water systems

Biopharmaceutical testing services

- Structural characterisation and confirmation
- Physiochemical properties
- Process-related impurities
- Product-related impurities
- Biosimilar comparability studies
- Immunochemistry/ELISA
- Potency testing
- QC release testing of biopharmaceutical products
- Raw material testing

Bioanalysis services

Ireland's only GLP certified laboratory employing 4 study directors with >20 years' experience in the field. Our lab has >250 validated bioanalytical methods with the capability to develop and validate methods for NCEs in all therapeutic areas - on small molecule, peptide and biologic drugs.

- Mass spectrometry
- Immunochemistry
- Bioanalysis in multiple matrices
- Non GLP drug discovery
- Pre-clinical toxicokinetic analysis
- Bioavailability & bioequivalence studies
- Preclinical, Phase 1-4 support
- Biomarker analysis

Pharmacokinetics services

- Non-compartmental and compartmental pharmacokinetic analysis
- Bioavailability and bioequivalence studies
- Preclinical toxicokinetic analysis
- PK/TK study design, protocol development and drug disposition consultancy
- Guidance on scaling from animals to humans
- In Vitro in vivo correlations

Stability testing & storage

At any given time, our dedicated team may supervise as many as 250 or more 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 1.)*.

-80°C and -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 1.

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
- Identify testing
- Absence testing

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.

Why choose Almac for analytical services?

Communication and scientific continuity are key, whether your analytical requirements 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 and 2)
- Gas chromatography (headspace)
- Gas chromatography – mass spectrometry
- Liquid chromatography – mass spectrometry (high resolution, ToF and QQQ)
- Inductively coupled plasma – mass spectrometry (ICP-MS)
- Ion chromatography
- Nuclear magnetic resonance (H, C, F and P probes)
- Optical microscopy
- Particle size analysis (wet and 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

Get in touch

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