ALMAC

Partnering to Advance Human Health

# Pharmaceutical Development

- Specialising in solid oral dose formulations
- 300,000ft$^2$ of drug product development footprint
- Multiple containment strategies for highly potent materials


# Pharmaceutical Development

- Dedicated non-GMP facilities supporting enhanced speed and flexibility to the formulation and process development phase
- Scalable solutions using the same operating principles, enabling a seamless transition between non-GMP and GMP phases
- GMP manufacturing of clinical trial material from Phase I-III and onwards to registration batch manufacture
- Analytical method development and validation, stability, microbiological, and release testing
- Available GMP footprint for product commercialisation, post development

Our drug product development service spans early to late phase clinical programs, offering technical expertise, dedicated project management, and a track record of on-time delivery from state-of-the-art facilities.

### Drug Product Development

Almac operates non-GMP and GMP facilities, allowing for seamless transition between formulation and process development, and clinical trial material manufacturing. We specialise in the following solid oral dose formulations with batch sizes ranging from grams to 100 kilograms.

- API in capsules or bottles, including micro-dosing
- Formulated blends in capsules or bottles
- Coated tablets and mini-tablets
- Multi-particulates: granules, beads/pellets
- Sachets and stickpacks
- Immediate and modified release
- Fixed dose combination products



# Early and Late Stage Development

### Technical Capabilities

Almac has a demonstrated track record of advancing pharmaceutical products from development into commercial phases. Our Technical, Quality, Safety, Regulatory and Project Management teams routinely support the following activities:

- High potency API processing
- Analytical method development and validation or method transfer
- Excipient compatibility studies
- Formulation/process development or technology transfer
- Optimisation and DoE studies
- Risk assessments and scale up
- Registration stability batch manufacture
- Commercial scale process validation manufacture
- Technical support post commercialisation

### Processing Capabilities

Our non-GMP and GMP development facilities have complementary equipment trains and integrated technical teams to facilitate technology transfer. Almac is equipped to deliver drug product using the following unit operations:

- Blending
- Roller compaction
- High shear granulation
- Fluid bed processing
- Tableting
- Coating
- Encapsulation including Xcelodose micro encapsulation
- Sachets/stickpacks
- Blistering and bottling capabilities to support clinical stability programmes

### Analytical

The Pharmaceutical Development team has dedicated analytical resources that support manufacturing activities from early phase development through registration stability and process validation. They provide method development and validation, IPC testing, stability testing, and release analysis of the product. In addition, Almac has in-house microbiological capabilities supporting all phases of development.

### High Potency Processing

Almac processes compounds with OELs as low as 0.05µg/m³/8 hours in non-GMP and GMP facilities. Many of our GMP processing suites are explicitly designed for processing highly potent APIs. Our health and safety approach includes:

- System based evaluation of every API for exposure potential
- Process risk assessment to define containment strategy and PPE
- Mitigation strategies to address potency challenges
- Health-based risk assessments to minimise potential product cross contamination

# From Development to Commercialisation

Our technical teams develop robust formulations and processes that are suitable for scale-up and commercial production. Almac's development and commercial teams work side-by-side, together with our experienced project management teams, to ensure a smooth transition of our clients' products from development to commercialisation into our extensive commercial manufacture and pack network.

# Post Commercialisation

**Paediatrics**

Clients with a commercialised adult dosage form often need a corresponding paediatric dosage form with an easy-to-use packaging format. One paediatric example that Almac has delivered is mini-tablets filled into stickpacks. Almac developed, manufactured and packaged mini-tablets for several clients.

We are accustomed to using tablet presses with multi-tip tooling and packaging equipment with counting systems to precisely meter the number of mini-tablets delivered to each stickpack.

## Get in touch


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