

OUR EXPERTISE IN:

Fluid bed top-spray granulation, blending, tableting and coating

Alkermes Contract Pharma Services, a division of Alkermes Pharma Ireland Ltd, has significant experience in granulation processes to provide you with expert solutions to fulfill your specific manufacturing needs. With more than 40 years of experience manufacturing for global markets at our dedicated site in Ireland, our key focus is to make quality medicines on-time, every-time for our partners.



Glatt GPCG 300 Top Spray Inserts at the Alkermes Athlone, Ireland Site

With our robust process development approach, as well as reliable process scale-up to pilot and commercial scales, we consistently provide reliable and high-quality commercial manufacturing.

Our in-house spray granulation and compression and coating expertise, from pilot to full commercial scale, allows for a successful tech-transfer process into commercial production. We can consistently provide granules with your desired compressibility and product performance characteristics.

Our thorough understanding of the operating parameters involved in fluid bed processing ensures we can resolve challenges that often present at the initial tech-transfer stage. Manufacturing processes can be optimized to mitigate product performance issues, ensuring that consistent manufacturing meets critical quality attributes.

One component of our Operational Excellence culture is that we employ Process Analytical Technology (PAT) as part of our ongoing process improvement activities into tech-transfers. The current focus of our PAT program is to fully characterize all raw material inputs for tech-transfer products.

KEY FEATURES OF THE PROCESS:

- **Robust process development approach**
- **High-speed, best-in-class process equipment**
- **Integrated in-process checker and continuous performance monitoring of tablet press**
- **Multi-floor manufacturing facility allowing through-floor product feed**
- **Vacuum transfer options available**
- **Fully embedded Operational Excellence culture**
- **Top-spray insert capacity of up to 1,275L**

To arrange a meeting to discuss how we can fulfill your manufacturing needs, please use contact details below:

Alkermes Contract Pharma Services

Telephone: +353 90 649 5126 Email: contract@alkermes.com

Key Available Equipment



Fluid Bed Processor – Glatt GPCG 300

- 120 or 300 top-spray inserts (525L or 1,275L capacity)
- Automated recipe control system
- Manual and/or vacuum product loading
- Gravity discharge to IBC via in-line screen/mill
- HEPA filtration
- Dedicated dust collector



Blenders

- IBC tumble blender (various IBC sizes 200L – 2,000L)
- Through-floor or vacuum charging of integrated process control
- In-line milling and screening options
- Automated IBC washstation
- Crossflow blender options



Tablet Presses – Fette P2100 29 Station

- 130,000 tablets/hour
- Integrated checkmaster for IPC
- Integrated datacontroller for continuous process control
- In-line de-duster and metal detector
- Through-floor feed from IBC
- Closed equipment train (IBC to tablet cart)



Tablet Coaters

Glatt 1500 60" Pan:

- Up to 5 spray guns
- Automated recipe control (flow rates, temperature, humidity)
- Wash-in-Place (WIP) system
- Contained gravity charging from IBC/tablet cart
- Inlet and exhaust HEPA filters

Vector 48" Pan:

- Up to 3 spray guns
- WIP system
- Automated recipe control
- Inlet and exhaust HEPA filters



Alkermes Ireland Facility at a Glance

- FDA/EMA licensed
- From scale-up to full-scale manufacturing
- Experience in solid oral dosage form manufacture, including high-potency and difficult-to-make compounds
- Quality by Design (QbD) and PAT solutions
- Multiple products manufactured and/or packaged
- Global markets – supply product to 100+ markets
- EU QP release testing
- Exceptional compliance track record, no major observations, no 483s
- Highly skilled workforce
- Located in a low-tax jurisdiction
- Equipped capacity of 2 billion solid oral dosages annually

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