

OUR EXPERTISE IN:

Fluid bed Wurster bead-coating, layering and encapsulation

Alkermes Contract Pharma Services, a division of Alkermes Pharma Ireland Ltd, has significant experience in bead-coating 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 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 fluid bed coating, layering and encapsulation expertise, from pilot to full scale, allows for a successful tech-transfer process into commercial production. We can consistently provide beads with your desired specifications and product performance characteristics.

Our thorough understanding of the operating parameters involved in fluid bed processing ensures we can resolve challenges, which 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**
- **100% checkweighing of filled capsules, with automated acceptance/rejection**
- **Multi-floor manufacturing facility allowing through-floor product feed**
- **Vacuum transfer options available**
- **Fully embedded Operational Excellence culture**
- **Wurster bowl capacity up to 420L**

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

- 32" Wurster Bottom-Spray Insert with HS technology
- Wurster bowl capacity up to 420L
- Automated recipe control system
- Manual and/or vacuum product loading
- Gravity discharge direct to IBC or via in-line screen/mill
- Wash-In-Place (WIP) system
- HEPA filtration
- Dedicated dust collector



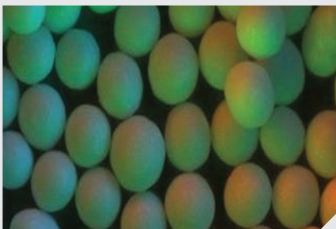
Blenders

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



Encapsulators

- Bosch GKF2000 and GKF2500 ASB 100%:
- Integrated 100% checkweigher
 - Integrated capsule polisher/de-duster
 - In-line metal detector
 - Up to 150,000 capsules/hour
 - Capsule sizes 0, 1, 2, 3, 4
 - Various dosing chamber sizes to meet capsule fill weight requirements
 - Through-floor feed from IBC
 - Closed equipment train (IBC to finished product drum)



On-line Particle Characterization

Eyecon™

- Employs fast imaging for assessing particle size, shape and even surface information
- Measures particle size from 50µm to 3000µm
- Applications include milling, spheronization, granulation and off-line analysis
- Max particle speed: 10m/sec
- Measurement time: 2 sec

Advantages

- Provides actual images of the particles/spheres through non-product contact
- Measures at the wet phase of process, e.g., wet granules or spheres directly after extrusion
- Perfect for tech-transfers as the same device, software and optical system are used in both the bench-top and in-line options

Eyecon™ registered mark of Innopharmlabs



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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