



Alkermes has been manufacturing commercial scale solid oral dosage products for over 45 years. This case study demonstrates a large pharmaceutical contract manufacturing engagement in which there has been five years trouble free supply with OTIF (On-Time-In-Full) consistently >95%. Process improvement initiatives were also delivered, which enabled significant capacity and yield improvements. These improvements resulted in significant cost savings for the partner.

Five Year Trouble Free Manufacturing for Large Pharma Company

Project History

In 2004, we were approached by a large international pharmaceutical company, to supply pharmaceutical contract manufacturing services for a solid oral dosage product. This marked only the second time this large pharmaceutical company sought assistance (pre-launch) from a third party to manufacture a product on its behalf. The Alkermes Athlone Ireland site was chosen as the preferred site to fulfill the expected commercial demands of the product as the launch was being rolled out throughout Europe.

Why the Alkermes Contract Pharma Services, Athlone Ireland plant was chosen?

Alkermes Contract Pharma Services manufacturing plant in Ireland was chosen because the site met the partner's requirements of experience and expertise in solid oral scale-up and manufacturing. The manufacturing capacity afforded by the Athlone facility, together with its excellent compliance record supplying product from an FDA/EMA inspected site, provided the large pharmaceutical company with the assurances it required to outsource its manufacturing requirements. The Athlone plant also had well-established credentials in delivering process improvements for partners. Dozens of products have been successfully manufactured in the Athlone site since the 1970's - the majority of which are solid oral dosage forms.

The Challenge

The immediate challenge was to develop a high yield, robust process to manufacture a multi-coated enteric coat product where other companies had experienced significant problems in aggregation and in functional coat failure. An additional challenge was to deliver a solution quickly as the product had high volume requirements for launch.

Alkermes' Athlone Site

Located on a 40-acre site, with over 220,000 sq. ft. of dedicated cGMP grade facilities, this site has a proven manufacturing track-record with many

products optimized and manufactured for partners in multiple territories. The facility has an equipped annual capacity of 2 billion solid oral doses. The Athlone site is an FDA/EMA inspected facility.

The Result

A number of significant achievements resulted from our involvement in this project. A robust process development and tech transfer process was achieved in significantly less time than the partner's best case time estimate for the project.

- The entire process including equipment build and qualification, and process development took less than 10 months
- Operations moved directly into 24/7 production from validation, immediately achieving a commercial run-rate for this multicoated bead product of >100 batches/annum (up to 340 million doses)
- Process and product improvement initiatives were delivered and/or demonstrated to deliver, with significant capacity and yield improvements achieved
- Combined cycle processing championed by us delivered a capacity increase of 22% - this approach was later implemented in the partner's own facilities
- One process improvement resulted in an increased return on active ingredient. This resulted in a 25% increase in active pharmaceutical ingredient (API) yield per batch - a significant cost saving that was passed on to the partner
- Process scaling achieved through use of process development scale Glatt 5 and 30 equipment enabled further optimization and cycle development away from commercial cGMP and cost constraints associated with large scale processes.

The Athlone plant manufactured at full capacity for more than 5 years consistently delivering OTIF in excess of 95% and ranking at or close to the top of the partner's league table of suppliers.

Over the 5 year period more than 1 billion doses of product were manufactured for this partner.

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

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