



Hosokawa Micron's Nitrogen Purged Milling System with Self Test and SIP meets AstraZeneca demands

A new nitrogen purged milling system for delumping an active pharmaceutical ingredient prior to packaging has recently been supplied to AstraZeneca by Hosokawa Micron Ltd. Designed in conjunction with AstraZeneca engineers to provide integrated and additional safety features and superior cleaning procedures the milling system demonstrates best operating practices for handling potentially explosive fine powder APIs.

The milling process has been introduced to the production line to deliver a homogenous free flowing, lump free product of consistent particle size.

To facilitate the homogenisation of this active pharmaceutical ingredient the system has been designed incorporating a classic homogenisation mill, the Bepex Bexmill. With its low energy, gentle action the Bexmill is ideally suited to handling sensitive products such as pharmaceuticals where a significant temperature rise would be detrimental.

The Bexmill has a single vertical rotor which rotates close to a conical screen mesh and by careful selection of screen mesh size and adjustment of rotor speed lumpy materials can be rendered free flowing and of a consistent particle size. Air flow through the unit is minimal and the product temperature rise insignificant ensuring very gentle size reduction with minimum fines.

The Astra Zeneca material is transferred from a pressure filter dryer into a receiving vessel and then metered into a Hosokawa pharmaceutical design of easy clean Bexmill via a rotary valve. The Bexmill is a slow speed comminution device which is very effective in delumping without product damage.

After milling the product falls into a receiving hopper and is then transferred to the packaging drums using a pharmaceutical design of inclined screw conveyor.

The whole system is operated under a positive pressure of nitrogen and has an integrated self leak test facility. The system is pressurised to 0.1 bar and until the leak integrity test has proved that no leak has been detected and a green light been activated the system cannot start. Once the system has passed the leak test then the milling sequence can commence.

Designed to be easy clean by hand the whole system can be readily stripped down before a final sterilisation in place with compressed air and peracetic acid at 0.1 bar takes place.

AstraZeneca is one of the world's leading pharmaceutical companies manufacturing a powerful range of products designed to fight disease in important areas of medical need; cancer, cardiovascular, central nervous system, gastrointestinal, infection, pain control and respiratory. Their commitment to the well being of their employees is of paramount importance to the company. 'We are always looking at the opportunities for product, process and environmental improvement with our personnel a key factor in the determination of technology both in terms of technical input and health and safety. AstraZeneca has total commitment to meet or exceed legal requirements and international agreements in respect of Health and Safety and Environment and to provide a safe and healthy work environment for all our employees. said Mr. John Sherwood, Associate Principal Scientist, Product Development PR&D at AstraZeneca Macclesfield.

Hosokawa Micron Ltd. was responsible for the complete processing package and worked with AstraZeneca very closely to ensure all the special processing requirements were met.

