

Keep Customers HAPI with System for Flexible R&D Batch Milling and Pack-Off

As the market for more effective and potent drugs grows, the potency of the drugs inevitably increases. The requirement to safeguard and protect both the product and the operators is of paramount importance whilst taking into account the demands for ensuring the systems are designed with maximum flexibility in mind for processing highly potent Active Pharmaceutical Ingredients (HAPI).

Hosokawa Micron Ltd has recently assisted a leading pharmaceutical manufacturer to address extremely stringent production demands and personnel protection requirements when during the design of an R&D batch milling and pack off system designed to process HAPI materials of a specific particle size.

The system design was made further complex due to the dimensional constraints of the existing facility and the need to achieve the most ergonomic working environment for all operatives across multi-shift operations.

Using their extensive experience, supplying and planning contained processes for the production of high potency, high value products, Hosokawa Micron engineers designed a two storey, contained system that met all the customer's requirements and allowed considerable production flexibility, from processing small R&D batches to operating as a continuous manufacturing system.

Hosokawa Micron engineers integrated into the end user's engineering team and following extensive on site ergonomic assessments in consultation with multiple shift operators who collaborated to achieve the optimum design outcome. The resulting ergonomic system design delivers optimum flexibility in terms of range of particle size and shape production and various filling and weighing options to meeting all of the customer's requirements and generating genuine involvement from production personnel.

The combined batch milling and packing system features an upper tier, high containment isolator with integrated pharmaceutical hammer mill. This feeds directly into the flexible, continuous liner, filling and weighing system contained within a lower tier laminar flow booth, complete with HMI containment screens. The system offers containment to Level 4 OEB, which will repeatedly achieve containment between 1-10µg/m³ and can handle batches up to 500litres from the dryer above.

The system has been designed to be hazardous area located and engineered to meet hazardous area classification of Zone 1 and 21 IIB T4.

If required the system can be operated under an inert atmosphere by purging all internal areas with nitrogen offering further flexibility should the products be hygroscopic or explosive, for instance.

The Milling Process

The milling isolator provides a fully contained environment during active product handling giving total barrier isolation. The isolator is integrated into an existing product flow from a dryer positioned above the unit with HAPI material fed from the dryer through hygienic rotary valves at a controlled rate into the pharmaceutical hammer mill, which can run at speeds of up to 6000 rpm, dependant on the particle size required. The integrated mill has a series of interchangeable meshes to give variable particle size and shapes that add increased operational flexibility to the system.

The mill is easy to dismantle for cleaning and mesh changing. The mill is one of Hosokawa's specifically designed mills for isolator integration; which ensures all components are easily removable and in most cases eliminates the requirement for the operator to handle and lift large, heavy components while keeping all motors out of the processing area and housed within the technical area to the rear.

The pharmaceutical hammer mill delivers a wide range of particle sizes, typically less than 50 micron with low quantities of ultrafines. Temperature monitoring at the hammer mill ensures that material stays within temperature tolerances to prevent degradation of the product and is interlocked within the system.

Contained sampling from the Milling isolator via a 270 RTP can be undertaken. This allows the measure particle size and other QC end product tests to ensure product is maintained within specification.

Filling and Weighing

The filling and weighing system is integrated within a laminar flow booth directly below the milling isolator giving direct material discharge to the filling packing head and maintaining the benefits of the compact, small footprint within the space limitations. Milled material is gravity fed into continuous liner, single liners or 23ltr charge bottles, located on the fill/weigh platform, via a 100mm charge point valve; to deliver low containment product transfer.

A containment screen located at the compact inward sealer offers additional barrier protection to the operatives from the potential risk of airborne particles within the laminar flow booth by increasing the laminar flowbooth face velocity during the actual pack off process.

All internal composition of the system is designed for minimal operator intervention and minimal material handling. The system is fully WIP with integrated spray guns positioned to ensure efficient clean down.

The system incorporates a free standing extraction fan complete with safe change filter housing with double H14 HEPA filtration for additional operational safety and reduced contamination risk to surrounding work areas.

Hosokawa Micron worked in partnership with the customer to develop Standard Operating Principles to assist in meeting the customers demand for repeatable containment and Operator Exposure Levels designed to protect both personnel and product.



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