



Contained API Particle Size Reduction Facility Designed for Fully Flexible Operation

Close cooperation with one of the world's largest pharmaceutical companies has enabled Hosokawa Micron Ltd to develop a unique Contained Particle Size Reduction Facility that is suitable for flexible milling down to ultrafine particles of active pharmaceutical ingredients at R&D, pilot scale and small scale production volumes.

The Contained API Particle Size Reduction Facility includes three mills plus a lump breaker, three material feed options and operator exposure levels of <1µg/m³. Manufactured to cGMP design and incorporating full SCADA control the system is the first size reduction facility of its kind to offer such high levels of 'complex but not complicated' operational flexibility that is crucial in today's fast moving and competitive market.

The system consists of two separate but interconnecting isolator chambers, the milling chamber and the product collection chamber. Product feed and mill placement is at the rear of the unit. Production operatives work from the front of the unit.

Interchangeable Size Reduction

The Milling Chamber is engineered for multi-powder size reduction with three separate mills available for use within the system. The interchangeable mills are mounted onto wheeled skids which are wheeled into position for docking. Interlocking seals ensure mills are fully engaged and connected ready for operation and enable the <1µg/m³ OELs to be achieved.

The system's originally specified Impact Mill for fine grinding and the Spiral Jet Mill for finer grinding are supplemented with an additional Fluidised Opposed Jet Mill for finest micronising. The Microniser was originally part of another system but was re-engineered to meet the skid mounted requirements of the new size reduction plant.

The grinding chamber also houses an in-line lump breaker for coarse grinding and preconditioning the powder prior to fine size reduction.

Multi-Feed Options

Because of known problems associated with the different handling characteristics of the materials to be processed in the facility three feed options are incorporated into the system, with the option to switch to the most appropriate; a screw feeder, a rotary valve and manual feed via a small hopper that may be the best solution when small batches are to be processed.

Product Collection Chamber

Whilst isolator 1 is for production of small and gramme batches, isolator 2 is for large batch production, sub-division and dispensary operations. Product is collected using a reverse jet filter.

In-line laser diffraction particle size analysis or manual sampling options are available in this chamber to ensure accurate product specification.

The Contained API Particle Size Reduction Facility features half suit technology for an enhanced ergonomic and less restricted working environment with lift platforms providing easy operator accessibility for all procedures. Easy clean construction eliminating dust collection and dead spots enables hand held lance WIP operations to meet stringent standards.

With operational flexibility in mind the system is upgradeable to closed loop intelligent system control should this be required in the future.

'Hosokawa Micron engineers have worked closely with the customer's production and engineering teams to develop this new dimension in flexible API processing with every opportunity taken to deliver a long term, 'future proof' processing facility. We have been able to use existing equipment and associated performance data to deliver to the customer a highly customised processing solution as a result of our longstanding working partnership.' Says Mike Coffey, Pharma Team Leader, Hosokawa Micron Ltd.



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