

Isolation Technology: Case Study

High Containment Integrated Filter Dryer Discharge, Milling and Pack-Off Isolator

A customer active in the hormone production recently searched an appropriate solution for grinding material and clean packaging after the filtering and drying process.

The following requirements had to be met:

- To provide a safe barrier between the operator and the active drug substance to provide both operator and product protection
- System designed for multi product use for OEB5 category potent compounds
- Isolator designed for the automated discharge and manual heel removal, milling and dispensing of product discharge from filter drier.
- The system is to enable manual sampling to be achieved via the filter dryer sampling port which is integral to the discharge hatch
- The system is designed also to mill and pack other products introduced to the isolator via a RTP Rapid Transfer Port.
- System to operate in an inert atmosphere during product discharge.
- To enable the process plant to be Cleaned In Place



Dec's solution is based around a three-chamber isolator to provide a high containment environment during the automated discharge by means of an agitator, milling and dispensing of product from a filter dryer.

The isolator has been designed to offer a DEL (Design Exposure Limit) $<50 \text{ ng/m}^3$ of time weighted average and an STEL (Short Term Exposure Limit) $<25 \text{ ng/m}^3$ for operations lasting less than two hours.

The upper chamber, designed to receive and mill the discharged product, features the filter dryer outlet port enabling a smooth and free-flowing transition from the filter dryer into the isolator, a product chute into the mill with a dedicated tool for manual heel removal through the dryer's discharge port, the cone mill as well as the weigh system indicator panel. It also includes a DEC MPTS sampling system for taking samples of the milled material. Glove-guards prevent operator entrapment when the filter drier agitator is running.

The middle chamber houses a weigh platform and a DEC continuous liner pack-off head for primary containment. Both middle and upper chambers include Rapid Transfer Ports (RTP) for product and sample transfers into and out of the containment system, independent isolator differential pressure controls and HEPA filtration systems. They are designed to operate at a negative pressure and with nitrogen purging during processing. Once the target weight is reached and the endless liner is sealed, they pass into the lower chamber through another continuous liner/bag connection. The material is therefore double packed and sealed to achieve this very high containment level before leaving the enclosure in the drums. A roller system allows for easy drum manipulation.

The isolator and process equipment cleaning is essentially designed for Wash In Place, using provided spray balls and spray guns.

The isolator is installed within an Atex classified area and is controlled via a PLC with operator interface via a touch screen HMI. Due to the hazardous area classification the main control panel is installed in the non-hazardous client technical area.

The SMEPAC verified $< 25 \text{ ng/m}^3$ containment system conforms to cGMP standards and was fabricated in accordance with pharmaceutical standards for secondary manufacture with a fully welded design and rounded corners thus providing smooth interior surfaces.

Dec develops, designs and supplies custom-made containment system solutions for both potent and aseptic compounds that meet the growing challenges within GMP industries.

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