



Roll Compaction - HPAPI Containment Solid Dose Solutions

High Potency Drugs - OEB Level 5 (& Level 4)

THE BACKGROUND

A pharmaceutical clinical production application required both cGMP conditions and OEB 5 operator protection as high potency solids were being used in the process.

The Fitzpatrick Company's Contained Compaction System CCS320 was selected by the customer for the dry granulation operation stage due to its ability to achieve the desired capacity and particle size distribution. Although the CCS achieves OEB 3 & 4 containment levels with an on-board PCS system^[1], in order to enhance the safety levels and reach OEB 4 & 5, further design solutions were needed.

Critical to the customer was that containment should be preserved during charging, discharging and cleaning of the equipment. The end goal was for a safety guarantee, both for the operators and surrounding environment.

THE SOLUTION

The Fitzpatrick Company & Extract Technology are leading companies in their respective fields. In order to produce a state-of-the-art dry granulation solution with an OEB 5 containment level, they designed an ergonomic solution that integrated a CCS320 into an Extract Technology containment isolator, which delivers an operator protection to <1 µg/m³.

The Fitzpatrick CCS320 is ideal for this application as it is the most compact model on the market, which makes it ideal for integrating into an isolator. Because all the process parts are on the frontal section there is superior separation between technical and material contact components.

Raw materials and process components are transferred in & out of the isolator via Rapid Transfer Ports (RTPs). Special aids were designed for ease of assembly/disassembly of the CCS whilst working through the gloveports. Full containment is achieved at all times even during product loading, transferring and equipment cleaning.



The Fitzpatrick Company's CCS320 integrated into Extract Technology containment isolator

^[1] PCS = Product Containment System. Operator exposure to active ingredients is minimized and it prevents product loss or contamination.



Roll Compaction - HPAPI Containment Solid Dose Solutions

High Potency Drugs - OEB Level 5 (& Level 4)



THE DESIGN FEATURES

- The isolator provides a very high protection factor to OEB level 5, or $<1 \mu\text{g}/\text{m}^3$ over an 8-hour TWA / over the task duration.
- Full access to the roll compactor operation is through 8 gloveports.
- The chamber is a fully welded construction, fabricated from 3mm thick 316L stainless steel.
- Sanitary clamp and connections are provided for services and utilities to the CCS320.
- 270mm diameter rapid transfer ports are provided for introduction of product and for product to be discharged from the dry granulation system.
- A negative pressure single-pass airflow regime is complemented by an in-line HEPA filtration on the inlet and double filtration on the exhaust.
- A handheld spray nozzle is provided for wash-down after each batch.
- The isolator control system is fully supported via PLC and touchscreen HMI for ease of use and functionality access.
- The integrated FitzMill™ is designed to deliver maximum flexibility and is a mainstay of API and OSD pharmaceutical manufacturers alike. Multiple rotor (blade) options help to achieve a more controlled particle size distribution and minimize fine particles.
- Rotor/blade speeds are adjustable, creating a PSD from fine to coarse.
- The relationship between the spinning blade tips and the distance to the mill screen and housing cover (throat) is locked by design to the optimal distance in order to eliminate operator error. This provides consistent results and minimizes the quantity of fines generated.
- Screen hole diameters & open area percentages are optimized to produce higher capacities, lower milling temperatures and generate fewer fines.



Entry Rapid Transfer Port (RTP)



Complete isolator providing OEB 5 containment with integrated compactor