Flexible Containment Solutions Guide

DoverPac® Containment Systems

Mill Containment System - *Underdrive Design*

OVERVIEW

Milling is a common operation throughout the Pharmaceutical Manufacturing Process. Sizing of powders is a dusty operation and with more potent powders being processed the need for containing this operation becomes even more critical from safety and cross contamination avoidance purposes.

In addition to contained powder throughput, it is imperative that access to the interior of the mill be made available without breaking containment in case the screen blinds, for changing to a different mesh, impeller change, or cleaning.

Figure 1

1. Underdrive Mill
2. DoverPac®
3. Charging Canister with Transition Adapter
4. Screen Access Enclosure Hardware
5. Outlet Canister

HOW DOES THE SYSTEM WORK?

The configuration shown in Figure 1 consists of the basic mill with modifications to support the attachment hardware needed for the standard DoverPac® charging and offloading systems. In addition, a flexible enclosure interface is provided between the base of the charging canister and the mill's inlet housing.

Safety is maintained as provided in the base mill design. Safety Grids are included in the inlet and outlet canisters. In addition, the interlocks are relocated to the Charging Canister and Screen Access Enclosure Ring.

In the event that a screen blinds during operation, the mill is turned off and the screen is accessed using the enclosure shown in Figures 2, 3, and 4. This is accomplished by:

- Applying the Lifting Shroud to the canister
- Removing the protective shroud from around the enclosure (used when the enclosure is in the stowed position only, not shown in this document)
- Inserting hands in the integral glove sleeves in the enclosure and opening the tri-clamp
- Hoisting the canister and using the glove sleeves again to remove the impeller and screen

The enclosure is manufactured from clear ArmorFlex® film that will allow room light to illuminate inside the enclosure for easy viewing. It is also equipped with a bag in/bag out sleeve which is used for housing the tool needed to loosen the bolt that secures the impeller and bagging out the screen as required.

The opening at the top of the enclosure includes an encapsulated o-ring that is clamped onto the bottom groove of the canister. The bottom of the enclosure has a similar arrangement that is clamped to the interface ring shown in Figure 3.

Figure 2. Shroud used to hoist canister.

Figure 3. Grooved interface ring

Figure 4. Integral glove sleeve for manipulating screen.

FEATURES

- Validated containment technology
- Clear film
- Passive system
- Flexible materials
- Disposable components
- Retrofit to existing mills
- Adaptable to other mills and size reduction designs

BENEFITS

- Nanogram containment levels achieved
- Supports visibility for maintenance
- Does not affect ATEX and Ex ratings
- Ergonomics maximized
- Reduced cleaning and cleaning validation
- Low capital and operating cost
- Speed of implementation

WHAT CONTAINMENT LEVEL PROVIDED?

OEB 5 with results in the nanogram range. This is based on proven applications, third party testing to the "SMEPAC" protocols on similar designs, and the 100% inflation tests performed on the deliverable systems.

WHY USE THIS OVER OTHER TECHNOLOGIES?

The cost of ownership, ergonomic advantages, and speed of delivery benefits of this flexible solution far outweigh those of rigid isolation systems.

OTHER POTENTIAL APPLICATIONS

- Continuous liner hardware on outlet of mill for contained filling in drums
- Transfer Sleeve on outlet of mill for direct transfer to IBCs or other vessels
- Transfer Sleeve on inlet of mill with drummed materials being introduced using the DoverPac® Drum Transfer System (Flexible Containment Solution Guide # FCSG 003)

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