Flexible Containment Solutions Guide

DoverPac® Containment Systems

Contained Blending - Transfer Sleeve, DoverPac®, Continuous Liner Technology

OVERVIEW

Two methods of containing blenders have been demonstrated. Included here are the use of flexible enclosures and separate, disposable powder transfer systems.

The systems described in this containment guide center around bin blending and V-Blender applications in Oral Solids Dosage (OSD) manufacturing using Transfer Sleeves, DoverPacs® and Continuous Liners. Blending involves the controlled mixing of dry primary powder particles and excipients. The powders can range in properties and potency and, if not contained, can present cleaning and exposure issues.

Dry mixing of granular and other processing constituents includes a significantly high number of blending steps. This includes potent and highly hazardous compounds, excipients, and materials such as lubricants as processing aids.

As demonstrated by the Risk-MaPP principles, both current good manufacturing practices (cGMP) and Industrial Hygiene (IH) needs can be met by containing the process at the source. By employing flexible containment and using the logic diagrams from the Risk-MaPP process, cleaning is minimized and the operator is protected with this Engineering Control. As such, processes in multi product facilities can be safely performed without the risk of cross contamination.

Used for lab scale and production operations at multiple International Pharma manufacturers, our contained Blending applications take the idea of retrofits to another level. Here, existing and new equipment are supported as a tool to eliminate the risks posed by uncontrolled powder processing. At no time are the blenders' angle of repose affected so as to change the blending performance.

Note that the powder containment applications described below are based on proven designs supported for customers based on the process equipment that they specified. ILC Dover does not have any specific ties to these equipment suppliers and does not recommend one type of blender over another. Rather, this guide depicts a sampling of flexible containment applications to a variety of styles of equipment as standard and customized containment solutions.

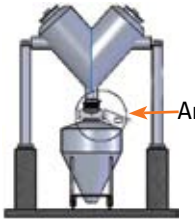

Figure 1a

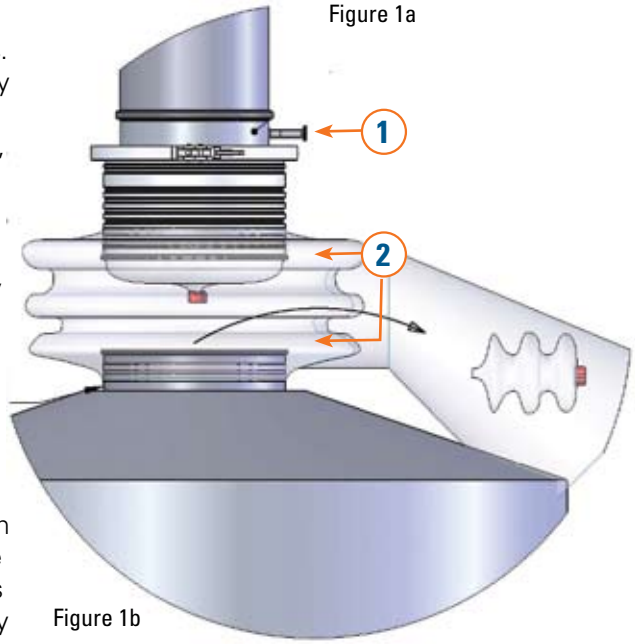

Figure 1b

1 Vac/Purge Port
2 DoverLoc®

HOW DOES IT WORK AND WHAT ARE THE APPLICATIONS?

Three methods of flexible containment using powder transfer systems have been applied to blenders. These include charging and offloading with transfer sleeves, charging and offloading with DoverPacs® and offloading with a continuous liner system.

This rugged film provides a safe working environment while enabling the enhancements developed through numerous installations using this flexible containment technology.

The Transfer Sleeves, Continuous Liners and DoverPacs® are made from ArmorFlex® film. This rugged monolayer film brings regulatory pedigree for materials of contact as well as proven use from multiple process applications.

The use of flexible containment allows the end user to process contained when needed or follow existing, open processing procedures when containment is not required. In both cases, cost savings are realized by modifying an existing design or using an existing piece of equipment with no modifications.

Charging and offloading with transfer sleeves

A transfer sleeve is essentially a flexible chute that attaches to the blender and the piece of process equipment being used to fill or offload the blender. Contained attachment is achieved through the use of a multiple groove canister on the blender and on the IBC, for example. The sleeve is then clamped onto the blender and IBC to support powder flow.

In the case of a bin blender, the bin can be attached to the tablet press or to an interface in the floor of the suite where powder transfer to a piece of equipment on a lower floor is part of the process.

Gemco V-Blender to IBC

In the example shown in figures 1a and 1b, a 30 cubic foot Gemco blender is being emptied to a rigid IBC. The application posed a challenge in lining up for docking with the IBC and in clearances while the blender rotates.

The system includes a 5 groove multiple o-ring canister attached to the V-Blender, a 2 groove canister clamped to the IBC, the Transfer sleeve, the DoverLoc®, and the crimp components. The transfer sleeve is also made with an ArmorFlex® film.

Charging and offloading with DoverPacs®

DoverPacs® are a proven method for contained transfer from vessel to vessel. This system consists of a liner that is attached to a multiple o-ring groove canister. By incorporating a fill and discharge neck the same liner can be filled at one process point and discharged into another.

DoverPacs® utilize the crimping system and ArmorFlex® family of films developed by ILC. Various standard and custom designs are available to fit any process need from lab scale to full production.

Conta Bin Blender Charging and Discharging

While DoverPacs® can be used for charging and discharging any type of blender, the wall mounted Bin blender shown is an example of an application with this flexible containment technology. In this design, the process is supported by the installation of a single, 8"(200 mm) multiple o-ring groove canister on the bin which allows for contained powder transfer through one port for charging, figure 2a, and offloading, figure 2b, the bin. This minimizes the capital expense versus a rigid isolator even further and allows for existing bins to be used without modification.

Following this step the filled 20L DoverPac® is used to charge a capsule filler.

Offloading with a continuous liner system

Utilizing a similar multiple o-ring groove canister, ArmorFlex® film, and crimping technique as above, this system allows contained offloading into drums. Liners are factory packed with standard bundles of 150' (45 m), 100' (30 m), and 50' (15 m). Custom lengths are also provided.

Gemco V-Blender to Continuous Liners

Figure 3 is an example of offloading a 30 cubic foot V-blender with a Continuous Liner system to drums. In this case the rotational clearance did not allow the Continuous Liner canister to be installed directly on the blender as in other applications.

To account for the clearance, a three groove canister was mounted on the blender and the standard canister was mounted on the Transfer Stand shown. In addition, the stand allows the Operator to reach the valve on the outlet of the blender and the transfer sleeve since this interface is 92" (2337 mm) above the floor in this installation.

A transfer sleeve is then used as the contained chute to direct the powder from the blender to the Continuous Liner. The Continuous Liner is pulled into a drum that sits on the existing scale in the floor between the blender supports. This allows for the drum to be weighed as part of the process.

Input from the operation of this system included "this saved us significant cleaning time as we no longer need to hose down the entire suite". This is a key in the Risk-MaPP logic for supporting operations in a multi process facility by eliminating cross contamination concerns.

Figure 2a

Figure 2b

1 Bin
2 DoverPac®

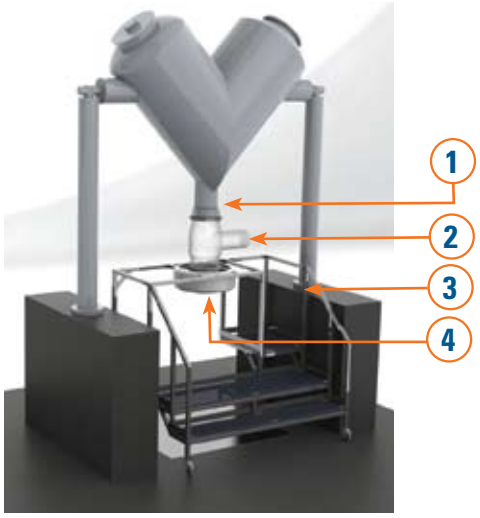

Figure 3

1 Blender Mounted Canister
2 Transfer Sleeve
3 Transfer Stand
4 Continuous Liner System

WHAT ARE THE FEATURES AND BENEFITS OF THIS TECHNOLOGY?

Features

- Retrofit to existing equipment design
- Process and Technical areas separated
- Validated containment technology
- Passive system
- Flexible materials
- Disposable components
- Adaptable to other process equipment
- No blender shape modifications

Benefits

- Complies with the Risk-MaPP initiative
- Provides the lowest overall cost of process ownership through low capital and operating cost including reduced cleaning and cleaning validation
- Fastest turnaround of a processing suite for subsequent manufacturing campaigns
- Process is contained without contamination of motor, drive shaft, and controls
- Nanogram containment levels achieved
- Does not affect ATEX and Ex ratings
- Ergonomics maximized
- Speed of implementation
- No affect on blend uniformity

WHAT CONTAINMENT LEVEL PROVIDED?

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

OEB 1	OEB 2	OEB 3		OEB 4	OEB 5	
10,000 to 1000	1,000 to 100	100 to 50	50 to 10	10 to 1	1 to 0.1	0.1 to 0.01

Occupational Exposure Levels above are in µg/m3.

WHY USE THIS OVER OTHER TECHNOLOGIES?

One of the driving forces of this technology is that it reduces the risk of cross contamination in multi process facilities and it provides safety to the operators in both multi process and dedicated facilities. By using this disposable Engineered Control, highly hazardous powders are contained at the source which significantly reduces cross contamination risks and cleaning of process suites and rigid containment devices.

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

Tools such as Lean Manufacturing come into play more and more. For example, the time to clean and validate the cleaning are major bottlenecks for processing efficiencies in the plant. Being able to minimize this part of the process results in getting products to market faster and at an overall reduction in operating costs when considering labor, utilities, and waste disposal costs. It also supports getting multiple products to market faster within an existing facility without risking product safety.

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