Disposable Process Solutions Guide

DoverPac® Containment Systems

DoverPac SF (BioPharmaceutical) From Lab Scale Through Production Processes

OVERVIEW

The DoverPac® SF for BioPharmaceutical applications consists of a series of standard and customized applications based on the DoverPac® SF (Split Flange) technology (FCSG 007). This expansion of single-use manufacturing is designed to meet the needs of speed of implementation, ease of facility design, reduced validation, cost savings over cleaning and cleaning verification, and reduced capital costs to the operation.

HOW DOES IT WORK?

The DoverPac® SF can be attached to a variety of process vessels with by an integral sanitary flange (either sealed or clamped to the liner) or via our patented multi o-ring technology.

Materials of Contact

The ArmorFlex® Film is utilized to provide structural integrity, as well as meet the rigorous demands for materials of contact. Using existing and specific reference, monographs, key needs, such as no animal derived components, extractable/leachable limits, and food contact compliance, to name a few, are addressed.

Figure 1 shows the basic design with a 4 inch/100mm sanitary flange.

The Sanitary Flange Interface

The sanitary flange is injection molded and then thermally welded to the liner. This is done with a blended lap weld which keeps all of the load in shear and eliminates any possibility of powder hang-up or bioburden build up in an otherwise raised lip at the seal area.

The unrestrained design uses a separate lifting bar when it is supported for vessel charging. This is significantly more robust in larger volumes and supported weights than an encapsulated plate. In fact, customer testing has shown the 100L version to hold 165 pounds/75 kgs. Reusable restraints are also available for added support.

Figure 2

The DoverPac® SF is also available with an optional S-fold on the neck as shown in Figure 2. This functions as an integral "clamp" to shut off powder flow when making the connection to the vessel.

Multi O-ring Canister Attachment

The interface to the vessel can also be supplied in our patented multiple o-ring technology. This configuration is shown in Figure 3. Attachment of the first liner to the first groove in the canister is made. The powder transfer operation is completed and the neck attached to the vessel is then removed using our crimp separation method. The subsequent liner is then attached to the next groove above the stub and the stub is then bagged out.

Standard solutions are also available for DN 100 and 150 flange interfaces. A variety of configurations are available including 1L, 5L, 10L, 15L, 25L, 30L, 50L, and 100L.

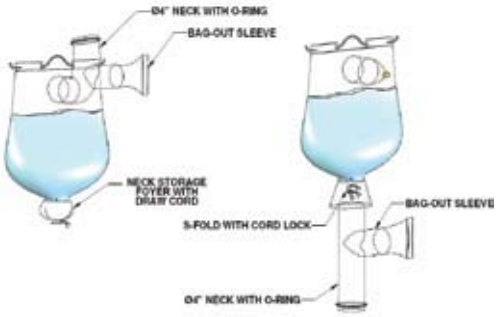

Figure 3

WHAT ARE THE APPLICATIONS?

Use of powder transfer devices within existing buffer prep processes whether new or existing operations, is gaining momentum as well. Figure 4 illustrates just such an example during the Factory Acceptance Test (FAT) stage of the project at METO where dispensing to weight operations were being trialed. Now that this has been successfully completed, process installation efforts are underway.

Since this was a dispense to weight operation within a tightly controlled tolerance, the need to separate the support frame and scale from the drum inverter was needed. Figures 5 and 6 show the application of a flexible sleeve with molded sanitary flanges as a method for achieving this need.

Figure 4

Figure 5

Figure 6

FEATURES

- Flexible
- Clear
- Sanitary, DN and multi o-ring flange interfaces
- Range of Sizes
- ArmorFlex® Family of Films
- Gravity feed
- No capital
- Reduced cleaning and disposal

BENEFITS

- Can be manipulated to overcome bridging, also achieves over 99.5% product discharge
- Operators can see product without exposing product
- Interfaces with any vessel interface
- Supports clinical through production scale up
- Assures ruggedness, static dissipation and material of contact compliance
- No expensive mechanical systems, eliminates validation of mechanical components, simple to use
- Best overall cost of ownership, small footprint
- Supports Green Initiatives

WHAT CONTAINMENT LEVEL PROVIDED?

Often applied for cGMP containment, however, if a configuration is selected that interfaces with a DoverPac® multiple o-ring canister as in Figure 3, containment in the nanogram range can be achieved.

WHY USE THIS OVER OTHER TECHNOLOGIES?

- Reduced cost of ownership
- Eliminates cleaning and cleaning validation
- Eliminates waste treatment of cleaning solutions
- Best product recovery
- Visual access to drug product being manufactured
- Liner can be manipulated to overcome bridging

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