

Flexible Containment Solutions Guide



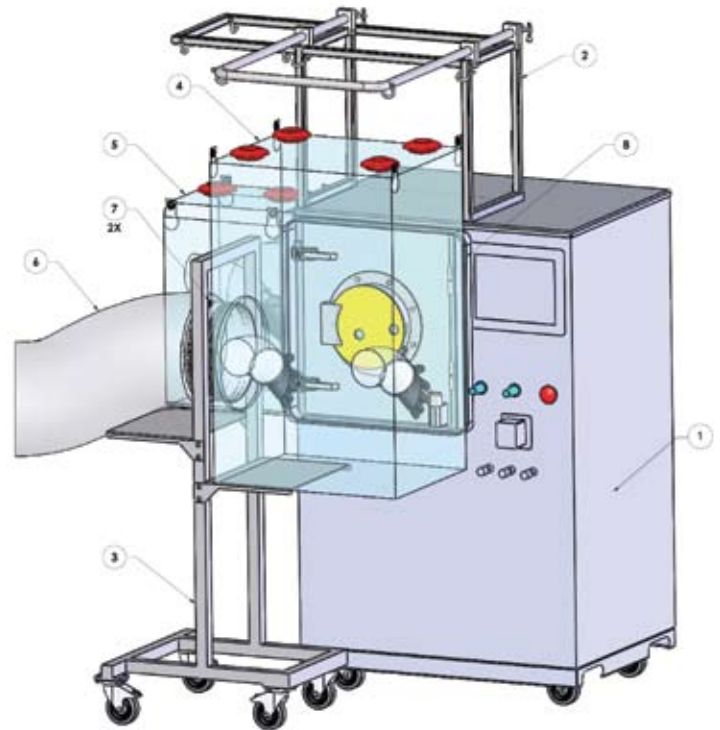
Tablet Coater Containment System – O’Hara LCM Tablet Coater

OVERVIEW

Recently delivered for lab scale operations at an International Pharma manufacturer, the installation described in this Containment Guide takes the idea of retrofits to another level. Here, a new piece of equipment was needed but cost savings were realized by modifying an existing design. Flanges added to the unit by the original equipment manufacturer (OEM) allow this end user to process contained when needed and to use existing procedures when containment is not required.

Containment for the O’Hara LCM Tablet Coater is provided by two individual rectangular enclosures. One enclosure surrounds the pan access door and the second the exhaust plenum access door.

The enclosure is manufactured from clear ArmorFlex® film that allows room light to illuminate inside the enclosure for easy viewing. This rugged film provides a safe working environment while enabling the enhancements developed through numerous installations using this flexible containment technology.



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| 1 Coater | 5 Filter Change Out Enclosure with HEPA Filters |
| 2 Enclosure Support Frame | 6 BIBO Sleeve |
| 3 BIBO Canister Support Frame | 7 BIBO Canister |
| 4 Coater Enclosure with HEPA Filters | |

HOW DOES IT WORK?

The pan access enclosure is used for product charging and removal as well as sampling, cleaning and spray gun maintenance. It has one pair of glove sleeves. A single entry/removal point provides a means for moving product and supplies in and out of the enclosure. This entry/removal point supports the use of a bag-in/bag-out sleeve or interface with ancillary containment devices such as an in-process isolator.

The enclosure is mounted in such a way that it can be collapsed inward toward the front of the coater. This simplifies loading and unloading product through the circular door on the coater. The enclosure is fully extended to provide clearance when opening the larger pan access door for cleaning operations.

The exhaust plenum enclosure is mainly used for cleaning operations. It has a pair of glove sleeves and a cleaning wand sleeve. It can also be equipped with a storage/waste sleeve if desired. Both enclosures also include HEPA filters to balance the pressure in the enclosure and allow it to move freely as the operators perform various operations.

Attachment flanges running outward from the cabinet around each of the access doors provide a means of attachment for the enclosures. This allows for containment to be applied to the process area of the equipment with the technical area segregated from any contamination. A bag-in canister is mounted on a mobile stand with integral product staging table. An external enclosure support frame supports the enclosures without need of ceiling attachment.

The enclosure also includes a spray-wand cleaning sleeve to allow misting of the interior of the enclosure during cleaning. Spray mist of the inside of the flexible enclosure and surfaces of the equipment within the contained area eliminates airborne contaminants prior to removing the containment. Cleaning of the surface of the equipment is done following normal practices.

WHAT ARE THE FEATURES AND BENEFITS OF THIS TECHNOLOGY?

Features

- Retrofit to existing equipment design
- Process and Technical areas separated
- Validated containment technology
- Clear film
- Passive system
- Flexible materials
- Disposable components
- Adaptable to other process equipment

Benefits

- 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
- Supports visibility for maintenance
- Does not affect ATEX and Ex ratings
- Ergonomics maximized
- Speed of implementation

WHAT CONTAINMENT LEVEL IS 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.

WHAT ARE THE APPLICATIONS?

This containment technology can be applied to any Oral Solid Dosage (OSD) type of processing equipment. Applications to myriad Tablet Presses, Coaters, Dedusters, Blenders, Granulators, Mills, Roller Compactors, Spheronizers, Extruders, Fluid Bed Dryers, and weighing/subdivision processes have been demonstrated successfully.

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.

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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