



Combining Containment Strategies

In some cases using multiple containment strategies in a single piece of equipment is best to suit the pharmaceutical process. The Weighing Isolator described below is designed to provide complete operator and environmental protection during weighing and sub-dividing of highly potent powders in a pharmaceutical warehouse. The key process constraint in this design is that (5) different API's can be weighed & sub-divided within an 8 hr work day, with 100% validated CIP cleaning between each weigh.

The isolator system is of fully welded 7 gauge 316L stainless steel construction, with 5/8 inch corner radiuses, and laminated safety glass. It operates in a negative pressure mode with HEPA filtered turbulent airflow. The inlet and outlet HEPA filters are "push-push" type with safe change ability. Negative pressure inside the isolator is provided by a blower with a variable frequency drive maintained by an Allen Bradley MicroLogix control system.

Transfer of the compounds in and out of the isolator system is critical in this process. A large bagging ring located on the rear wall of the isolator is used to introduce and seal large drums of powder to the isolator. Moving weighed and sub divided powders from the isolator is done via a 270mm RTP system on the side wall and a split butterfly valve through the floor and into a lower pack-off booth without breaking containment. A Spray nozzle arrangement inside the isolator allows for 100% cleanability & drying without operator intervention. Waste liquid exits the isolator via a diaphragm drain valve.

A pack off station under the floor of the isolator main chamber contains provisions for either a split butterfly valve or a continuous liner system. This station has a separate negative airflow system which assures that OEL level stays below 500 nanograms/cubic meter during the undocking or bag cutting process.





Process Description:

Large drum of potent powder is attached and sealed to the isolator via the drum ring in the rear wall. Using the gloves in the main isolator chamber, the operator removes the drum lid and opens the drum liner. Powder is then scooped from the drum and weighed on a wash down scale inside the isolator. Small lots of weighed powder are packed and transferred from the isolator using the 270mm RTP system in the right end of the main chamber. Larger lots of powder are poured through the split butterfly valve in the floor of the main chamber into either poly bottles or a plastic continuous liner. A floor scale inside the pack off booth provides the weight reading. The negative airflow through HEPA filters in the pack off booth maintains the low OEL level when the liner is cut and sealed or when the split butterfly valve is disconnected. The booth door can be opened and the liner or bottle removed. The main isolator chamber is cleaned via the spray wand system before opening.

Conclusion:

The use of multiple containment strategies can be effectively employed in an isolator for handling of highly potent powders. With the inclusion of CIP skids and cleaning programs with specified temperatures, pressures, & flows, the Isolator can be 100% cleaned without operator intervention to allow for efficient and effective weighing strategies all within one Isolator design.