dedusters

Factors to consider when purchasing a wash-in-place or clean-in-place tablet deduster

Andre Petric
Kraemer US

This article describes the types of tablet dedusters available, explains what you should consider when selecting deduster for your tableting process, and compares the benefits of wash-in-place and clean-in-place dedusters.

Tablet dedusters are available in non-dust-tight, dust-tight, wash-in-place (sometimes called wet-in-place), and clean-in-place versions. Non-dust-tight dedusters are the most common type, but these aren't suitable for toxic or highly potent formulations because they can allow dust to escape during operation, especially when dust-collection air volume is lacking. Non-dust-tight machines also require disassembly for cleaning, which exposes the operator or cleaning personnel to airborne powders.

Dust-tight tablet dedusters have positive connections to upstream and downstream equipment along with gaskets and seals to prevent dust migration during operation, but like non-dust-tight dedusters, they also require disassembly for cleaning and are unsuitable for hazardous or highly potent formulations. To protect operators and washing personnel in hazardous applications, you must use either a wash-in-place (WIP) or clean-in-place (CIP) deduster.

WIP dedusters are dust and water tight and meet validated containment levels during operation. WIP machines allow the introduction of water, or water and detergents, into the machine, with all areas becoming fully wetted without disassembly. The water washes the machine's entire inside, preventing dry-powder exposure and removing most powder from the machine. This allows the operator or cleaning personnel to safely disassemble the machine for final manual cleaning and drying, with no dust hazard.

Like WIP dedusters, CIP machines are dust and water tight and meet validated containment levels during operation, but they also use validated cleaning protocols to verify that no residual material remains in the machine. You can fully clean and dry CIP machines without disassembly. They require no human intervention, allowing you to run another product or batch as soon as the CIP machine has completed the washing and drying cycle.

Selecting a WIP or CIP deduster

While WIP and CIP dedusters cost more than dust-tight and non-dust-tight dedusters, the added cost of either type typically represents only a small part of the cost of a containment press and suite. However, because the deduster removes hazardous dust from tablets, the choice is important. The deduster is part of a contained system in which the tablet press, deduster, and contained tablet collection container must work together seamlessly.

Because you can opt for functional and operational customizations to fit your production and user needs, you should develop a user requirements specification (URS) to document all system expectations and obtain approval from all user groups.

Answer the following questions prior to purchasing a WIP or CIP deduster:

- What are our normal production requirements?
- How hazardous is our product? What operator exposure limit (OEL) level—operator exposure limit times the weighted average—do the materials being handled require?
- How easy is a particular deduster to assemble and disassemble?
- What layout do we require to handle upstream and downstream processes?
- How will we control water flow, and do restrictions on water usage exist?
- How will we manage the dust collection makeup air?
- How will we handle an equipment malfunction?
- Will the process need metal detection?
- Will we need a diverter for multiple collection containers?

Normal production requirements. Identify your needs related to capacity and dedusting efficiency as well as the physical arrangements you require in a typical deduster. These include tablet size and shape, rate produced by the press, tablet press outlet height, and tablet collection container height.

Hazardous products. Product and powder hazards are broken down into five bands, OEB 1 through 5, with 1 being the highest level of allowed exposure and 5 being the lowest. These bands correspond to OEL levels. The OEL levels are measured in micrograms per cubic meter (mcg/m³), with 100-1,000 mcg/m³ being OEB 1 and <0.1 mcg/m³ being OEB 5.

Validate the dust tightness of a WIP or CIP machine using the Standardized Measurement of Equipment Particulate Airborne Concentration (SMEPAC) guideline. SMEPAC is a guideline sponsored by the International Society of Pharmaceutical Engineers (ISPE) that gives performance testing criteria to allow you to accurately compare machines.

Assembly and disassembly. Evaluate the ease of assembly and disassembly of the dedusters you're considering. Does disassembly and reassembly require special tools and procedures?

Layout. Consider your required layout and determine how the machine will connect to upstream and downstream equipment and how you will make and break connections when disassembling and cleaning the machine. These connections may be split butterfly valves, other containment-type valves, or continuous liner systems, each of which require vertical height that you must account for in the layout. The connections for the press, tablet chute from press to deduster, deduster, metal detector, and tablet collection container must all be WIP or CIP to ensure that no dust escapes from the system.

Water control and usage. Determine where the water will go during the WIP or CIP process. Water usage can also be a factor because you must collect some hazardous material and dispose of it at a hazardous-waste collection facility. By minimizing water usage, you can keep disposal costs to a minimum over a machine's life. If cleaning off-line, you must also determine how you will disconnect the deduster from the upstream and downstream equipment in a contained method.

Dust collection. Removing the dust consistently from a deduster, with no fluctuations in volume and vacuum pressure throughout a batch, is necessary for proper system performance. Determine how dust collection makeup air will enter the deduster and what happens if an upset occurs. If the deduster is pressurized, will pressurization cause dust to be blown into the production room?

The tablet press, deduster, and tablet collection containers all connect in a series, and the press and deduster may each have a separate dust collection system. If so,

you must balance the dust collection systems correctly. If they aren't balanced and the press' dust collection airflow is stronger than the deduster's dust collection airflow, tablets could be pulled back into the press. Dust collection airflow can also cause problems with the tablet flow out of the deduster and into the tablet collection container.

Equipment malfunction. Determine how you will handle any equipment malfunction. What is your plan during an upset condition? What if you have to open the machine during production? Do you have a plan in place to open the machine safely in an emergency using personal protective equipment?

Metal detection. Determine your need for metal detection. Identify how you will introduce metal-detector test tablets in a closed manner. How will you remove the test tablets in a contained manner after they have passed through the metal detector? How will you remove rejected tablets from the metal detector in a contained manner?

Diverter. Determine whether you need a diverter at the deduster discharge. A diverter allows you to use multiple collection containers to avoid having to shut down the press and deduster while you swap containers.

WIP versus CIP dedusters

The main issue preventing fully automated deduster cleaning is that dedusters have many nooks and crannies that are difficult for an automated system to clean in a verifiable and fully validated manner. As a result, WIP dedusters are much more common than CIP dedusters.

In theory, CIP would seem to save cleaning time, but in reality, the effort of validating a consistent clean for every product is extremely time consuming. You need to store the CIP recipes electronically in the machine's control system. In addition to the cleaning process, you also need to validate the drying process to ensure that the deduster is completely dry before production starts again.

Both WIP and CIP dedusters require much thought and coordination to be effective. WIP and CIP deduster suppliers can help you lay out and procure a robust system that can provide high levels of effective, trouble-free containment for your specific application. *T&C*

Andre Petric is president at Kraemer US (201 962 8200, www.kraemerus.com). The company manufactures tablet dedusters, capsule polishers, diverters, and accessories for the pharmaceutical industry. *A version of this article originally appeared in the October 8, 2018, issue of* Tablets & Capsules' *e-newsletter* Solid Dose Digest.