

TABLETS & CAPSULES

Solid Dose Digest

Insights, advice, and industry news about formulating, manufacturing, and packaging solid dosage forms brought to you by Tablets & Capsules magazine

Feature

Ten tips for selecting cartridge dust collection equipment for tableting operations

David Steil, [Camfil Air Pollution Control](#)

While compressing tablets doesn't generate a large amount of fugitive dust, collecting whatever is generated safely and efficiently helps you ensure the operation performs as intended. The following 10 tips can help you get the job done right.

Good tableting operations are a delicate balance of airflow, static pressure, climate control, precise material handling, and consistent compression. Thus, the dust collection equipment linked to these operations either contributes to reliable and consistent performance or detracts from it. It all depends on whether the vendor has properly designed and applied the dust collector and its components.

Because cartridge-style dust collectors remove dust efficiently and need a relatively small footprint, they are the best choice for collecting dust from tablet presses. Compactness and efficiency, however, are not the only concerns because dust collectors are subject to the scrutiny of several agencies. The FDA will demand that you prove you're delivering safe products to patients; the National Fire Protection Association (NFPA) will examine the measures you've taken for explosion protection; OSHA will want data about the explosivity of the dust and environment, the indoor-air quality, and other safety concerns; and the EPA will want to know what is in the collector's exhaust stream to the outdoors. And then you, the end-user, must satisfy all these regulatory bodies while also maximizing quality and productivity.

It can be a complex undertaking. When choosing a dust collection system for tableting operations, the most important factors to consider include: 1) the air-to-media ratio, 2) containment, 3) surrogate performance testing, 4) negative pressure, 5) the location of the dust collector, 6) the combustibility of the dust, 7) the type of explosion protection equipment, 8) real-world destructive test data, 9) filter media, and 10) downstream air recirculation.

The following 10 tips can help you address those factors.

1. Use a conservative air-to-media ratio.

The air-to-media ratio, also known as the air-to-cloth ratio, is defined as the volume of air—cubic feet per minute—that flows through the collector in relation to the square feet of filter media that the vessel contains. This ratio is an important and often misunderstood element in dust collector selection and sizing. The recommended air-to-media ratio for cartridge filters that tableting applications use is 2.5-3.0 cubic feet of air per square foot of media.

Some equipment suppliers use air-to-media ratios as high as 5-to-1 to recommend a small collector, which requires less space and may cost less. But overly high ratios can cause inconsistent airflow that creates several problems: 1) static pressure that is out of specification, causing the press to malfunction; 2) a shorter filter life, creating lost production time and higher change-out costs; and 3) frequent and excessive pulse cleaning, shortening filter life and impeding operation of the dust collector and tablet press.

Using a conservative (low) air-to-media ratio can reduce these problems and may allow you to operate for 1 to 2 years between filter changes. The initial expense of the dust collector will be higher, but the payback in maintenance savings is fast, and the system will be much more reliable.

2. Determine the need for containment.

Knowing what equipment and information you need begins with understanding the toxicological properties of the material that you must capture, i.e., the potent, toxic, and/or allergenic properties of the compound. Those properties are important in determining the Occupational Exposure Limit (OEL) of the active pharmaceutical ingredient (API). The OEL is the amount of material in the air to which you can safely expose a worker over an 8-hour shift and a 40-hour work week, without him or her potentially suffering adverse health effects, i.e., the maximum air concentration, expressed as a time-weighted average in micrograms per cubic meter of air. You should perform a risk-based exposure evaluation to determine which methods can offer proper dust control.

In most cases, you will require some level of isolation and/or containment because pharmaceutical dusts are often hazardous, and thus you can't release them into the surrounding environment. That's why pharmaceutical companies use high-efficiency particulate air (HEPA) after-filters to serve as backup protection to the dust collector and to allow the release of the filtered air directly outdoors. Or you can recirculate the filtered air back into the building, depending on the results of the risk assessment (photo).

In cases where the substance is highly potent or where multiple-product manufacturing makes cross-contamination a concern, you should specify a



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January 8, 2018



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contained dust collection system. Typical containment systems use bag-in/bag-out (BI/BO) technology for the filter cartridges to ensure that you replace filters safely (photo).

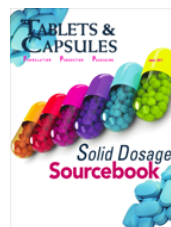
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containment system also uses a dual-valve, continuous liner at the system's discharge to capture and contain dust that releases from the cartridges during cleaning and falls into the hopper (photo). Most cartridge dust collectors direct pulses of air to the reverse side of filters to clean them. These pulses also have the potential to cause issues with the up-stream tablet press if the system is not designed properly.

3. Consider surrogate performance testing for containment applications.

When containment is necessary, surrogate testing can help you assess risk. In surrogate testing, a substitute (surrogate) compound simulates an API so you can verify the effectiveness of isolation and containment equipment and predict real-world performance. The test conditions mimic those of the actual workplace as closely as possible but without the expense or health concerns of handling the actual API.

You can perform the testing on equipment that handles an API of unknown toxicological properties or as a means of verifying the performance of an existing system. You also can perform surrogate testing during factory-acceptance testing and/or site-acceptance testing to ensure that the equipment performs properly once installed. By validating equipment performance during a project's engineering phases, you can reduce costs while you ensure proper selection of equipment.

4. Consider negative-pressure requirements.

In tabletting applications, dust most often travels to the collector from a local pick-up point, usually where you feed the material into the die of the press. Thus, it is sometimes necessary to maintain negative pressure—a partial vacuum—in the turret enclosure. That way, you capture the dust inside the tablet press' housing. If you have a contained tablet press that is processing a hazardous API, negative pressure is a must to ensure a controlled environment while reducing the risk of exposure to the fugitive dust.

Using a contained dust collector that is correctly sized, with the correct air-to-media ratio, will create and maintain a negative-pressure environment inside the tablet press' housing. It is also critical that you control the dust collector's reverse-pulse cleaning system. Otherwise, you risk creating neutral or positive pressure in the tablet press' housing. That can cause a containment breach, improper operation of the tablet press, and ultimately downtime to correct the situation.

5. Locate the dust collector outside the GMP space whenever feasible, especially when handling combustible dust.

In most cases, for reasons of functionality, cost, and convenience, you should locate the dust collector in an indoor maintenance or mechanical area adjacent to the Good Manufacturing Practice (GMP) space. Sometimes manufacturers place dust collectors outdoors due to space limitations. Whatever the case, if you're using explosion venting, you must calculate what explosion-vent duct lengths you require, if any, and determine how to route the ducting outdoors to a safe location. Correct inlet ductwork configuration is also a must to ensure correct and consistent airflow from the tablet press.

If you must locate the dust collector within the GMP space, the FDA's requirements will impose tight controls on the collector, just as they do on other equipment in GMP areas. If a combustible dust is involved and/or the material is hazardous, chemical suppression and isolation will usually be the default technologies, and those are typically the costliest methods of explosion protection.

6. Establish whether your dust is combustible.

Another major area of concern in dust collection involves the deflagration and explosion potential of the material being collected. The degree of risk depends on the physical characteristics of the dust relating to K_{St} —the rate of pressure rise, P_{max} —the pressure developed inside the collector during a deflagration, and minimum ignition energy (MIE). To determine whether the dust is combustible, you must perform explosibility testing in accordance with ASTM test methods as stipulated by the NFPA. Unless you find that the dust is completely inert ($K_{St} = 0$), you must incorporate some form of explosion protection into the dust-collection plan. The pharmaceutical industry typically handles materials with K_{St} values higher than those of industry in general, so the risks are higher, and the equipment decisions are more complex.

7. Identify the best type of explosion protection equipment for the application.

The most common options for the dust collector itself are an explosion vent or a chemical suppression system. Explosion venting (photo) is the most basic and

least expensive choice, but it may not be an option if the collector is located within the GMP space or centered in the building.

If explosion venting is not feasible, you likely will use chemical suppression, as noted above. You will also likely use suppression on dust collectors located in mechanical areas if they handle a hazardous or potent material, because you can't release hazardous materials directly to the atmosphere. If that's not the case, explosion venting will likely be feasible, and you will need to size the components and determine whether to vent to the outside by installing the collector outdoors or to vent the deflagration exhaust by running ductwork through the building structure to a safe location.

You must also protect the ductwork itself against explosion. If you use chemical suppression on the dust collector, you most often will use chemical isolation for the ductwork, although it is also possible to use mechanical isolation, in which fast-acting dampers and valves prevent the deflagration from traveling to the upstream equipment. All these options have limitations, and their costs can vary widely.

Given the importance and complexity of combustible-dust issues, you should seek help from an independent professional engineer who can perform a proper risk assessment and specify an explosion-protection approach that complies with NFPA requirements (or ATEX requirements in Europe), the local authority having jurisdiction (AHJ), and the requirements of your insurance carriers.

8. Ask the dust collection supplier to provide real-world destructive test data for explosive dust applications.

The NFPA uses relatively conservative textbook calculations in developing its standards for explosion-protection equipment, and justifiably so. However, the NFPA also allows you to use real-world destructive test data in place of its calculations, provided the equipment supplier's data show that the collection system's design meets a specific set of criteria for a given situation. Although it's often overlooked, the use of real-world destructive test data is permissible.

Vessel strength is an important factor in sizing explosion-protection equipment. A heavy-duty dust collector, one that has been destructively tested to demonstrate a pressure rating that is higher than basic dust collectors, will stand up better to a combustible-dust explosion. It will often allow you to use a simpler and less costly explosion-protection system and still comply with current standards. Stronger vessels also increase the options for equipment placement, potentially saving space inside your facility and reducing the need to replace the unit should an event occur. Find out if your dust-collector supplier can provide real-world test data to assist with this strategy.

9. Determine the best filter media and pleat configuration for the job.

Tablet presses generate fine, dry, and potentially hazardous dusts that require high-efficiency filtration media. Typical of these is a polyester-cellulose blend with a microfiber synthetic melt-blown laminate or nano-sized-fiber surface layer. High-efficiency filter media provide 99.99 to 99.999 percent efficiency on particles 0.5 micron and larger by weight, which is equivalent to a rating of 15 to 16 on the MERV scale. MERV stands for minimum efficiency reporting value, a standard developed by the American Society of Heating, Refrigerating, and Air-Conditioning Engineers. Since temperature and humidity are well controlled in the GMP space, fluctuations pose no challenge unless you have located your collector outdoors.

In that case, the media must be able to handle a wide range of environmental conditions. Furthermore, if the tablet press includes a clean-in-place or wash-in-place system, you might need a high-efficiency, spun-bond polyester media with an oleophobic treatment, which would enable the filters to withstand the moisture that the cleaning systems generate. A bypass damper can also reduce or eliminate moisture in the airstream before it reaches the collector, thereby allowing you to clean the press in place without shutting down the dust collector. You may also need carbon-impregnated media if the material collected is highly combustible and if the risk assessment shows that your system needs static dissipation.

Using filters with pleats, which optimize airflow through the system, is also recommended. Some cartridge filters use wide-pleat spacing that improves use of the media and creates more uniform airflow through the cartridge. The result is more efficient performance at a lower average pressure drop. Wide-pleat spacing also allows dust to release more readily during pulse cleaning. In sum, overall performance is enhanced, leading to consistent, uniform airflow and longer filter life, which reduces maintenance costs and minimizes costly shutdowns.

10. Consider air recirculation downstream of the dust collector.

If your facility is in a region where it gets very hot or cold, consider air recirculation. By recirculating heated or cooled air through the plant, the cost to replace that conditioned air decreases or disappears. The savings can be considerable. Most dust-collection equipment suppliers have cost-calculation software that enables engineers to project the savings. Inputs include the system's airflow, its geographic location, utility costs, and other factors.

When recirculating air downstream of the collector, adding a HEPA after-filter is recommended, and if you're filtering hazardous or toxic dusts, you must use one. HEPA filters provide backup protection and a final scrub of the air before it returns to the facility. Connecting a secondary filter module to the dust collection system usually requires ductwork and transition sections. But in some applications, the HEPA after-filter mounts on top of the collector and thus consumes no additional floor space. Safe-change, containment, HEPA-



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filter systems are available, and you should base the design and selection of after-filter components on a risk assessment.

If you are recirculating the air back into the facility when handling explosive dusts, you will need some type of outlet duct isolation. In some instances, an integrated HEPA filter can double as an outlet flame front arrestor if the supplier has properly tested and documented their equipment.

When used on a collector handling explosive dust, HEPA after-filters, together with the dust collector and ductwork, must comply with NFPA standards for combustible dust handling.

This article is an update to an article by David Steil, "[Ten tips for selecting cartridge dust collection equipment for tableting operations](#)," in the March 2012 issue of *Tablets & Capsules*.

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