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AIR POLLUTION CONTROL

5 Ways Dust Collectors Help Ensure a Controlled Environment when Tableting APIs

In pharmaceutical manufacturing, tablet processing generates dust that can be dangerous when it contains active pharmaceutical ingredients (APIs).

Although these airborne dust particles are often invisible to the eye, they can harm workers, reduce air quality, cross-contaminate other products and create fire and explosion hazards.

To maintain a clean and safe work environment, dusts must be captured and contained before they can be inhaled by workers, spread to other products or cause combustible dust explosions.

This eBook examines five ways cartridge-style industrial dust collectors designed for pharmaceutical tablet manufacturing help to ensure a controlled environment by safely collecting and disposing of dust.

Reduce Occupational Exposure

Regular exposure to certain types of API dust particles can irritate the eyes and skin and cause chronic health issues.

Other fine dusts can travel deep into the lungs, become embedded and cause serious respiratory conditions such as occupational asthma and even lung cancer.

Under OSHA, manufacturers must control toxic dust emissions to comply with the established permissible exposure limit (PEL) for workers. If no existing PELs are applicable, OSHA recommends the company to create, implement and measure its own environmental safety plan to comply with OSHA's general duty clause. Pharmaceutical companies also develop occupational exposure limits (OELs) for their proprietary materials.

To effectively capture and filter processing airborne particles, it's critical to understand the characteristics of the dust which can include the PEL/OEL, Kst, Pmax, MIE for each API and associated excipients.

One of the best ways to reduce workers' exposure to hazardous dusts is to install a dust collection system with high-efficiency primary and secondary cartridge-style filters. Capturing dust at its source by incorporating a hood or extraction arm into process machinery prevents it from traveling throughout the plant.

In most cases, the hazardous nature of API dust requires containment because it can't be released into the environment.

Highly potent applications can require any or all the following:

- ☑ *HEPA secondary filter system installed downstream from the dust collector to give the air a final cleaning before exhausting it to the atmosphere.*
- ☑ *Bag-in/bag-out technology for the primary filter cartridges to reduce workers' exposure to API dust during change-outs.*
- ☑ *Continuous liner technology to capture dust released from cartridges during cartridge pulse cleaning as it falls into the hopper.*

Capture Airborne Particles

Tablet presses generate fine, dry and potentially hazardous dusts.

These dusts require high-efficiency filtration media. Primary filter media should be selected for each application based on the dust particle size, flow characteristics, quantity and distribution.

An effective filter media is a polyester-cellulose blend with a microfiber synthetic melt-blown laminate or nano-sized-fiber surface layer. This high-efficiency filter media stops 99.99% of the dust at 0.5 microns and can have a 15 MERV efficiency rating (the ASHRAE standard that ranges from the lowest 1 to the highest 16).

High-efficiency filter media stops 99.99% of the dust at 0.5 microns

Filter cartridges that are pleated with wide, uniform pleats effectively release the collected dust when the system pulse cleans, keeping the airflow unrestricted for a longer period of time.

When the pleats of the filter media are tightly packed, the reverse pulse cleaning system of the dust collector will not eject the dust that has settled in between the pleats. Tightly packed pleats increase the resistance of the air through the filters, which shortens filter life.

The recommended air-to-media ratio for cartridge filters for tableting applications is 2.0 to 3.0 cubic feet of air per square foot of media. This ratio represents 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.

Using this low air-to-media range along with the proper filter design can reduce problems such as consistently high differential pressures, frequent pulse cleaning and reduced filter life which can adversely affect the tablet press.

Provide Fire and Explosion Protection

Many APIs and other pharmaceutical ingredients are combustible and can cause explosions if not handled correctly.

Tableting applications that generate combustible dusts require extra measures to protect against explosions within the production area and inside the dust collector itself. To reduce this risk, dust collectors shall be fitted with an explosion vent or a chemical suppression system, depending on the application and dust characteristics.

The most cost-effective option is the explosion vent. However, the vent is not always possible if the collector is located indoors without access to an outside wall or without ability to vent through the ceiling.

Chemical suppression with isolation is used when:

- *The collector is in a mechanical area that is processing a hazardous material that can't be released directly into the atmosphere.*
- *There is no direct access to an outside wall or ceiling location where the explosion vent ducting can protrude.*

If an explosion vent is feasible, you will then determine what size and how many are required, the location where the dust collector will be placed and how much explosion vent ducting (if any) will be required. The inlet and possibly the outlet ductwork must also be protected against the possibility of an explosion as determined by a risk assessment.

Because combustible dust issues are very complex, and incidents can be devastating, it is important to use a qualified and reputable supplier with proper documentation. That way you are certain that your facility complies with National Fire Protection Association standards and the requirements of your local fire marshal and insurance carriers.

Inlet and possibly outlet ductwork must also be protected against the possibility of an explosion

Decrease Cross-Contamination Risk

Cross-contamination is a serious challenge for solid-dose pharmaceutical manufacturers.

It's a particular concern for highly potent applications and in multiproduct manufacturing facilities. Without proper extraction and a dust collection system, particles will settle on floors, equipment and other surfaces where they are difficult to remove.

Traditional cleaning products like mops, brooms, compressed air and standard vacuum cleaners can't effectively collect all the airborne and settled dust from the processing area. Even worse, they tend to kick the dust up into the air, redistributing it to other parts of the plant and potentially contaminating other products.

A single dust collector placed in a room collecting ambient airborne ingredients in the work area isn't good enough either. With this design, much of the dust settles in the work area before reaching the collector, making cross-contamination inevitable.

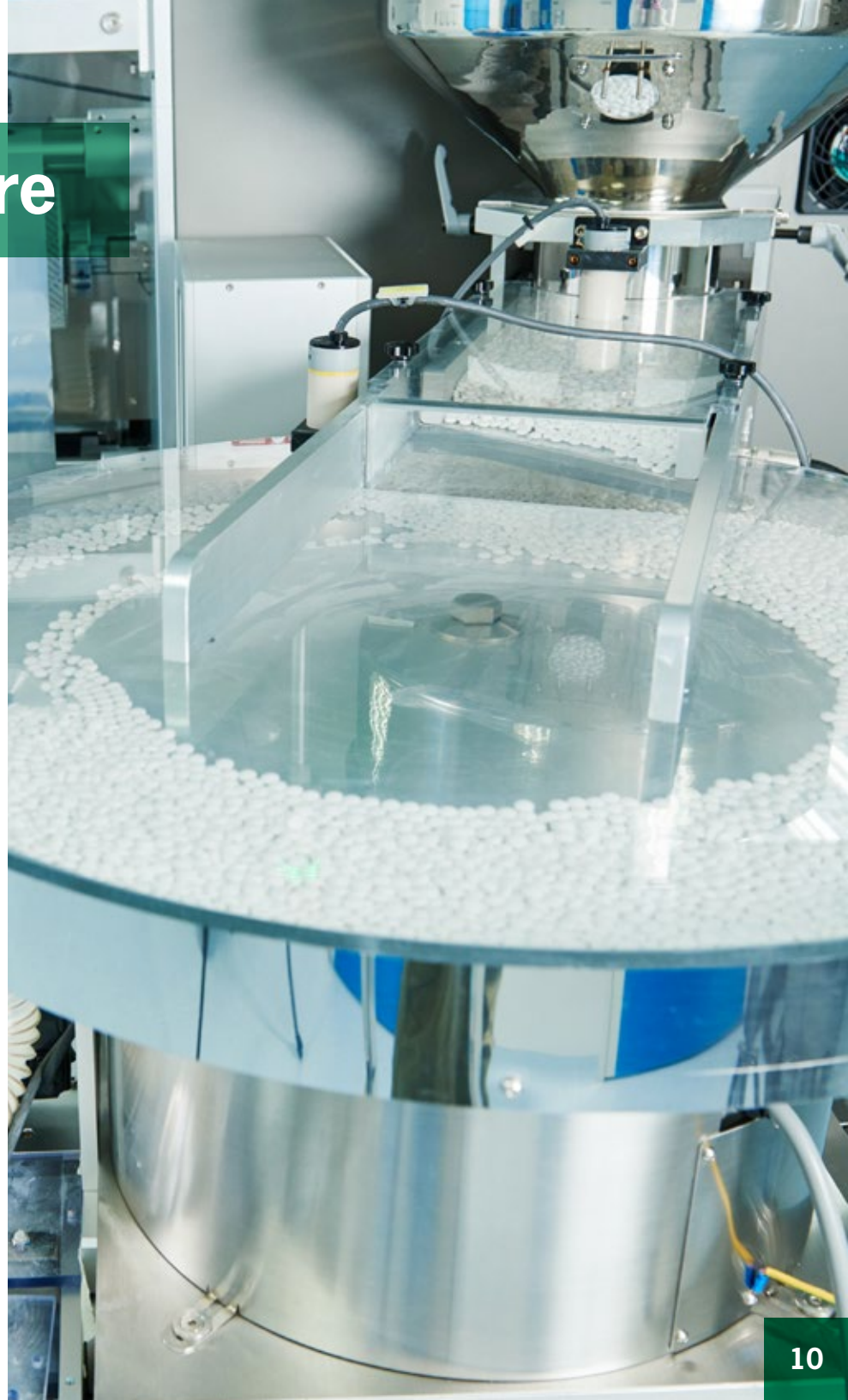
A proven engineering control to prevent dust particles from cross-contaminating is to use a quality industrial dust collection system that collects particles at the source using properly designed extraction hoods. Dust collectors should be placed in a location that facilitates proper operation and maintenance while properly addressing both containment and NFPA requirements. This is typically a mechanical area or space adjacent to the processing suite. Several other design features come into play to control cross-contamination, including the filter change process (bag-in/bag-out) and waste material handling (continuous liner technology) coming from the dust collector.

Maintain Negative Pressure

In tableting 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.

This means 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, proper negative pressure is necessary to ensure a controlled environment while reducing the risk of exposure to the fugitive dust.

Using a contained dust collector that is properly sized, with the correct air-to-media ratio, will create and maintain a negative pressure environment inside the housing of the tablet press. 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.



Controlling dusts generated in pharmaceutical manufacturing and processing is vital.

That's because airborne particles can seriously harm employee health, cross-contaminate other products and cause devastating explosions.

A high-efficiency dust collector designed specifically for the processing application is an accepted and proven engineering control that will filter hazardous contaminants and combustible dusts to make indoor environments safer. With the help of engineering consultants and reputable and experienced equipment suppliers, solid dose manufacturing facilities can minimize risk factors and maximize dust safety requirements and product quality.

For further information, contact **800-479-6801** or **870-933-8048**, email **filterman@camfil.com** or visit **camfilapc.com**.

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