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White Paper

A best practice approach to handling waste powder from OSD manufacturing

The loss of active pharmaceutical ingredients (APIs) during oral solid dosage (OSD) production is inevitable. Managing material loss is vital for reasons of safety, regulatory compliance, and cost.

Commonly, dust management strategies employ filter-based collection technologies. However, while such systems can be effective, they are costly to maintain and can often result in significant material waste.

Cyclone technology can address these challenges by localizing dust capture, preventing filter blockage and even enabling pharmaceutical manufacturers to recover lost APIs in a cost-effective and compliant manner with zero maintenance costs.

Introduction

Managing the dust generated during powder processing is important in all types of manufacturing. The potential for dust explosions is well documented, and most industries set limits on the amount of particulate material to which operators can be exposed [1].

In pharmaceutical production, the need to contain and manage dust is particularly important, for a number of reasons [2]. Dust produced when APIs are processed can be hazardous, especially some of the highly potent actives that are used to produce cancer drugs. Numerous studies illustrate the health risks associated with inhalation in the pharmaceutical manufacturing environment [3, 4].

The strict quality requirements imposed on pharmaceutical manufacturers also encourage effective dust management. The U.S. Food and Drug Administration (FDA) and other regulatory agencies set rules on yields and drug potency, which require that all API that is lost as dust during processing is accounted for [5].

Furthermore, while the cost of APIs varies considerably, in general they are expensive [6]. It follows, therefore, that pharmaceutical manufacturers are keen to minimize waste and — in circumstances where protocol permits — even return material to production processes in less regulated applications.

This white paper will discuss how pharmaceutical manufacturers have historically managed dust generated during the production process historically and explain why cyclone technology is able to revolutionize the process.

Powder Loss: the problem

The physical processes applied to APIs during pharmaceutical production generate dust, irrespective of the type of dosage form being manufactured [7, 8].

For example, the stress forces applied during tablet compression inevitably cause some of the API to be lost [9]. Similarly, a proportion of API is always lost as dust during encapsulation and filling steps [10].

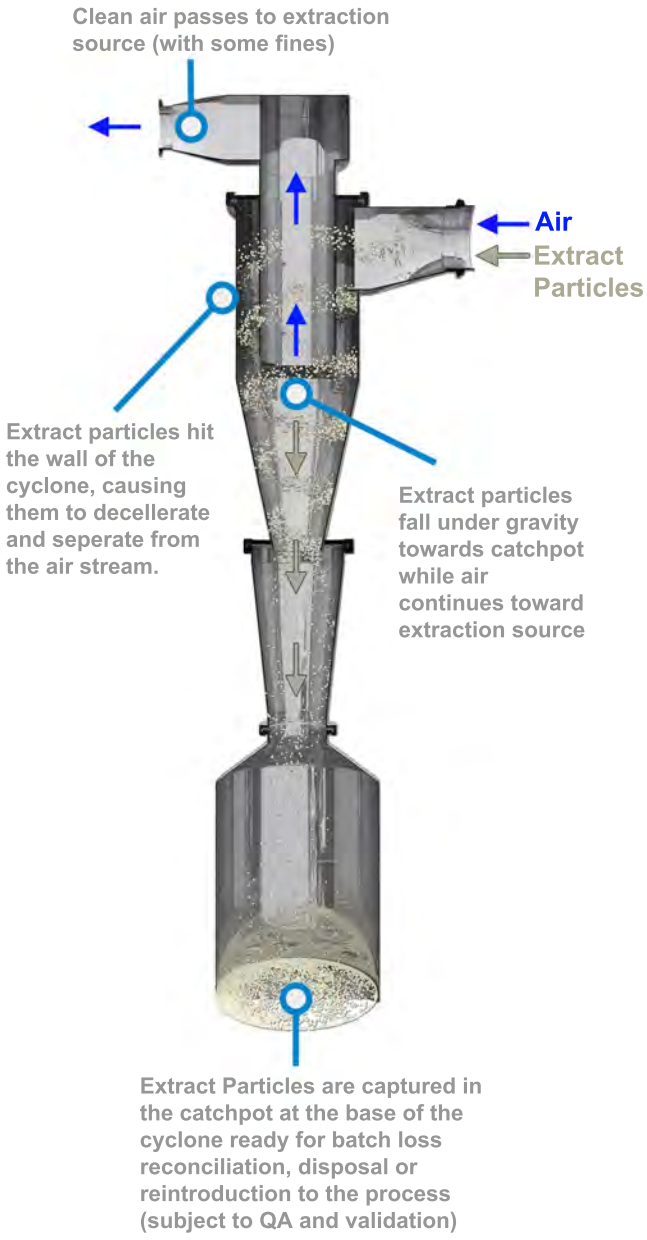
Cyclone Technology: the solution

Traditionally API dust from pharmaceutical processes such as compression or encapsulation has been removed from the process environment using vacuum ventilation systems that employ filters to prevent material from being released.

While vacuum-based ventilation systems are effective at limiting operator exposure to hazardous material, they have some significant drawbacks in terms of waste, cost, and regulatory compliance. For example, filter-based recovery systems are effective at preventing dust generated during API processing from being released into the environment. However, such filters can rapidly become clogged — or blinded — by API and binder particles. This clogging negatively impacts airflow, causing a reduction in pressure.

As a result, filters need to be regularly replaced, which can be an expensive, technically challenging, and time-consuming process, resulting in significant production delays.
Powder recovery systems such as the Hanningfield Uni-Dust cyclone series do not use filters. Instead, the cyclones use vortex separation.

Cyclone technology does not require filters, instead utilizing vortex separation to perform particle capture. Vortex separation relies upon a helical rotating air flow in a conical chamber, or cyclone. Any particles circulating in the airstream have too much inertia to follow the airstream and are ejected, hitting the exterior wall of the unit. This causes the API dust particles that hit the outside wall of the cyclone and decelerate, causing them to fall to the foot of the cyclone, where the catchpot is located.



No Maintenance

In addition to eliminating filter replacement costs, cyclone technology helps maintain correct airflow and pressure in the extraction system. This ensures there is no risk that operators will be exposed to potentially hazardous dust, which can occur when filters blind and dust extraction effectiveness decreases.

With no filters, no moving parts and no mechanical complications, cyclones offer a maintenance free solution with an ever-increasing return on investment.

Reconciliation

One major advantage of cyclone technology over traditional dust management systems is that they are designed to be installed inside the process room.

It is common for pharmaceutical manufacturing operations to use a centralized extraction system to remove dust from multiple processing environments. In such setups it is often difficult to determine the origin of any API that is recovered with any degree of integrity, much less use it for batch reconciliation purposes.

In contrast, cyclone systems are suitable for integration into existing extraction lines between the process machine and the local exhaust ventilation line. Hence by placing the cyclone inside the process room, material integrity is guaranteed as the recovered API dust never leaves the room. It is therefore much more straightforward to determine its origin and use it to meet reconciliation requirements.

The in-process room integration also minimizes the risk that an API from one production process will contaminate another production process in a multi-product facility.

Containment

Another major challenge facing pharmaceutical manufacturers is not simply about preventing the material being released into the environment.

The FDA current good manufacturing practices (cGMPs) guidance recommends that pharmaceutical producers account for API lost during production through a process known as batch reconciliation [11].

The idea is to ensure each OSD form meets potency specifications by comparing theoretical yields with actual yields at each stage of the manufacturing process. Any difference in drug components, including APIs, which is observed throughout the manufacturing process must be explained.

Cyclones can both improve and simplify batch reconciliation by allowing for the precise measurement of the weight of the recovered API. The collected material can be safely and easily disposed of or, if manufacturing protocols allow, returned to the production process. This is another significant advantage for manufacturers, as it minimizes API loss.

Example Applications

Compression Machines

Encapsulation Machines

Conclusion

The creation of dust during the pharmaceutical manufacturing process is inevitable. Regulations designed to ensure operator safety and drug quality mean pharmaceutical manufacturers must adopt a best practice approach to recovering and accounting for API material that is lost as dust.

While filtration based dust collection technologies can go some way to meeting safety and containment requirements, such systems make batch reconciliation almost impossible. Furthermore, filtration-based systems require regular, expensive, and technical challenging maintenance that can result in considerable manufacturing downtime.

Cyclones can overcome the problems associated with traditional dust management and collection technologies. With higher efficiency, lower operation costs and improved batch reconciliation integrity, cyclone technology offers pharmaceutical manufacturers measurable and meaningful advantages. These advantages highlight cyclone technology as a best practice approach to the handling and management of dust from OSD processing.

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Video: http://www.hanningfield.com/cyclone-3d/

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