



Experts in Solid  
Dosage Technology

A Division of *Spraying Systems Co.*

SOURCE: [FLUIDAIRINC.COM/BLOG](https://fluidairinc.com/blog)

## 5 Important Maintenance Areas to... **Increase Equipment Reliability**

Within the world of Oral Solid Dosage, the medications that command the highest premium tend to be the most difficult to process with predictably rare ingredients. These products often require the use of high-shear granulators, mills and Wurster coating fluid beds. These machines are workhorses, often running for decades while requiring only minimal maintenance. When they do fail, however, the result can be the rejection of not just one, but several very high value batches. To help you prevent such failures, here are the five most common areas that can be easily prevented through proper inspection.

### SYSTEM FILTERS

All outside air is considered to be dirty for the purposes of fluid bed processing. All fluid beds have at least an inlet HEPA filter. On a lab scale fluid bed, this may be just a drum filter inside the machine. On a pilot or production scale unit, this would be the last of a series of pleated filters in an air handling unit. Regardless of size and style, these filters should be inspected on a monthly basis for machines that are being run regularly. Inspection of these filters could prevent catastrophic failure, like the possibility of releasing contaminants into the process, without warning to the operators.

The next filter in the system is the bowl filter plate. The filter plate allows the air to flow into the product bowl while minimizing the transfer of product into the plenum. Regardless of the style of filter plate, some product will always sift through it. It's important to carefully inspect the filter plate every time it is washed to ensure no product is captured within the screen, to prevent possible cross contamination.

The chamber filter bags and cartridge filters are the most abused portion of any fluid bed system. They are wetted, heated, dried, shrunk, stretched, scraped and tumbled in washing machines. It is failures in these bags that lead to the highest percentage of product yield loss. As filter bags become blinded by product, the increased vacuum places huge stresses on the seams. It is important for the seams to be carefully inspected every time the bags are washed to ensure that there are no seam failures. Filter cartridges, while less likely

to catastrophically fail, are more likely to be damaged in cleaning. They have a PTFE coating to reduce product adherence, but that coating is easily scraped away.

Always gently used compressed air to blow product out from the inside of the filter and use low pressure water to rinse the

surface. To ensure systems continue to run efficiently please order filter bags and cartridges well in advance, we recommend having a few spares on hand as lead times are often a few weeks. When ordering, remember to ask if filter bags are made 100% with FDA product, contact approved and lot traceable materials - Fluid Air filter bags always are.

Outlet HEPA filters are designed to prevent the dust that inevitably migrates past the chamber filters from getting into the atmosphere. Outside the building, this could be an EPA issue. Inside the building, it could be a workplace safety issue. The outlet HEPAs should be inspected with the same care and frequency as the inlet HEPA filters.

### GASKETS & SEALS

Over time, all gaskets and seals will become dry, crack and crumble. The seals with the most likely impact on product are the agitator seal in a fluid bed dryer and the impeller and chopper seals in a high-shear granulator;

all three of these locations are extremely high wear, product contact areas. The operators often inspect the agitator and impeller seals as a part of their cleaning process, but they rarely remove the chopper to clean behind it and inspect the seal. This area may retain old product which may create a cross-contamination risk and rapidly abrade the shaft seal. The failed seal, hidden behind the chopper, may not be noticed for several product batches. It's imperative that the chopper be removed every time the machine is cleaned.

The next most common failures are gaskets on the high shear granulator lid, the fluid bed chamber and bowl, and the fluid bed plenum inlet seal. These items should be visually inspected by the operators every time the equipment is used.

Just like filter bags, gaskets and seals should be ordered and spares should be in house to prevent integral machines being down for maintenance.

## HYDRAULIC OIL

High-shear granulators, fluid beds, and tote lifts use hydraulic power for their operation. Although the hydraulic power packs are out of sight, it is vital that they be part of any planned maintenance schedule. Maintenance personnel should observe the hydraulic power packs while the equipment is being operated. The oil in the units should be tan/brown. The temperature should stay below 140° F and the oil level should be unchanged. If the oil level is low, there is likely a leak which must be located and fixed. When adding oil to a system, cleanliness is paramount. New oil, in sealed five gallon buckets does not meet the cleanliness requirements. It should be pumped through a filter and into the reservoir tank. We suggest changing the system filter once per year and inspecting the oil every six months.

## NOZZLES

Nozzles are often disassembled for cleaning and tossed into plastic bins, without regard for their extremely sensitive nature. Air atomizing nozzle spray setups consist of two main components: the air cap and the fluid cap. In both components, the sharp machined edges of the liquid orifice and the air annulus grab the liquid droplets, shear and spread them to form the spray pattern. Scratches caused by mishandling will create additional sharp edges and grab more liquid causing the spray pattern to become inconsistent. This is especially important in Wurster coating because

some product will receive a heavy coating and may begin to agglomerate while other product receives only partial coating. Nozzles must be treated with the same care as any calibrated lab equipment. Operators should be trained to carefully inspect nozzle setups during assembly. Setups that are damaged should be replaced.

## CYLINDERS

Pneumatic and hydraulic cylinders are used in fluid beds, high-shear granulators and tote lifts. The less cylinders are used, the more maintenance attention they require. If equipment is sitting unused, the film of oil on a cylinder can dry damaging the cylinder seals as they are dragged over the dry metal surface. It is important that if equipment is idle, maintenance is scheduled to stroke the cylinders as often as once a month. The filter lift cylinder in a fluid bed has an extremely long stroke and is often left in the extended position for long periods of time. When in operation, it is expected to hold the filter bag up without drifting. If it drifts, it could cause impact on the product, damage top spray granulation arms, or, in extreme cases, become a safety issue for operators. We recommend that the holding capability of filter bag cylinders be checked during 6 month planned maintenance intervals.

*Here at Fluid Air, we have an extensive amount of experience in solid dosage processing equipment. Our Field Engineering team consists of engineers who are experts in all areas of the equipment. Our Field Engineering team is available to provide on-site equipment operation, maintenance and process training tailored for your facility. They are also available to perform planned maintenance inspections of your equipment providing the highest level of care for your equipment while freeing your maintenance staff to focus on the day to day tasks required to keep your operation running smoothly. Regardless of your needs, Fluid Air can partner with you to fulfill them.*