Eight tips for controlling bacteria levels in rewet agglomerated powders

In my last column (January 2018 PBE), I discussed agglomeration as an integrated step of the total powder process when manufacturing powder with good flowability, bulk density, and mixability. Of greater importance when agglomerating materials for the high-care, high-sanitary-requirement markets, such as pharmaceuticals, low-count specialty ingredients, and infant formula, is pathogenic bacteria control. This is especially true when using rewet agglomeration, a process that’s significantly more challenging than interspray or once-through agglomeration since rewetting requires reintroducing water into the fluid bed and processing at temperatures favorable for microbiological growth. Rewet agglomeration is used to prepare materials for tabletting in the pharmaceutical industry; to create free-flowing, dustless drink mixes in the food and beverage industry; and to create easy-to-mix dairy and soy protein-based blends for the nutritionals industry. Because of the bacteria issue, however, some industries — for instance the infant formula industry — have gradually been moving away from rewet agglomeration. Unfortunately, this reduces a manufacturer’s ability to take advantage of dry blending to incorporate heat-sensitive ingredients or maximize production capacity.

While no powder product can be made commercially sterile, in this column I’ll offer recommendations that will minimize the risk of pathogenic bacteria contamination by the rewet agglomeration process.

Tip #1: Start with a base powder with a low-microbiological count.

This may seem like a statement of the obvious, but similar to the way that spray drying won’t improve the solubility of milk-based powders, rewet agglomeration won’t reduce the microbiological count of the starting powder. The goal is not to add to the count. If the agglomerator is directly coupled to the spray dryer, then the existing procedures in place will be adequate. If the agglomerator is a separate unit operation within the plant, you must ensure that the intermediate powder handling steps include the proper safeguards for hygiene and microbiological control. If the starting powder comes from an outside source, either as a full formula or a base with blend components, the challenge is significantly greater. Storage of the incoming materials in hot rooms will reduce bacterial counts, but the high thermal resistance of the bacteria in low-moisture environments makes this approach unreasonable for large manufacturing operations. In these cases, the best approach is to work closely with the supplier to ensure that proper policies and procedures are in place at its manufacturing facility.

Tip #2: Use sterile ingredients.

Anything that comes into direct contact with the powder is...
considered an ingredient. This includes the fluid-bed air supply, the binder, and the atomizing air used in the spray nozzles. The fluid-bed air supply should be dehumidified, reheated to the necessary temperature, and HEPA-filtered with a minimum efficiency of 99.97 percent down to a 0.3-micron particle. If the binder is water, it should be softened and sterile-filtered with a 0.2-micron filter. If the binder is a solution of a carbohydrate or product, it should be kept at a temperature of at least 145°F, and the binder tank and line must be cleaned at least once per day. The atomizing air should be oil-free, dehumidified to a -40°F dew point, heated to a minimum of 150°F, and sterile-filtered with a 0.2-micron filter.

Tip #3: Employ adequate and validated cleaning procedures for equipment and piping systems.

Again, this is a statement of the obvious. Cleaning procedures for the rewet agglomeration system should include the fluid bed itself, the cyclone, the exhaust ducting, the powder transport lines, the binder solution system, the spray bars, and the process air supply ducting. The latter is often missed and can be contaminated with powder during an abnormal shutdown situation where air flows backward from the fluid bed. If a baghouse is used for final emissions control, it should either be equipped with a clean-in-place (CIP) system or have bypass ducting installed for cleaning. Finally, the cleaning process must include an adequate dry-out step after the process.

Tip #4: Test the rewet system at operating conditions before starting production.

The two most critical control parameters for a rewet agglomeration process are the binder ratio (water-to-powder) and the binder distribution across the powder surfaces. Improper water distribution can lead to poor agglomeration and lump formation. The wet lumps will accumulate in the bed, typically at the weir used to control the bed level, and create an ideal environment for microbiological growth. Water distribution across the spray bar should be checked quantitatively and qualitatively. Quantitatively, a variance in flow rate across the nozzles of less than 15 percent is acceptable. Qualitatively, the sprays should be fully developed and uniform. Figure 1 shows two spray bars — one with poor water distribution and one with good water distribution.

Tip #5: Control buildup within the agglomerator.

Controlling material deposits in the rewet agglomerator is important since the moisture levels in these deposits is generally high enough to support bacterial growth. Deposits can form on the spray bars due to overspray from an upstream bar, a partial nozzle blockage, or the spray bar surface temperature being below the dew point temperature in the rewetting zone. Deposits on the agglomerator’s chamber walls and in the exhaust duct can occur from operating at too high a relative humidity. One can either complete studies to develop the sorption isotherms for the powder being agglomerated or experimentally determine relative humidity limits by observing chamber-wall conditions during operation. Once the limit is identified, the relative humidity in the chamber can be controlled with a simple water balance and adjustment of the exhaust-air temperature. Raising the exhaust temperature is better than lowering the binder addition rate as the latter will have an adverse effect on your agglomerate’s quality.

Tip #6: Monitor the operation.

Routine monitoring of your agglomeration operation is very important. Thoroughly understanding the process will enable you to diagnose and correct small problems before they can cause serious quality issues. Also monitor your end product. In the final agglomerated powder, observe and record its moisture, bulk density, particle size (mean, percentage of overs, percentage of fines), and mixability. If the powder’s physical properties change without a change in the incoming powder quality or the operating parameters of the agglomerator, there’s a good chance of a water distribution issue. To avoid these problems, check the chamber for buildup, ideally through a sight glass. The chamber exhaust relative humidity should be estimated by performing a water balance.

Check the powder bed’s fluidization hourly, through a sight glass if possible. Poorly mixed areas, or “dead spots,” will lead to lump formation and, in the worst cases, can lead to total blockage of the fluid bed. Typically, a dead spot results from a partial blockage of the fluid bed’s air-distribution plate and cannot be remedied with a system cleaning.
Normally, a scalping sifter is installed after the rewet agglomerator to catch oversized agglomerates and lumps. Inspecting the sifter’s overs can tell you if there’s a nozzle problem or lumps are being formed in the bed. If small lumps are found in the overs, a good practice is to slightly open or “crack” the final weir every hour to let any lumps accumulating behind the weir to pass out of the bed and into the scrap drum. Remember, these lumps have a high water activity and are at an ideal temperature for bacterial growth.

**Tip #7: Minimize interventions.**

Most of the bacterial contaminations in high-care powders come from interventions—that is, opening the process system to the room environment to inspect, clear blockages, or sample. Designing agglomeration vessels with adequate sight glasses and lights for inspections without having to open the system is important. Similarly, sterile samplers should be included in the process design. If an intervention can’t be avoided, proper procedures should be in place to minimize contamination risk. These procedures can include special gowning, hairnets, beard covers, and sanitized rubber gloves and tools for operators. The pressure inside the agglomeration chamber should be increased to slightly positive to prevent air outside the chamber from flowing into the process.

**Tip #8: Protect downstream processes.**

Perhaps the most important function of the scalping sifter after the rewet agglomerator is to keep wet lumps out of the downstream powder handling systems. In large plants, pneumatic transport systems convey powder to large storage silos. These systems are seldom wet-cleaned for the obvious reason of eliminating the potential for water ingress. Wet lumps will accumulate in the large powder hoppers and eventually break up and sporadically release bacteria into the process. These sporadic high microbiological counts are very difficult to trace and troubleshoot.

**Summary**

The rewet agglomeration process is challenging for manufacturers, especially in high-care markets, since it requires reintroducing water into the fluid bed and processing at favorable temperatures for microbiological growth. While no powder product can be made commercially sterile by a means that will be accepted by consumers, following the proper policies and procedures will help minimize pathogenic bacteria contamination risk when implementing a rewet agglomeration process.

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**For further reading**

Find more information on this topic in articles listed under “Agglomeration” in Powder and Bulk Engineering’s article index (in the December 2017 issue and at www.powderbulk.com).

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If you have a question or an agglomeration topic you’d like to see addressed here, send it to the editor at jbrenny@cscpub.com.