Milling of Heat Sensitive Pharmaceutical Powders

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Introduction

Heat generation during the milling process is a challenge that customers across all process disciplines will have experienced. The effect of heat generation on material during milling can result in damaged tooling, ruined batches and, in severe cases, can even cause an explosion.

Heat is predominately generated within the gearbox and the screen located in the machine housing. The temperature of these parts increases as they run for long periods of time and as a result of the natural generation of heat from revolutions of the gearbox and impeller.

The Problem

Product Quality

Heat generation during milling first and foremost can affect product quality and ruin batches of highly valuable APIs. Materials that are very sensitive to heat, as a result of containing high levels of fat or oils for example, can be affected by even the smallest of temperature increases during production. As such, it is crucial to keep temperature rises as low as possible and even remove them as a variable during production.

Tooling

If the wrong tooling is selected, screens can break and impellers can be damaged. In severe cases, a blinded screen can even cause damage to the gearbox as the motor works harder and harder attempting to mill the product. It is vital that material passes through the screen easily and quickly, while still achieving the PSD the customer requires.

If material remains in the screen too long, it is exposed to more heat, which increases with every revolution of the impeller. When a machine is running at 3600RPM, it is easy to see how a particle can quickly spoil from remaining in the screen for a long period of time (see figure 1).

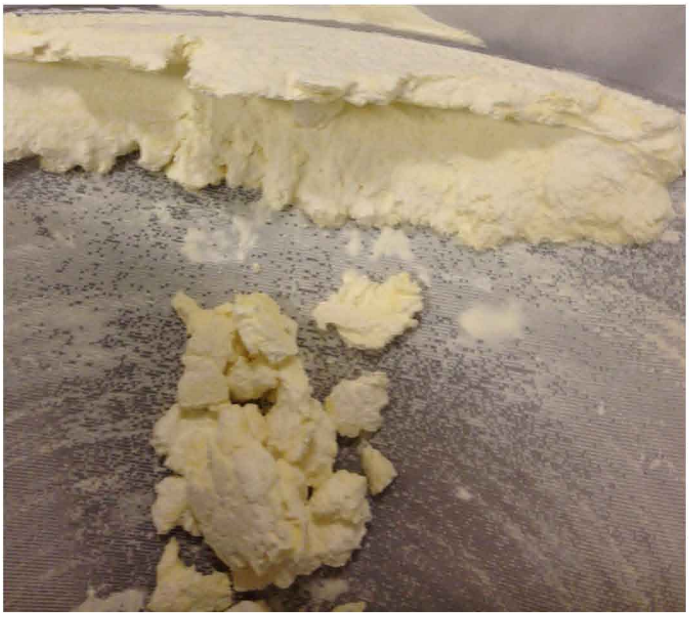

Figure 1: Screen blocked with hardened lactose powder

The Solution

If you are faced with a heat sensitive product, one of the first steps is selecting the correct hole size for your material as this ensures that the product passes quickly through the screen. Not only does this give the customer a better particle size, tighter PSD and less fines, but also reduces the chance the particle will be affected by heat from remaining in the screen too long.

A second step, which may be suggested based on your application or following trials, is the use of an Over-Driven conical mill instead of its Under-Driven counterpart. As the impeller of an over driven mill is powered by a belt drive from above, there is little to no heat generation to the screen or impeller.

For customers with more sensitive products, or products that have the potential to explode, there are some additional options available.

A ‘cooling jacket’ can be retrofitted to the outside of the machine housing. A constant stream of cold water is passed through the cooling jacket bringing the standing temperature of the machine housing down and keeping it low even during the milling process. The temperature of the water can be changed easily to bring the machine housing down to an acceptable level where the customer finds the most optimum milling conditions. A cooling jacket should ensure the screen and impeller do not rise in temperature, and as long as water temperature can be changed, the housing can be cooled in line with any rises in temperature during milling.

Figure 2: Temperature probe located against screen of a conical mill

A final option to give the customer more confidence in their control over any temperature increase, is the addition of a temperature probe to the machine housing (see figure 2). A temperature probe can be located against the screen and/or gearbox, providing a cost effective and easy way to monitor temperature increases which may affect product quality or operator safety. When the surface temperature of the screen or gearbox reaches a level deemed potentially hazardous, the machine will cut out and the impeller will stop within three seconds.

When a product is very sensitive, even the smallest amount of time can cause irreversible damage, so this fast reaction time is crucial. As all products are different, customers can request the pre-set cut out temperature of the probe, giving each customer greater control over their own process.

Conclusion

There is no doubt that the milling of heat sensitive products can be a challenge and present difficulties in production. However, with the proper steps taken and executed, heat generation can be brought under control, minimising risk to the product and most importantly the operator.

By working closely with the supplier, a solution including as many options as necessary can ensure a working system that is both productive and safe.