tablet coating

Some advantages of non-perforated coating pans

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This article briefly describes some advantages of using non-perforated pans to coat tablets and pellets.

Most tablet coating systems in the pharmaceutical industry use perforated coating pans, and most pellet manufacturing (pellet coating) systems use fluid-bed processors, which mix, moisten, and agglomerate powders or apply successive layers of API to a core (powder layering). This article describes how non-perforated coating pans (also called solid-wall pans) can improve tablet coating and powder layering operations.

While perforated pans are popular today, the first coating systems used non-perforated pans. As the pan rotated, low volumes of air circulated through the mouth of the pan in an open environment. The systems consumed little air and energy, and the smooth pan surface was easy to clean. They were a good choice for applications where controlling cost was important. Furthermore, non-perforated pans were well suited to applying sugar coatings and organic solvent-based coatings, because neither required high volumes of air. However, the industry perceived that the pans were limited to these applications and, as coating processes evolved, the pans fell out of favor, mainly because they were not suitable for applying aqueous coatings or for processing hydroscopic products, which require high drying efficiency. As a result, equipment manufacturers began building coating systems that used perforated pans.

Perforated pans

Perforated pans became popular when pharmaceutical manufacturers switched from organic solvent-based coatings to aqueous coatings. The switch was a natural response to the volatility of organic solvents; the high cost of explosion-proof installations, which became necessary in the 1980s to account for that volatility; and the introduction of the Clean Air Act and its amendments in the early 1990s. Those laws mandated a reduction in the emissions of volatile organic compounds. Since that time, many of the products and processes registered with the FDA have referenced coating systems that use perforated pans, then the best technology to apply aqueous coatings. It is notoriously difficult to switch coating systems after registration and, since perforated pans could coat large volumes of product, perforated pans became dominant.

In a typical film coating operation with a perforated pan, spray guns apply the coating to the product while the pan rotates, exposing each side of the product to promote coating uniformity. At the same time, air enters the pan enclosure, typically from the 45-degree position (upper right) and flows diagonally, passing through the product bed and thus drying the coating. The humid air that results then exits the pan through the perforations in the pan's circumference, often at the 225-degree position (lower left). Tablet coating systems with perforated pans use large volumes of air for high-efficiency drying and provide repeatable results. However, their airflow can interfere with spray patterns, and the pan perforations make them difficult to clean because you can never be sure that each perforation is clean inside and underneath. Furthermore, the pans lack flexibility in the sense that they cannot easily coat different products and batch sizes.

Today's non-perforated pans

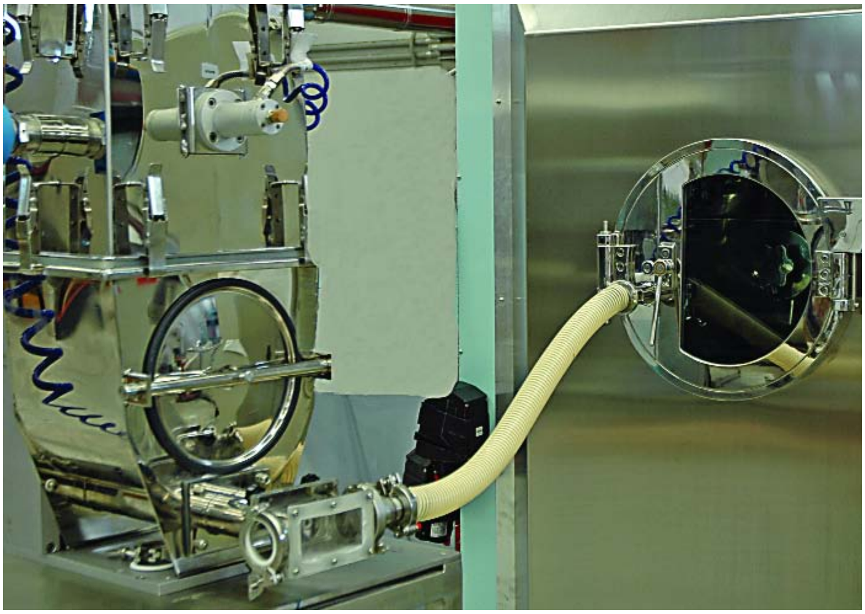
To improve the drying and heat exchange that non-perforated pans provide, equipment manufacturers created systems that added "immersed swords," which are perforated diffusers. One system [1] used two swords, one to inject air and one to exhaust air. Another system [2] injected air from the back of the pan and exhausted it through the swords. However, the new technology wasn't fool-proof: High-velocity airflow occasionally caused products to stick to the sword surfaces.

This mixing baffle [5] has a unique shape that offers gentle yet efficient mixing in a non-perforated pan.

My company sought to improve non-perforated pans by creating a different system to blow and exhaust air through a high-volume air diffuser-exhauster [3]. It divided the back of the pan into rotating and non-rotating sections, allowing all the ducts and hoses supplying drying air, coating solutions, and atomizing air (as well as wires connecting to sensors), to be routed through the non-rotating section. The design also included an adjustable air guide comprising two concentric tubes, one for inlet air and one for exhaust air. You can use SUPAC [4] to help ease the switch from perforated to non-perforated pans.

Baffles. As in perforated pans, baffles are important in non-perforated pans. Baffle design and configuration play a role in mixing the product and thus they influence how uniformly the system coats and dries the product. The photo on page 41 shows one type of baffle [5] that offers gentle yet efficient mixing due to its unique shape. If mixing is gentle, the pan can rotate quickly without damaging the product, which maximizes the rate of coating application and thus shortens processing time. With so many different types of mixing baffles available, evaluate them carefully, taking into account their shape and mixing efficiency when you analyze the overall coating system. You can also conduct a test by adding tablets of a different color to an existing rotating batch to evaluate how efficiently the baffles mix the product.

Air turbulence. Another factor that influences how quickly and thoroughly a coating system can dry a product is air turbulence. Air turbulence is inversely proportional to the product's distance from the air-induction port (also known as the blowing point). In other words, all other factors being equal, the closer the product is to the air-induction port, the more quickly and efficiently the system dries the product. Using an adjustable air-induction port that is centered over the product bed gives you precise control over air direction and lets you select the point at which the air contacts the product.



Powder layering in a perforated pan requires a dosing screw to dose powder and a pneumatic system to transfer powder into the pan.

Another advantage of non-perforated pans is their ability to coat virtually any size of product (from sugar crystals to 50-millimeter-diameter chewing gum cores) without modifying the equipment. They can also apply aqueous films, highly viscous solutions (such as sugar syrup), and powders. Batch size is also flexible, and batch size doesn't strongly influence product loss or air usage. The exception is coating pans with immersed swords, which should have a product volume large enough to cover the perforations in the swords. My company guarantees satisfactory performance at batch sizes that use as little as 15 percent of maximum capacity. And unlike perforated pans, non-perforated pans are easy to clean (including WIP) and allow you to coat and polish products in the same vessel. They are also generally cheaper than systems that use perforated pans and cheaper than fluid-bed processors.

Coating examples

To demonstrate some of the advantages of non-perforated pans cited in this article, my company conducted two trials in a lab-scale coater [6].

First trial. In this trial, we coated and dried 40 kilograms of 415-milligram tablets. The pan rotated at 8 to 10 rpm, while product temperature was 42°C, and inlet air temperature was 70°C. After coating, the average tablet weight was 427.07 milligrams, a gain of 2.9 percent. The process lasted 65 minutes, and total product loss was 3 percent.

Second trial. In this trial, we coated a 23.160-kilogram batch of sugar spheres with ibuprofen. The pan rotated at 10 rpm, while product temperature was 36°C, and inlet-air temperature was 50°C. After coating, the batch weighed 26.949 kilograms, a 16 percent gain. The process lasted 186 minutes, and total product loss was 2 percent.

The small product losses in these trials show that most of the material dosed into the process coated the tablet or pellet. Had we conducted the tablet coating trial using a perforated pan, product loss would likely have been as high as 15 percent. It's impossible to make a similar comparison for the second trial, since perforated pans cannot perform that process because the small powder particles would be lost through the perforations.

Conclusion

Although the industry has long favored perforated pans for tablet coating and fluid-bed processors for pellet manufacturing, today's non-perforated pans offer greater flexibility than before thanks to better baffles and air systems. Drying efficiency is comparable to that of perforated pans, and cleaning is easier. For powder layering, non-perforated pans provide better coating uniformity, rounder pellets, and higher accuracy than fluid-bed processors. *T&C*

References

1. A previous version of Nicomac's coating system
2. IMA GS coating system
3. Nicomac coating system
4. FDA guidance for Scale-Up and Postapproval Changes (SUPAC) of immediate-release solid oral dosage forms. See www.fda.gov/cder/guidance/supac.htm. SUPAC is designed to lower the regulatory burden associated with alterations in components and composition, manufacturing site, scale-up or scale-down, and manufacturing (process and equipment) of a marketed product.
5. 3D Nicomac shark fin baffles
6. A 50-kilogram Nicomac LAB 50

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