To succeed in today’s demanding pharmaceutical manufacturing environment, a tablet coating process must be as efficient as possible. This means that each step or aspect of the coating process must be optimized to suit the requirements of the specific product being coated, including how the tablets are fed into and discharged from the coater and how the coater is cleaned between batches or products. Optimizing each of these steps will minimize process time and ensure high-quality coated tablets despite variations in batch size or the depth of the tablet bed in the coating drum.

Pharmaceutical manufacturers face high demands for both cost efficiency and flexibility. This article discusses ways modern production coating equipment addresses these demands without sacrificing coating quality, including speeding up tablet discharge, easily adapting to process changes, and providing automated, effective cleaning.

IMPROVING COST EFFICIENCY AND FLEXIBILITY IN TABLET COATING PROCESSES

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**Tablet feeding**

The tablet feeding process transfers uncoated tablets from a storage container to the tablet coater drum. An optimized feeding process should be quick but gentle enough to prevent damage to the tablets. Pneumatic transfer processes should be avoided because they subject uncoated tablets to excessive mechanical stress and damage, making them a high risk to good manufacturing practice (GMP).

Manufacturers use many types of containers to supply uncoated tablets to coaters. Whichever type of feeding container you use, ensure that the container lifting unit and transition chute are customized to suit the coater's feed opening. When planning a new coating line, consider the tablets' angle of flow during feeding and the available height of the installation space. Uncoated tablets with poor flow characteristics may require a flow-aid mechanism to ensure complete tablet discharge from the feeding container. For tablets containing highly potent active ingredients, the coater feeding process is subject to a high risk of contamination. Such applications require containment valves and enclosed lines between the feeding container and coater to contain any dust generated during feeding.

**The coating process**

Once the tablets are loaded into the coating drum, the coating process can begin. Tablet coating consists of three sub-processes, or steps: mixing, spraying, and drying. During film coating, the coater executes each of these steps simultaneously; during sugar coating, there are usually separate cycles for adding the sugar solution, coating and mixing the tablet cores, and drying.

**Mixing.** Thorough mixing is a basic requirement for tablet coating. To ensure an even surface quality throughout the batch, the coater must expose all the tablets to the spray guns with a similar frequency so that they receive approximately the same amount of coating solution. To achieve this, coater manufacturers incorporate baffles on the inside of the drum that act as mixing elements. When developing a coater, the manufacturer carefully shapes these elements and adapts them to the drum geometry, so they create a gentle mixing action in the tablet bed as the drum rotates.

While older coaters were often equipped with large, sometimes height-adjustable, replaceable mixing elements, the mixing elements on modern coaters are significantly lower and fixed, as shown in Figure 1. These lower mixing elements provide a more uniform tablet-bed surface and prevent a wave-like, tumbling action in the tablet bed. The uniform tablet-bed surface prevents tablets from being sprayed at different distances from the spray nozzles, which can excessively moisten tablets at close distances or cause the spray droplets to dry in the air at greater distances.

Because the mixing elements are continuously covered by the tablet bed, they are not directly exposed to the coating spray. This prevents a partial film coating from developing on the metal surface of the elements, which can then dry and flake off, leading to surface defects on the tablets and contamination of the batch.

Uniform movement of the tablet bed is always an advantage, even for very different filling levels. In
sugar-coating processes, the mixing elements must not allow the highly sticky sugar-coated tablets any opportunity to get stuck in low- or no-flow recesses in the drum. Ramp-shaped mixing elements, as shown in Figure 2, are particularly suited to this process because they allow the sugar-coated tablets to glide over them, even if the tablets are very sticky.

**Spraying.** To apply coating solution or suspension to an entire batch of tablets as quickly as possible, it’s beneficial to maximize the number of spray nozzles and/or the tablet-bed surface area that’s exposed to the spray guns during coating. For this reason, drum coaters with an extended drum, a longer spray arm, and more spray nozzles, as shown in Figure 3, have become increasingly popular for film coating processes in recent years. The extended drum flattens out the tablet bed, exposing a greater percentage of tablets to the spray guns during operation.

Depending on the coating solution and the required droplet size, film coaters use either airless or two-substance spray nozzles. Airless nozzles, as shown in Figure 4, create an exceptionally homogeneous spray pattern at high pressure levels. As discussed earlier, it’s critical to maintain the correct distance between the spray nozzles and the tablet bed to prevent either over-moistening the tablets or the coating droplets drying before reaching the tablet bed. Maintaining the correct angle between the nozzles and the tablet bed surface is also critical. Many modern film coaters use auxiliary motors to precisely regulate the nozzle distance and angle automatically without requiring manual intervention by the operator.

Monitoring the spraying process with two-substance nozzles is usually limited to the spray-air pressure, the pattern-air pressure, and the coating solution spray rate.
For particularly valuable or highly potent products, the coater may also monitor the liquid pressure in each coating solution line and trigger an alarm, automatic nozzle cleaning, or shutdown if it detects a malfunction such as clogging. Visual control systems with imaging technologies are not currently available but are being developed.

**Drying.** A modern coating process, as shown in Figure 5, uses optimized, high-volume spray rates that require suitable volumes of treated drying air. The air-line profiles and inlet openings on these systems are designed to keep the velocity of the drying air entering the coating drum low to minimize turbulence and pressure loss across the drum perforation and exhaust air system. Turbulent airflow in the coating drum causes some of the spray droplets to dry before contacting the tablet bed and be carried away in the exhaust airstream. This wastes coating solution and results in longer process times. It also affects tablet quality and limits the number of batches of the same product you can run without cleaning the coater.

The high drying capacity of modern coating systems makes it possible to coat even highly hygroscopic products, such as phytopharmaceuticals or plant extracts, with aqueous solutions.

These systems can generate a lot of waste heat, however, so double-walled, insulated coaters that feature air-handling units equipped with heat recovery systems are in high demand. Such systems are not only more energy efficient, they are also safer because they maintain a temperature of less than 60°C on all metal surfaces. Moreover, because the systems mix cold and hot air in the air-supply system, they permit quick and precise temperature control.

Some products may require more complex machine lines with added components, such as a molecular sieve for air drying; a humidifying system or supply-air humidity control, or, for organic solvents, even a closed drying system that circulates inert nitrogen gas. Explosion-protected machine lines such as these can be very complex, particularly if multiple control circuits overlap and safety-related factors, such as a product with a very low minimum ignition energy, significantly affect the procedure.

**Tablet discharge**

After coating, tablet discharge should be as quick as possible but gentle enough to prevent damage to the coated tablets. In recent years, helix-shaped welded discharge elements have replaced the special discharge inserts (called “scoops”) that were previously temporarily installed in the coater opening for the discharge process. These modified permanent elements serve as mixing elements when the drum rotates forward during coating but help to remove all tablets from the coating drum without any residue when the drum rotates backward.

For large production coaters, as shown in Figure 6, the number of discharge elements and their volume are selected so that a production batch of several hundred kilograms of tablets can be discharged completely in approximately 10 minutes without operator interference and while remaining gentle to the product.

For containment applications, the contamination risk decreases over the course of the coating process. A risk analysis should determine whether tablet discharge through containment flaps is required or whether no special discharge measures are necessary. In any case, process designers must take suitable measures to ensure that no product dust can emerge from the coater prior to, during, or after the entire coating and cleaning process.

**The cleaning process**

Coating systems require cleaning after a product change or a specific number of batches of a single product (a “campaign”). A GMP-compliant coater design is always a prerequisite for a successful cleaning process. Modern coaters generally feature cleaning nozzles that wash down all product-contact surfaces, from the air supply flap upstream from the coater to the exhaust air flap downstream from the coater. Operators must also rinse all hose connections between the coating solution tank, pump, and spray nozzles as well as the nozzles themselves.

Three-dimensional cleaning nozzles, as shown in Figure 7, have proven successful for cleaning coaters and reducing cleaning time, as they achieve a great mechanical effect if the pressure of the cleaning agent is sufficiently high. The cleaning process should require as few manual activities as possible, so all cleaning nozzles should be permanently installed or very simple to install without having to access the contaminated areas.

![Figure 6](image-url)

*Figure 6*

*Production coater during discharge process*
To clean the coater as quickly and as cost-effectively as possible, minimize the number of cleaning nozzles and optimize their cleaning effect. This includes controlling and adjusting the spray pressure, temperature, and concentration of the cleaning medium as well as appropriately spacing the cleaning nozzle from the surface to be cleaned.

An efficient coating unit must have controls for all functions and control circuits and must guarantee reproducibility of the coating and cleaning processes in fully automatic mode, even for complex units. Data exchange via all interfaces with higher-ranking or parallel systems is necessary to ensure gap-free process documentation and error analysis. Conformity with good automated manufacturing practice (GAMP) and 21 CFR part 11 are standard.

Equipment operators are frequently required to operate various equipment types, such as coaters, mixing granulators, and fluidized-bed systems, from different manufacturers. As a result, user-friendly human machine interfaces (HMIs) are becoming increasingly important, and clearly arranged, intuitive interfaces for operating elements with distinct graphical representations are obligatory.

**Conclusion**

As in many industries, cost pressures in the pharmaceutical industry continue to increase, driving efforts to improve process efficiency and reduce production times. These concerns affect all pharmaceutical manufacturing processes but are particularly important for tablet coating, which can be very costly in terms of time and energy use. Production coating units must be increasingly flexible to handle tablets with diverse formulations, shapes, and sizes, as well as capsules and pellets, with a wide range of different coating solutions. Coating processes also require flexibility with respect to fill level to meet the requirements of varying batch sizes and products. Finally, the number of highly potent formulations is growing, requiring manufacturers to implement suitable precautionary and containment measures while keeping in mind the associated costs. Moving toward more completely automated coating processes will help manufacturers meet these demands while maximizing the efficiency and reproducibility of their coating processes.

**Figure 7**

Three-dimensional cleaning nozzle on production coater spray arm

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