The evolution of coating technology

Pan coating is one of the oldest pharmaceutical solid oral dosage manufacturing processes. The process was created for adding a sugar coating to compressed tablets primarily to mask the tablets’ unpleasant taste. An operator placed uncoated tablets into a solid, rotating pan and then ladled, dosed, or sprayed a sugar-based solution over them. The process could also include a sealing coat and/or subcoats and a wax topcoat to give the tablets a shiny finish.

Pan coating was considered an “art,” because the quality of the coating depended largely on the skill of the operator. Inconsistent coating uniformity, long drying times between coats, and the long overall process time (24 to 48 hours or longer) were the main problems associated with solid pan coating. Subsequent developments such as the Pellegrini pan and the Glatt immersion sword helped to reduce processing times, but the most significant advancement in tablet coating equipment was the development of the perforated coating pan (or drum) by Eli Lilly, which Thomas Engineering commercialized in the 1960s.

As the perforated drum rotates around a horizontal axis, an inlet air-handling unit delivers conditioned, heated air into the coater and spray guns spray coating solution onto the tablets. The air is drawn through the tablet bed, drying the coated tablets, and exhausts via a sealed plenum on the outside of the drum. The perforated drum allows the coater to use more drying air, which greatly reduces drying time compared to a solid-pan coater.

Mixing it up

It was quickly discovered that fitting blades (called baffles) to the inside of the coating drum improved tablet mixing, provided greater coating uniformity, and reduced coating times while allowing for greater variation in batch sizes. Companies have introduced many different baffle designs over the years—including plough, “rabbit ears,” tubular, Fischer, and the more recent spiral and helical designs—all aiming to eliminate “dead zones” in the center of the tablet bed and reduce tablet damage during coating.

Controlling the process

A key focus for the pharmaceutical industry is product reproducibility, so coater manufacturers began introducing automated coating systems as far back as 1986. This allowed for recipe-controlled batches with control of key process parameters such as drum speed, airflow, and temperature. Early automated systems preceded the Good Automated Manufacturing Practice (GAMP) guideline, which was introduced in 1995 to help the pharmaceutical industry work with the FDA and international regulatory agencies and became part of the International Society for Pharmaceutical Engineering’s guidance documents in 2000. GAMP is largely about automated system validation, but other guidelines, such as the FDA’s 21 CFR Part 11, also play a key part in pharmaceutical validation requirements.

Drum interchangeability

Another innovation was the ability to use several different drum sizes with a single coating machine. Introduced by Thomas Engineering in 1990, this development provided companies with much greater batch-size flexibility, particularly for R&D and pilot-plant-sized coaters. The exchangeable-turret tablet press (developed by Fette) became available at around the same time, and the increased flexibility in both tablet compression and coating were key advancements in solid dose manufacturing technology. Production-sized coating systems with exchangeable drums have only been available for the last 10 years.

Increased containment

Developing new drug products to treat orphan diseases or target cancer involves the use of more toxic or potent APIs. Coating systems handling such APIs must be able to contain any dust created when loading, coating, and discharging the tablets. Most modern coaters meet these requirements using methods such as transferring the tablets via split butterfly valves and increased sealing, monitoring, and sampling. Companies must also implement suitable washing/cleaning regimes.

Continuous advancement

Continuous processing is a popular discussion topic in the pharmaceutical industry today. The continuous coater is another major innovation introduced by Thomas Engineering. Extending the coating drum and fitting the coater with additional spray guns allows for a shallower tablet bed, which results in greater coating uniformity, gentler tablet handling, and faster coating times—often less than 25 minutes.

While these advancements have already made operating today’s tablet coaters less of an art and more of a science, coating technology is sure to continue to evolve, improving coating quality and production efficiencies even further to meet future demands. T&C.

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