TABLETING

Improving Coating Quality:

New Technologies Promise Improvements

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Although coating has been a standard part of pharmaceutical tablet and pellet production for decades, some problem areas still persist — quality, productivity, and flexibility. Aspects of these problems are sometimes accepted or overlooked, due to presumed lack of solutions. But improvements are possible, and some technological breakthroughs are particularly promising.

Ensuring Consistent Quality

Tablet quality is perhaps the most visible area of improvement. Defects are sometimes only aesthetic—like discoloration, tablet-to-tablet color variability or logo bridging. Although a small amount of those might be tolerable, functional defects such as film cracking, tablet breakage and tablet edge or surface erosion put an entire batch at risk, potentially resulting in major financial loss.

Most manufacturers seek to prevent these problems by regularly checking parameters and adjusting them as necessary. Increasing and simplifying the process control results in better, faster feedback, giving the operator an opportunity to monitor quality and adjust accordingly.

This approach can help, but is it enough to achieve real process stability? This approach can leave open a relatively large risk for errors and inaccuracies, because the coating regulation and optimization process depends on the operator's expertise. What if there is no suitably skilled operator available due to the shortage of skilled workers in the labor market? What if the expert retires or simply is on vacation and there is no appropriate replacement? And if a suitable operator is available, what happens with long coating processes that require 20 or more hours and therefore demand shift rotations? And even with the most experienced operator, tracking all the parameters—especially with batch size changes, complex coating processes or demanding products that are, for example, very sensitive to humidity or temperature — poses challenges.

The solution to such systemic uncertainty? Further automate the coating process, from parameter control and feedback to adjustments. Some new coating technologies can monitor parameters such as temperature, humidity, flow rate, batch quantity and much more; obtain the optimal coating conditions for the specific product and thus minimize the risk of losing parts of or entire batches. One could say they create the absolutely reproducible coating process, regardless of complexity. Of course, operator expertise helps, because a good operator can intervene manually, if necessary. But near complete automation ensures that you no longer have to be an expert to achieve consistently high product quality.

But what does this automatic self-regulation look like? The answer can be found in the context of the second main problem area, where automation boosts optimization.

Lower Costs, Higher Sustainability

Some coating process deficiencies are sometimes accepted as a given. For example, "wasted" suspension is widely tolerated. It is common to use 50 percent more suspension than theoretically necessary for coating, because a loss of up to 40 percent is considered normal. With "standard" coatings, this may not incur major financial losses. But with functional coatings—like coatings with API or with controlled-release ingredients—costs can add up. But even standard coatings come with hidden costs, like cleaning and disposal, as well as logistical ones. After all, if you use more suspension, that much more must be transported and stored. Also, "resource wastage" and "environmental impact" are less viable, given growing concerns of sustainability and the corresponding legal regulations. Producing companies must react now or they will fall behind.

Here, automation provides an answer as well—especially automatically adjusting the suspension application and drying. One can achieve this using sonar technology. Acoustic wave sensors continuously monitor the volume and inclination of the product bed, which varies according to drum speed. If spray distance is off, the system adjusts using a nozzle arm with a three-point extension, without needing to pause the machine. A vacuum generated inside the drum automatically regulates drying. That vacuum can vary depending on the batch size, and via automatic air exhaust flaps, which can be opened individually and continuously. These permit controlling air flow through the tablet bed, ensuring that the coating does not simply run over the product before being discharged unused.

A suspension application without ANY losses is not yet possible, but with these new technical approaches, only 10 to 15 percent more coating medium is needed instead of 40 percent. And that makes a significant difference.

But the "sustainability factor" of the automation solution does not end with the reduction of spray loss and water consumption during cleaning. More efficient drying and making adjustments without interrupting the coating process reduce process times by hours. Even before coating, the machine virtually adjusts parameters to the recipe, eliminating the need for manual fine-tuning. Some new coaters also allow product sampling during production. That means meeting regulatory requirements without sacrificing time. All this combined results in substantially lower energy usage.

This technological adaptability also allows for immense batch size variability within a single machine. That not only increases productivity, but also adds flexibility—the third key problem area.

Allowing for Flexibility

Almost everyone who implements coatings has to deal with scale-up and scale-down procedures in some form or another sooner or later – for example, when:

- producing for various countries, as multinationals do on a daily basis, meaning batch sizes need to be adapted to different market requirements
- validating, which can require about 10 percent of subsequent batch sizes
- producing under contract, where a wide range of batch sizes must be processed
- switching from laboratory to production scale

- accommodating market changes. This aspect is often skipped when investing in coating systems and other machines. That lack of consideration can be short-sighted, since high-quality production equipment often lasts 20 years or more. Markets almost inevitably change. Therefore, the ability to scale batch sizes is basically about future-proofing.

But why is scaling up and down a challenge? First, it means that companies need at least two machines—one for producing smaller batch sizes and one for larger batch sizes. Most coaters do not have a large enough batch size variability. Usually they can only go down to 40 percent of the maximum batch size. Needing several machines means high capital investment costs, energy expenditure and space requirements. In addition, the parameters cannot simply be transferred—even if the coaters are the same type and brand. Switching between machines requires a large number of manual adjustments and it makes consistency, quality and uniformity challenging, regardless of the machine or batch size.

The automated adaptability of some new coating technologies represents an improvement. Coaters that can monitor and adjust to batch sizes can achieve a batch size range from true 10 to 100 percent filling volume within the same drum. This eliminates the need for multiple machines due primarily to different volume requirements. This applies to validations and batches of different sizes, as well as to volume changes within a single coating process, such as coatings with multiple layers.

Although some coaters with this range have existed for years, batch size variability on them necessitates drum changes and manual adjustments. While that eliminates the need for multiple machines, it doesn't eliminate manual intervention risks. Drum changes also require extra labor and cleaning—including for different batches with the same active ingredient.

Finally, newer, more flexible coaters allow changing the coating medium without major alterations. This flexibility is also useful when a formulation compound is banned, like dioxide titanium in the EU. Trends towards more natural ingredients in favor of water-based suspensions may also call for recipe modifications. In the search for new recipes, experts can focus on formulation and leave the rest to the machine.

Newer, more flexible coaters also have shorter process times. That allows for more R&D activities as more formulation trials can be implemented over the same time. Saving time also matters with water-based suspensions, which have longer drying phases. Speeding drying time can also reduce product defects due to humidity.

Conclusion and Outlook

Coating can be optimized through a higher degree of automation. Benefits include shorter process times; consistent and high product quality; time and cost savings; and resource conservation. Tablet coaters with these technological possibilities represent the future of coating.

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