

Automation – the answer to coating inefficiencies

Coating is nowadays an integral part of pharmaceutical tablet and pellet production. The application still presents problem areas, which have an impact on almost every coating process and entail economic losses. **Oscar Benedi**, laboratory manager, Romaco Tecpharm, says automation is the best way to overcome these challenges.

Challenges in coating encompass three areas: the quality of the coating result, the productivity of the coating process and the flexibility of the tablet coater, being the process itself.

One of the first things that comes to mind with product quality is the prevention of aesthetic and functional defects such as discolouration, tablet-to-tablet colour variability or logo bridging and film cracking, tablet breakage and tablet edge or surface erosion. While the purely aesthetic defects can sometimes be tolerated, the entire batch is at risk if a functional coating is compromised. Depending on the product, this can mean significant losses.

QUALITY ON AUTOPILOT

All pharmaceutical manufacturers grapple with functional coating challenges and each has implemented internal procedures to overcome them. As differentiated as these approaches might be, they all seek to stabilise the coating process by regularly checking parameters and adjusting them if necessary. Currently, the common method for increasing and simplifying this process control is to improve technical feedback. It is then the operator's responsibility to react accordingly. This solution works, but is it enough to achieve real process stability?

There is a relatively large risk for errors and inaccuracies with this approach, because the regulation of the coating process is dependent on the expertise, experience and capability of the operator.

What if there is no suitably skilled operator available due to the shortage of trained

workers in the labour market? What if the expert retires or is on holiday and there is no appropriate replacement? If a fitting operator is available, what happens with long coating processes that take 20 or more hours and include shift rotations?

Even the most experienced operator can find it challenging to achieve the ideal coating settings and keep track of all the parameters, especially with batch size changes, complex coating processes or demanding products that are, for example, very sensitive to humidity or temperature.

"Resource wastage and the environmental impact are no longer an option"

The solution to this systemic uncertainty is to automate the coating process to a larger extent, including not only the control of the relevant parameters and feedback to the operator, but also their fully automatic adjustment where required. The new TPR Optima perforated coating pan from Romaco Tecpharm can do this. It monitors parameters such as temperature, humidity, flow rate, bed tablet level and more. It sets up the predefined optimal coating conditions for the specific product and minimises the risk of losing parts of or entire batches. One could say the TPR Optima creates a fully reproducible coating process – irrespective of complexity. Of course, the expertise of the operators is still needed, and they can intervene manually, if required. But the possibility of almost complete automation ensures that high level expertise is no longer needed to achieve consistently high product quality with this technology.

EFFICIENT AND SUSTAINABLE PRODUCTIVITY

Deficiencies in coating productivity were and are partly accepted as a given. For example,

'wasted' suspension is widely tolerated. It is currently common to plan for 50% more suspension than is theoretically needed to coat a product, because a loss of up to 40% is considered normal.

With standard coatings, this may not mean any major financial loss, but with functional coatings, for example coatings with API or controlled release coatings, the situation is quite different. But even with standard coatings there are hidden costs in the form of cleaning and disposal expenses, not to mention logistical expenses, because if more suspension is needed, more must be transported and stored. Furthermore, this form of resource wastage and the environmental impact are no longer an option, given the global change in sustainability awareness and the corresponding legal regulations. Producing companies must react now or they will fall behind.

In this case, automation is also the answer – to be more precise, the automatic adjustment of the suspension application and drying. Technically, this is implemented in the TPR Optima using sonar technology. Acoustic wave sensors continuously measure the distance between the spray nozzles and the tablet bed, which may vary depending on the process that is conducted. If modifications are required regarding the ideal spray distance or the set spray angle, they are carried out by the intelligent system using a nozzle arm with a three-point extension mechanism. The machine does not have to be paused for this purpose.

Did you know?

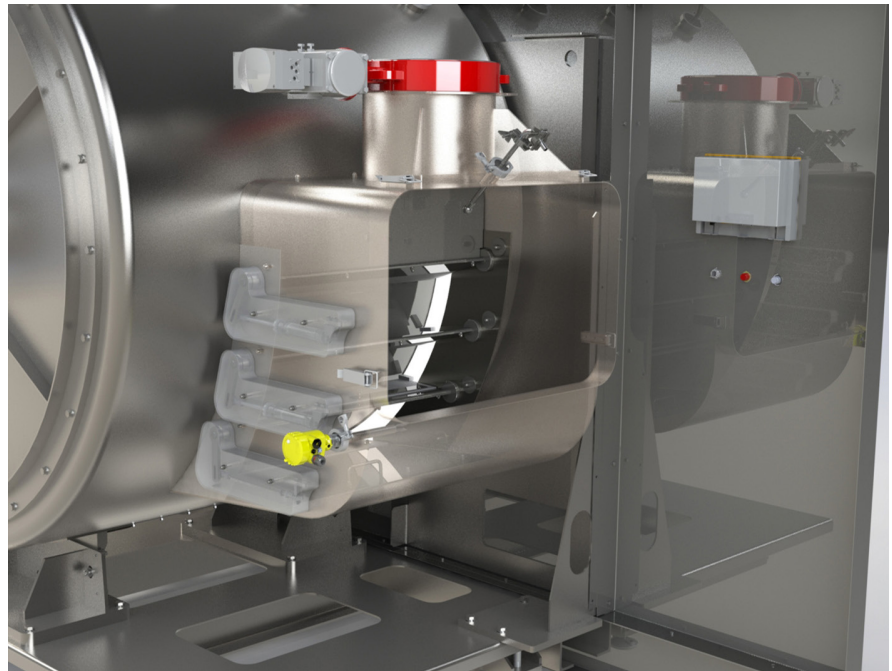
Automated parameter adjustment provides several advantages. In the demanding search for new recipes, pharmaceutical experts can concentrate on the formulation and leave the rest to the machine.

An automatic set of air exhaust flaps allows precise regulation of the path taken by the air flow through the tablet bed, ensuring maximum drying efficiency. A suspension application without losses is at present not yet possible, but with the new technical possibilities of the coating technology from Romaco Tecpharm only 10% to 15% more coating medium is needed instead of 40%, making a significant difference.

FLEXIBILITY TOWARDS MARKET TRENDS

Coatings encompass scale-up and scale-down procedures in some form or another. For example, when batch sizes must be adapted to different market requirements, for validations, contract manufacturing, or when market demands change over time. Often this isn't considered when investing in coating systems and other machines, although it is very important. After all, life cycles of more than 20 years are not uncommon for high-quality production equipment, and the market requirements almost inevitably change over such a long period. It is essential all coating providers can scale batch sizes to future-proof their businesses.

But why is scaling a challenge? Firstly, it requires at least two machines, one for producing smaller batch sizes and another for larger ones, as most coaters do not have a big enough batch size variability. The usual variable is 40% of the maximum batch size, so the resulting need for several machines is associated with very high investment costs, energy expenditure and space requirements. In addition, the parameters cannot simply be transferred from one machine to another – not even if they are the same type and brand. Scaling takes several manual adjustments with the risk of ensuring consistent quality and uniformity across all products, regardless of the machine or batch size.



Continuously opening Flaps control the air flow and path and thus enable precise coating and drying processes according to the respective batch size

The automated adaptability of the TPR Optima helps improve flexibility in production. With the ability to monitor and adjust to batch sizes, the tablet coater achieves a batch size range from true 10% to 100% filling volume with the same drum. This eliminates the need for multiple machines and the time and labour it takes to set up the right parameters for different systems coupled with the risk of errors and imprecisions.

A final aspect of flexibility in coating is the possibility to change the coating medium itself without major technical adjustments. This might be necessary due to imminent reformulation resulting from acute bans on formulation components, as in the case with dioxide titanium, which is already banned in food production in the EU.

CONCLUSION AND OUTLOOK

There is significant optimisation potential in coating which can be exploited through a

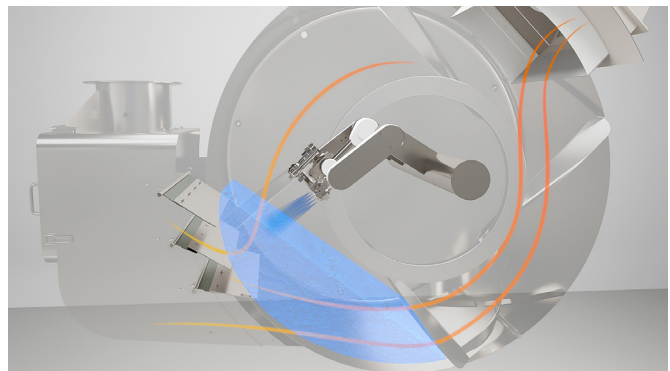
higher degree of automation. Shorter process times, continuously high product quality, time and cost savings and resource conservation are just some of the gains. Tablet coaters like the TPR Optima are set to represent the future of coating.

Finding new active ingredients is a long-term task, which is why many new products will be developed in the next few years through the recombination of known APIs or new forms of drug delivery. Coating will play a central part in this innovation journey. There will be more products with active ingredients in the coating layers and coated products that have not typically been coated in the past. The precondition for these new developments is and will be automation technologies that stabilise the coating process while making it more efficient and sustainable. ■

Romaco Tecpharm – www.romaco.com/products/tablet-coating



The TPR Optima tablet coater from Romaco Tecpharm creates a reproducible coating process



The batch volume and the tablet bed inclination are measured continuously using sonar technology

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