The biggest challenges in coating and their technological solutions

Is coating as efficient and economical as it could be? there are some problem areas that have not been adequately solved so far. A new generation of tablet coaters is addressing these challenges in an innovative way.

by Oscar Benedi, Laboratory Manager, Romaco Tecpharm

Coating is nowadays an integral part of pharmaceutical tablet and pellet production. Nevertheless, there are some problem areas that have not been adequately solved so far, some of which are nearly accepted, although they have an impact on almost every coating process and entail economic losses. To a certain extent, this is due to a presumed lack of possible solutions – but they do exist and are promising. In particular, a new generation of tablet coaters is addressing these challenges in an innovative way.

When talking about challenges in coating, there are basically three areas involved: the quality of the coating result, i.e. the quality of the products, the productivity of the coating process and the flexibility of the tablet coater, thus of the process itself.

Quality – How can high-quality coating results be ensured on a continuous basis?

One of the first things that comes to mind when thinking about product quality is the prevention of defects – aesthetic ones such as discoloration, tablet-to-tablet color variability or logo bridging and functional ones such as 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 losses in the six-figure range. It is therefore not surprising that this area is the one that all com-

A new generation of tablet coaters – the TP R Optima from Romaco Tecpharm

panies producing for the pharmaceutical industry are grappling with and that each has implemented its own procedures to do so. As differentiated as these approaches may be in detail, it is always a matter of stabilizing the coating process by regularly checking parameters and adjusting them if necessary. The common method for increasing and simplifying this process control is currently to improve the technical feedback – i.e. how well and quickly the technical systems give the operator feedback on process and product quality. After that, it is the operator's responsibility to react accordingly. This is definitely a solution that works, but is it enough to achieve real process stability?

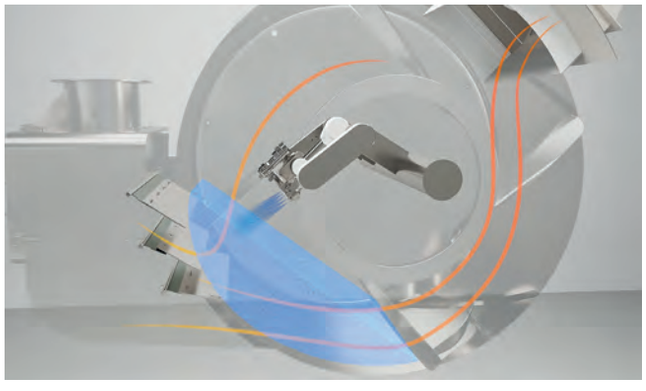
Reality is that this approach leaves a relatively large risk for errors and inaccuracies, because the regulation and control of the coating process is absolutely dependent on the expertise, experience and capability of the operator. What if there is no suitably skilled operator available due to the shortage of trained workers in the labor market? What if the expert retires or simply is on vacation and there is no appropriate replacement? And if a fitting operator is available, what happens with long coating processes that require 20 or more hours and hence include shift rotations? All this and similar scenarios aside, even for the most experienced operator it is not always easy to get 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. 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 is capable of doing so. It monitors parameters such as temperature, humidity, flow rate, bed tablet level and much more, sets up the predefined optimal coating conditions for the specific product and thus minimizes the risk of losing parts of or entire batches. One could say the TPR Optima tablet coater creates the absolutely reproducible coating process – irrespective of the complexity. Of course, the expertise of the operators is still needed and they can intervene manually, if they choose to. But the possibility of almost complete automation ensures that you no longer have to be an expert to achieve consistently high product quality with this technology. It is somewhat like having an autopilot. But what does this automatic self-regulation look like? This can be exemplified very well in the context of the second main problem area, where automation is also the means of choice for optimization.

Productivity – How can the coating process become more resource and cost efficient as well as sustainable?

The deficiencies in the productivity of the coating process were and are partly accepted as a given. An example is the amount of "wasted" suspension that is widely tolerated. It is currently common to plan for 50 per cent more suspension than is theoretically needed to coat a product, because a

Automatic extendable spray arm with self-adjusting movable spray nozzles allows for variable batch sizes from 10 to 100%

loss of up to 40 per cent is considered normal. With "standard" coatings, this may not mean any major financial losses, 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. On top of all that, this form of "resource wastage" and "environmental impact" is no longer an option in the long run, given the global change in awareness of sustainability and the corresponding legal regulations. Producing companies must react now or they will fall behind.



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

Here, automation is the answer as well, and to be more precise, especially the automatic adjustment of the suspension application and drying. Technically, this is implemented in the TPR Optima as follows: 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, the intelligent system carries them out by means of a nozzle arm with a three point extension mechanism during the ongoing process – the machine does not have to be paused for this purpose. An automatic set of air exhaust flaps, which can be opened individually and continuously, allows absolutely 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 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. The associated more efficient drying and the possibility to make adjustments without interrupting the coating process reduce process times by hours. And prior to the actual coating, time is additionally saved in the fine-tuning and preparation of a new batch, as the TPR Optima virtually adjusts itself to the recipe and the associated parameters. It also offers the option of taking product samples while the process is running. In doing so, regulatory requirements can be met without sacrificing time. All this combined results in substantially lower energy usage.

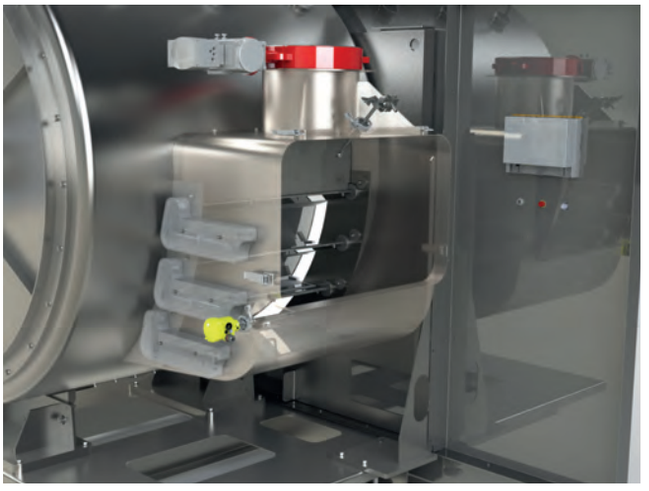
Another special feature of this technological adaptability is immense batch size variability within a single machine, which not only increases productivity, but above all brings flexibility – and that leads to the third main problem area.

Flexibility – How can companies be best prepared for trends, altering market conditions and changing customer requirements?

Almost everyone who realizes 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 Multi Nationals do on a daily basis, and batch sizes have to be adapted to the different market requirements
- when validations have to be carried out and about 10 per cent of the subsequent batch sizes have to be manufactured for this purpose
- when producing under contract, where a wide range of batch sizes must be processed
- when the switch from laboratory to production scale is pending

- or when market demands simply change over time.
This aspect is often not taken into account 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. Therefore, the ability to scale batch sizes is basically about future-proofing for all coating providers.
But why is scaling up and down a challenge? Firstly, it means that companies currently need at least two machines, one for producing smaller batch sizes and one for larger batch sizes, as most coaters do not have a large enough batch size variability. Usually they can only go down to 40 per cent of the maximum batch size at the most. 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. Consequently, a relatively large number of manual adjustments have to be made, and here again the problem of ensuring high quality and uniformity across all products, regardless of the machine or batch size, arises. Not to forget, of course, the time and work that goes hand in hand with manual adjustments.
The automated adaptability of the TPR Optima also represents an approach to improvement here. With the ability to monitor and adjust to batch sizes, the tablet coater achieves a batch size range from true 10 to 100 per cent filling volume with the same drum. This eliminates the need for multiple machines just because of different volume requirements, the time and manpower it takes to set up the right parameters for different systems and the risk of errors and imprecisions. What is more, this not only applies to validations and batches of different sizes, but also to volume changes within a single coating process, such as coatings with multiple layers. It could be argued that coaters with this range have been around for a while, and that is true, but the batch size variability of these technological solutions necessitated drum changes and manual adjustments, which removed the problem of purchasing multiple machines, but not the risks of manual intervention. Moreover, the drum changes created extra labor and cleaning efforts, including for different batches with the same active ingredient. This also becomes largely obsolete with the use of only one drum.
A final aspect of flexibility in coating is the possibility to change the coating medium itself without major technical alterations. There are several reasons why this could be required. For example, a reformulation may be a necessity due to imminent and acute bans on formulation components, as in the case of dioxide titanium, which is already banned in food production in the EU. An adequate substitute is presently being sought, also for pharmaceutical production. Trends towards more natural ingredients such as the departure from alcohol in favor of water-based suspensions may also call for recipe modifications.
Again, automated parameter adjustment provides advantages. In the demanding search for new recipes, the experts can concentrate on the formulation and leave the rest to the machine. Apart from that, process times are shorter, which further facilitates R&D activities as more formulation trials can be implemented in a given period of time. Saving time is also the big issue with water-based suspensions, which have longer drying phases. Due to more efficient drying with the "full" automation of the TPR Optima, this does not have the same impact as with previous technologies. As a matter of fact, the best possible drying is particularly important in this case, as too much humidity is one of the main factors for product defects.



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

Conclusion and outlook

As illustrated, there is significant optimization potential in coating that 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 with these technological capabilities will certainly represent the future of coating and are already supporting innovation: Finding new active ingredients is a very 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 endeavor. 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 are and will be automation technologies that stabilize the coating process, make it more efficient and sustainable.