Next-generation tablet coater - Totally adjustable batch sizes from 10 to 100 per cent

Tablet coater TP R Optima perforated coating pan from Romaco Tecpharm provides fully automatic adjustment of all parameters during the coating process for an impressive batch size range from 10 to 100 per cent filling volume with one and the same drum

Coatings are applied to tablets for different purposes. Amongst other things, they make tablets easier to swallow, protect them from light, air and moisture or mask an unpleasant taste when they are taken. Film coatings are additionally used to control the release of the active ingredient in the human body.

The TP R Optima coater enables tablet coatings of all kinds to be produced fully automatically for a wide range of batch sizes. The recipe with the predefined process parameters can be accessed by the machine operator on the HMI and is then running automatically. Parameters like the spray distance or angle no longer have to be adjusted (or readjusted) manually and nor do the exhaust air flows.

The parameters are monitored continuously during the coating process and automatically adapted by the system to the recipe. The operator is no longer required to be present throughout and is freed up for other assignments. This highly automated coater delivers absolutely reproducible results and optimal process control is guaranteed, because all manual intervention during the coating process is eliminated. For example, sampling can take place directly without having to stop coating and open the machine.

Sonar system measures batch volume and tablet bed inclination

The key to the TP R Optima tablet coater's ability to adjust the parameters fully automatically during the coating process lies in a sonar: acoustic wave sensors measure the complete tablet bed continuously and then use this information to determine the batch volume. The tablet bed inclination, which varies according to the turning speed of the drum, is measured in the same way.

Therefore, the new perforated coating pan from Romaco Tecpharm allows ultra-precise application of the spray liquids over the entire batch size range from 10 to 100 per cent. This is achieved thanks to the interaction between the sonar's realtime data and a nozzle arm with a three-point extension mechanism, which automatically adjusts the spray angle and distance without interrupting the coating process. The nozzle arm's long reach ensures that the suspension is always applied to the tablets exactly as per the recipe, even with very small batch sizes.

Efficient spraying and drying process enables shorter processing times

Drying is a particularly important step in the tablet-coating process, which begins while the spray liquid suspension is being applied. The inlet and exhaust air temperature and flow rate are crucial to the efficiency of the spraving and drving process, as is correct air flow behaviour in relation to the batch size. Near loss-free application of the suspension and rapid drying will otherwise be impossible. It is also extremely important to adjust the drving air, to prevent the product in the coater from becoming too moist, causing individual tablets to stick together.

The TP R Optima tablet coater uses a bypass to adjust the supply of process air. The vacuum that is created inside the drum can be varied according to the batch size; it stabilises the air flow and diverts the air towards the automatic air exhaust flaps. These flaps can be opened individually and continuously in a controlled way, so that the process air is guided



The GMP conform in-wall design of the TP R Optima tablet coater provides for a strict separation between technical and production area



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



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

through the product directly. The coater's high spraying and drying efficiency thus achieved, is reflected in short processing times - generally between one and three hours depending on the product - as well as lower energy usage.

The precise control of the air flow inside the drum also means accurate application of the coating suspension to the product for any batch volume between 10 and 100 per cent. In other words, the system prevents that the liquid just runs over the tablets and is discharged without being applied. Together with the high spray accuracy which results from the automatic adjustment of the spray arm, this adds up to significantly lower consumption of coating suspension - and a material saving of up to 60 per cent compared to other coating methods, depending on the application.

Detection and automatic clearance of clogged spray nozzles

The coating technology from Romaco Tecpharm includes a system for automatically detecting and clearing clogged spray nozzles. The risk of such blockages occurring is actually very low in practice but increases the higher suspension's viscosity. Directly downstream of the peristaltic pump, the coating pan has a load cell that measures the amount of spray liquid being pumped. If the load cell registers that liquid is no longer exiting from one of the nozzles, the coater initially attempts to unclog that particular nozzle by building up maximum pressure. If this is not possible, an individually-configurable mechanism takes over: depending on the product being processed, either the coating process continues and the system simply issues an

EXPRESS PHARMA 69

PHARMA PULSE

alert or the process is interrupted immediately. The coating pan's response to nozzle blockages can be fine-tuned to the product in question in this way.

GMP-compliant in-wall design

The TP R Optima tablet coater was designed in conformity with Good Manufacturing Practice (GMP) standards. All productcontacted parts on the inside of the coater are easy to clean using Washing In Place (WIP) procedures and readily accessible, so that cleaning validation is totally straightforward. No dead spaces exist where product residues could accumulate, leading to cross-contamination. The design of the spray arm particularly rules out such critical spaces due to its extendable and retractable mechanism.

Furthermore, the tablet coater's in-wall design enables strict separation between the "grey" area and the production



Blocked spray nozzles are automatically being detected and cleared on the spot

area in the cleanroom. If servicing is required, the work can be carried out without having to enter the cleanroom and decontaminate it again afterwards. What is more, the batch being processed does not necessarily need to be disposed of following a service assignment in the "grey" area and can be processed further once the work is completed.

Advanced sensors and actuators take processing automation to a new level Romaco Tecpharm's new perforated coating pan combines very high floxibility with promium

rated coating pan combines very high flexibility with premium product quality and a previously unattainable level of automation in tablet coating. The spray arm and its three-point extension mechanism are patented. Nevertheless, the system still allows individual parameters to be adjusted manually, if required. The TP R Optima tablet coater, which is available in seven different sizes, is thus equally suited for product development with laboratory-scale batch sizes and for scale-ups to larger production volumes. The machine is also ideal for

exhaust air as well as for cleaning

suppliers producing under contract who need to run a wide range of batch sizes on one line and therefore often face "last batch" challenges, especially during campaign manufacturing.

Author

Peripherical systems of the TP R Optima tablet coater for inlet and

Jordi Carrera, Sales Director, Romaco Tecpharm, S. L.



70 EXPRESS PHARMA