Tablet Coating: Optimal Uniformity and Flexibility Tablet Coater Saves Resources

Tablets are the most important oral dosage form in the pharmaceutical industry. The advantages of tablets are numerous. First and foremost is the ability to precisely control dosage and the high stability of active ingredients. In addition, tablets can be produced quickly and in large quantities and offer flexible design freedom in terms of size, shape, and color.

Tablets can be effervescent, dissolving, or dispersible, dissolving tablets, lozenges, or enteric-coated and retarding tablets, as well as uncoated and coated tablets.

Tablets are often coated. This involves applying a thin film of one or more polymers and other functional excipients (colorants or humectants) to the tablet, which can perform a variety of functions.

Tablets are coated to modify the release of the active ingredient, such as in enteric-coated or extended-release dosage forms, to protect the active ingredient from light or moisture, or to mask a bitter taste in the tablet formulation. In addition, tablets are coated to improve swallowability or to mask with colour (for unique identification or marketing purposes).

Coating of active ingredients is becoming increasingly important. This includes combination products as well as the combination of two incompatible active ingredients in one dosage form. In addition, different release profiles of the same active ingredient can be combined. In this case, the core contains the slow-release component, and the tablet coating contains the fast-release initial dose. Formulation approaches sometimes consist of up to four different film types. This results in long process times. In order to successfully develop and produce such formulations, coating uniformity is a mandatory requirement.

Coating uniformity is indicated by the Relative Standard Deviation (RSD) and has a very high analytical significance. The smaller the RSD, the more uniform the coating on the tablet. However, the exact determination of the RSD requires a high analytical effort, since the same individual tablets have to be analysed before and after coating, or components of the coating have to be quantified by content determination methods.

Not to be confused with RSD uniformity is the determination of color difference (ΔE) for coloured coatings. High ΔE values describe a noticeable color difference. The dimensionless quantity ΔE is often mistakenly equated with coating uniformity in % RSD, but this is a gross error and can completely distort the validity of a process.

Mixing, Spraying and Drying

The interaction of mixing, spraying, and drying is critical in tablet coating. Mixing, spraying and drying must be performed simultaneously and with the correct settings to achieve optimum coating uniformity.

Mixing

Smooth and gentle movement of the tablet cores under the spray cones is essential. The tablet cores must not be subjected to excessive mechanical stress to avoid damage.

For more than 20 years, L.B. Bohle (Ennigerloh, Germany) has successfully used an enlarged coating drum (length/diameter (L/D) > 1) with welded-in mixing spirals. The mixing spirals ensure continuous and gentle mixing of the tablet bed. Homogeneous mixing is achieved within minutes and is maintained throughout the process. The flat tablet bed reduces the melt pressure in the tablet bed. Due to the continuous guidance of the mixing spirals, the tablets are not strongly accelerated. Tablet breakage and twinning do not occur.

Drum Geometry, Spray arm Design and Reduced Coating Time

The drum geometry of the L.B. Bohle BFC tablet coater creates a large spray area in the moving tablet bed. This allows more spray nozzles to be used compared to shorter drums, resulting in a larger total spray area and higher spray rate. In addition to the coating suspension, the nozzle type, number of nozzles and nozzle to nozzle distance are of particular importance.

L.B. Bohle offers various solutions for adjusting the nozzle bed distance, the spray angle of the nozzles and the pressure parameters for atomisation.

Typically, the amount of suspension mass in film-coated tablets is 5–15% of the core mass. Of particular importance is the film thickness, which is not only important for active ingredient coatings, but must also be uniform for thin color (protective) coatings. Uneven film application within a batch, for example, results in color variations that degrade product quality or poor compliance.

Compared to conventional tablet coaters with L/D ratios <1, systems with enlarged drums allow up to 40% shorter process times due to higher spray rates.

Drying

It is critical to ensure optimal energy and mass transfer. This means that the energy must be applied directly to the tablet bed. The air flows directly and quietly into the tablet bed and effectively ensures rapid drying of the sprayed suspension. There is no heating of the coater periphery or housing.

Optimal airflow creates a smooth spray pattern that reduces spray drying. Spray nozzles are not hit by the supply air stream and remain cool during the spraying process. This minimises spray drying effects and achieves coating uniformity of >97% and better.

World premiere at Interpack 2023 – Coater optimised in terms of process, technology, and machine execution.

L.B. Bohle tablet coaters have been firmly established in the market for more than two decades and are recognised as technologically advanced.

L.B. Bohle has been able to further improvements of the BFC series through an intensive exchange with customers and continuous cross-departmental research and process optimisation. This has resulted in improvements in the areas of technology / machine equipment, cleaning, user-friend-liness and safety, hygienic design,

and sustainability. The goal is to optimise the daily production process by making production not only more flexible and faster, but also more resource-efficient with the best possible uniformity.

In the area of machine equipment, the focus is on a new machine control system. The iFix application makes it possible to monitor and control the processes. As an HMI (Human Machine Interface), iFix provides the necessary elements for operation. In addition, important data such as long-term data storage of measured values, alarms and messages, as well as data interfaces to external systems and a recipe management system are recorded.

The importance of coating small batches is constantly increasing. Despite existing laboratory coaters, there is also a need for high flexibility in production machines. The BFC tablet coater offers maximum flexibility, allowing batch sizes with a fill level between 10 and 100%. With a BFC 400, this corresponds to batch sizes of 65–650 l.

In the BFC, L.B. Bohle has redesigned the nozzle block. Nozzle angle and distance adjustment is motorised and automatic. In addition, the nozzle block is now slimmer and rounded. This makes it easier to clean, and an enlarged sight glass allows better process monitoring.

Easier to Operate and Safer

The coating process is already highly automated. Nevertheless, operators are present during the process to perform in-process controls, visual assessments or to take material samples.

In the new tablet coater, L.B. Bohle has implemented the operators' instructions in particular. The opening and closing of the side door is now assisted by pneumatic cylinders, reducing the amount of force required. The air supply shoes are separated, which means a significant reduction in weight and easier handling.

Safety aspects have also been taken into account. Inflatable seals are now standard. Fully automatic sampling and loading of tablets with the door closed increases operator safety.

The control panel has been redesigned in hygienic design and a status light embedded in the front of the machine supports process monitoring.

Fast Discharge and Effective Cleaning

At the end of the coating process, the coater is quickly, gently, and completely discharged by reversing the direction of rotation and adjusting the inclination. This is followed by fully automatic cleaning. An additional cleaning lance at the bottom of the unit is now integrated as standard. Further improvements reduce the cleaning time and ensure that the cleaning medium drains off quickly and without residue.

Focus on Sustainability

The pharmaceutical industry emits large amounts of greenhouse gases and generally has high energy consumption. L.B. Bohle has addressed the issue of energy consumption in the new design of the coater. For the first time, L.B. Bohle uses optional heat recovery in the ventilation system, which significantly minimises energy consumption.

A new energy monitoring system for the energy supply of the coater gives the manufacturing companies a complete overview of their own process and consumption.

Tobias Borgers

Tobias Borgers is a Marketing Professional, with a huge experience of multi -channel marketing initiatives. Proven abilities in creating successful exhibitions, integrated digital and traditional marketing campaigns, social media marketing, content management, lead generation, event and project management. Tobias holds a B.A. from University of Duisburg-Essen and joined L.B. Bohle in 2012.