The film coating process is characterized by a highly complex network of interdependent parameters. This article provides an analysis of the relevant parameters and their effects on the quality of the coating. It also provides a parameter map to help you set up the coating process.

The quality of film-coated tablets depends on three main factors: the properties of the substrate (e.g., the tablet cores), the film coating material, and the setup of the coating process.

As long as the tablet cores have sufficient hardness, low friability, and an appropriate shape, they pose no particular issue in terms of achieving good coating results. Ready-to-use film coating materials, such as those my company supplies [1], are carefully designed to perform well under a wide range of coating conditions and are very seldom cited as the root cause of coating defects.

By contrast, how the coating process is set up ranks as the most common cause of problems in film coating.

Analyzing the film coating process

The film coating process is essentially a combination of three interwoven unit operations:
- Application of the liquid coating material (typically a suspension) by atomization
- Conversion of the liquid coating to a solid film coating by drying, and
- Uniformity of film application by simultaneously blending the cores.

Each of these operations must be balanced to achieve the desired result: A substrate enrobbed in a smooth film of uniform thickness.

As Equation 1 shows, it is essential that the specific surface area of the substrate not vary from batch to batch:

\[
\text{Film thickness} = \frac{(\text{Applied coating weight} \times \text{Density of dry film})}{(\text{Substrate surface area})} \quad (1)
\]

While tablets have well-defined dimensions, the particle size distribution of sugar or cellulose spheres may be more variable, which affects the surface area to be coated. Likewise, if the dimensions of the tablets change, you
must adjust the target weight gain. Table 1 illustrates the effect of tablet size on film thickness.

<table>
<thead>
<tr>
<th>TABLE 1</th>
<th>Coated to the same target weight gain, smaller tablets exhibit significantly lower film thickness than larger ones</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diameter (mm)</td>
<td>11</td>
</tr>
<tr>
<td>Height (mm)</td>
<td>2.5</td>
</tr>
<tr>
<td>Weight gain (%)</td>
<td>6.0</td>
</tr>
<tr>
<td>Film thickness (microns)</td>
<td>51</td>
</tr>
</tbody>
</table>

Although film thickness is the target parameter of any coating process, it is very seldom used to determine the endpoint of coating runs. In fact, in most cases, it is not measured at all. Rather, for reasons of practicality, weight gain (WG) is usually used to determine the endpoint of the coating process. As shown in Equation 2, weight gain can be expressed as milligrams of film per square centimeter of substrate surface.

\[
WG (mg/cm^2) = \frac{(Concentration \times Spray \ rate \times Duration)}{(1,000 \times Number \ of \ tablets \times Tablet \ surface \ area)} \tag{2}
\]

It can also be expressed as a percentage of tablet mass, as shown in Equation 3.

\[
WG(\%) = \frac{(Concentration \times Spray \ rate \times Duration)}{(Total \ tablet \ mass)} \tag{3}
\]

Coating suspension

As Equation 2 shows, high concentrations of solids enable you to conduct shorter coating runs because the process attains the target weight gain in less time. At a glance, this appears to be a favorable exchange, but there are two major limitations to maximizing the spray rate and concentration.

The first limitation: A linear increase in the solids concentration of the suspension leads to an exponential growth in its viscosity. That may pose a problem because the pump that delivers the coating to the spray apparatus—usually a peristaltic pump—may not have the power to handle highly viscous liquids. Therefore, it is essential to determine the actual spray rates of a given liquid delivery system at different pump speeds and for different viscosities. See Figure 1.

The second limitation: High solids concentrations (high viscosities) negatively affect the atomization of the liquid, and the droplets may not be fine enough. Furthermore, the droplets may not spread over the tablet surface upon impingement, which will lead to uneven film formation.

Drying conditions

Drying conditions also strongly influence film smoothness and are reflected in the temperature and relative humidity (RH) in the product bed. Drying conditions are a function of the spray rate and the drying capacity, i.e., how well the drying air can take up water. This is defined by the inlet-air temperature and air volume, as well as by the heat loss of the equipment. The effect of the inlet-air humidity is often misunderstood. While higher inlet-air humidity leads to a higher RH in the product bed, it does not affect the total amount of water that can be evaporated.

Blending

The duration of a coating run, or more specifically, the spraying time, is defined by the target weight gain, the concentration of the solution, and the spray rate, as shown in Equation 2. The intensity of blending must be balanced with the duration of the spraying step. Obviously, a brief spraying step requires intense blending to achieve a homogeneous distribution of the film, whereas a process with long spray times can blend at a lower intensity.

In drum coaters—also known as pan coaters—“blending intensity” correlates directly with drum speed. In fluid-bed systems, blending is a function of the drying-air’s velocity and volume, which means a single parameter controls both the blending and drying conditions and thus film smoothness. The ability to adjust the blending intensity and drying conditions independently is an important advantage of drum coaters over fluid-bed coaters.

Mapping the process parameters

As Figure 2 shows, it is possible to map out all of the parameters discussed above and their interdependence. The map illustrates how two target parameters—the uniformity and smoothness of the final coating—can be controlled.

Coating uniformity depends on the spray duration, blending intensity, and film thickness. As noted above, thickness is a function of the target weight gain and the surface area of the substrate. Weight gain, in turn, is a function of the spray duration, coating concentration, spray rate, and tablet mass. Film smoothness is controlled by the droplet size, coating viscosity, and drying conditions.
Setting up a film coating process

While Figure 2 shows a great number of relevant parameters, only a handful of them can be used to optimize a coating process. Parameters such as tablet size, shape, and mass, as well as target weight gain, are usually fixed. The concentration of the coating suspension can be optimized within certain limits, as discussed above, but it can hardly be changed while the coating process is underway.

The parameters that can be adjusted during a coating run include:

- The inlet-air temperature and volume and the spray rate (drying conditions)
- The atomizing-air pressure (atomization), and
- The drum speed (blending).

Increasing the inlet-air volume increases drying capacity. Reserve some capacity so you can address over-wetting emergencies.

Drying conditions. The first step is to identify the combination of inlet-air temperature, air volume, and spray rate that will achieve the target bed temperature. In the case of a standard HPMC-based coating, for example, the ideal bed temperature is between 38° and 42°C. Again, you must determine the actual delivery rate of the coating suspension at the intended pump setting(s) and for the selected spray nozzle(s). Next, identify the correlation between the actual pump rate, the inlet-air temperature, and the resulting bed temperature. While this analysis must be conducted for each piece of coating equipment, it is usually sufficient to do it for only one (i.e., the standard) inlet-air volume. Increasing the inlet-air volume almost immediately increases drying capacity, but it is prudent to reserve some capacity so you can address over-wetting emergencies. Thus, coaters should only be run at about 80 percent of their maximum air volume under standard coating conditions. Figure 3 shows the correlation of outlet-air temperature, spray rate, and inlet-air temperature.

Atomization. Once the spray rate is set, adjust the atomizing-air pressure to achieve an appropriate droplet size distribution. As a general rule, the higher the viscosity and/or spray rate, the higher the atomization pressure must be.

Ideally, you would measure the actual droplet sizes in the spray plume, but that is usually not possible. Instead, the common procedure is to slide a sheet of paper (supported by a ruler or spatula) through the spray zone and...
visually examine the collected droplets. To prevent local over-wetting and poor homogeneity, avoid large droplets. Conversely, excessive atomization-air pressure could create droplets that are too fine and increase the risk of spray drying. High atomization-air pressure can also cause an undesirable indentation in the tablet bed surface (photos).

**Blending.** An important prerequisite for efficient blending is a sufficiently filled coating drum. Under-filled drums cause not only unnecessary physical stress on the tablets, but may also disrupt the flow of the tablet bed. Most coating drums contain baffles to enhance blending efficiency. These baffles are designed to travel through the tablet bed well below its surface. In an under-filled drum, the edges of the baffles are too close to the surface and thus push back against the tablets sliding down. This causes the tablets to be retained in the spray zone too long, which leads to over-wetting.

Over-wetting can also occur when the drum turns too slowly because it prolongs the dwell times of individual tablets in the spray zone. In general, high drum speeds improve blending efficiency and reduce the risk of over-wetting. High speeds, however, increase the risk of film defects and tablet damage. In fact, an excessive drum speed will cause tablets to become air-borne at the top of the tablet bed and return to the spray zone in an uncontrolled manner. That works against the objective: maintaining a smooth and even flow of the tablet bed throughout the coating process. Coated or partially coated tablets usually slide better than uncoated ones, so flow behavior will change during a coating run. Consequently, you may need to adjust the drum speed as coating progresses.

**Conclusion**

Following the recommendations presented here should lead to good results. Unfortunately, the film coating process is full of dilemmas: Improvement in one direction (e.g., higher solids concentration for faster weight gain) leads to poorer results in another (e.g., reduced smoothness). Although it is important to understand the interdependence of coating parameters, it is equally important to have (or gain) enough experience to find the right balance between the conflicting parameters for each new coating project. Optimizing the properties of the substrate (e.g., using appropriately shaped tablets of sufficient hardness and very low friability) and selecting trouble-free options for the coating material will limit the amount of work needed to optimize other aspects of the film coating process.

**Reference**

1. Vivacoat ready-to-use HPMC coatings from JRS Pharma, Patterson, NY.

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