Understanding the Film Coating Process

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Agenda

1. Introduction
2. Analysis of the Key Parameters in Coating
3. Setting up a Film Coating Process
4. Summary
Introduction: The Three-Legged Stool

The quality of a film coated tablet depends on:

- The coating process
- The tablet core properties
- The film coating material

Most coating defects are caused by a poor setup of the coating process!

The Elements of Film Coating

The film coating process is a combination of three interconnected unit operations:

Atomization

Drying

Blending
Analyzing the Coating Process

The target of the film coating process is, to enrobe the substrate (e.g. a tablet) in a smooth film of uniform thickness.

Analyzing the Coating Process: Film Thickness

A function of weight gain and the tablets’ surface area.

Understand the effect of tablet size on film thickness.
Analyzing the Coating Process: Weight Gain

\[ WG = \frac{Duration [\text{min}] \times Conc. \left[ \frac{g}{g} \right] \times Spray \ Rate \left[ \frac{g}{\text{min}} \right]}{Total \ Tablet \ Mass [g]} \]

Analyzing the Coating Process: The Coating Suspension

- A linear increase in suspension concentration leads to an exponential increase in suspension viscosity.
- Viscosity affects the overall sprayability of the suspension.
Analyzing the Coating Process: Atomization

Along with the spray gun design, suspension viscosity, spray rate, and atomizing air pressure define the size and velocity of the spray droplets.

Analyzing the Coating Process: Film Smoothness

Droplet size and viscosity in combination with the drying conditions in the coater have a direct influence on the smoothness of the coating films.

Defects resulting from poor balancing include orange peel, logo in-filling, and spray drying.
Analyzing the Coating Process: Drying Conditions

Parameters defined by the drying conditions are:

- Product Bed Temperature and Humidity
- Outlet Air Temperature and Humidity

Analyzing the Coating Process: Drying Capacity

The drying conditions are a function of the **drying capacity** and the **spray rate**, where the former is defined by:

- Inlet Air Temperature
- Inlet Air Volume
- (Inlet Air Humidity)
- Heat Loss of the Equipment
Analyzing the Coating Process: Drying Capacity

<table>
<thead>
<tr>
<th></th>
<th>blue</th>
<th>red</th>
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</thead>
<tbody>
<tr>
<td>Ambient Temperature</td>
<td>25°C</td>
<td>25°C</td>
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<tr>
<td>Ambient Relative Humidity</td>
<td>30%</td>
<td>60%</td>
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<tr>
<td>Water Content</td>
<td>5.9 g/kg</td>
<td>11.9 g/kg</td>
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<td>Inlet Air Temperature</td>
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<td>Outlet Air Temperature</td>
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<td>Outlet Air Relative Humidity</td>
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<td>54.9%</td>
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<tr>
<td>Outlet Air Water Content</td>
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<tr>
<td>Evaporated Water</td>
<td>13.9 g/kg</td>
<td>14 g/kg</td>
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Setting up a Film Coating Process

- Duration
- Concentration
- Viscosity
- Spray Rate
- Atomizing Air
- Tablet Shape
- Weight Gain
- Pan Speed
- Film Thickness
- Uniformity
- Even & Smooth Coating
- Droplet Size
- Smoothness
- Bed Temp
- Bed rH
- Outlet Temperature
- Outlet Dew Point
- Drying Capacity
- Inlet Temperature
- Heat Loss
- Inlet Volume
- Inlet Dew Point
- Atomizing Air
- Spray Rate
- Viscoisty
- Concentration
- Duration
- Bed Temp
- Bed rH
- Outlet Temperature
- Outlet Dew Point
- Drying Capacity
- Inlet Temperature
- Heat Loss
- Inlet Volume
- Inlet Dew Point

measurable response parameters

process set points
Setting up a Film Coating Process

Spray Rate: Understand the capabilities of your liquid handling system!

<table>
<thead>
<tr>
<th>Viscosity [mPas]</th>
<th>Pump Setting</th>
<th>X-20%</th>
<th>X-10%</th>
<th>X%</th>
<th>X+10%</th>
<th>X+20%</th>
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<td>65</td>
<td>70</td>
<td>70</td>
<td>70</td>
</tr>
</tbody>
</table>

Actual Pump Rates [g/min]

Inlet Air Temperature [°C]

- 50: bed temperature too low
- 60: ideal bed temperature
- 70: ideal bed temperature
- 80: bed temperature too high
- 90: bed temperature too high

Spray Rate*: Understand the impact on the product temperature!

The ideal bed temperature for an aqueous, HPMC-based coating is 38-42°C
Setting up a Film Coating Process

**Blending**
- Pan Speed

**Drying**
- Inlet Temperature
- Inlet Volume
- Spray Rate
- Atomizing Air
- Bed Temp
- Droplet Size

**Atomization**
- Atomizing Air
Setting up a Film Coating Process

Atomization Air

0 bar 1 bar 3 bar

Setting up a Film Coating Process

- Duration
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- Spray Rate
- Atomizing Air

- Tablet Shape
- Weight Gain

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- Film Thickness

- Uniformity

- Even & Smooth Coating

- Droplet Size

- Smoothness

- Inlet Temperature
- Heat Loss
- Inlet Volume
- Inlet Dew Point

- Drying Capacity

- Bed Temp
- Bed rH

- Outlet Temperature
- Outlet Dew Point
Setting up a Film Coating Process

Blending
- Pan Speed

Drying
- Inlet Temperature
- Inlet Volume
- Spray Rate
- Atomizing Air
- Bed Temp
- Droplet Size

Atomization

Pan Speed
- 4 rpm
- 8 rpm
- 16 rpm
Setting up a Film Coating Process

Summary

- The coating process is characterized by a complex network of interdependent parameters.
- Nonetheless, thorough understanding of the available materials and equipment allows for a rational set up of successful coating processes.
- If not – reach out for JRS Pharma’s application technologists!
Thank you for your attention!

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