

Tablet Film Coating: A Practical Guide



Colorcon[®]
Working Together for a Healthier World

Why film coat?

1

Branding

Customized colors, logos and finishes help distinguish products and enhance brand recognition.

2

Patient Compliance

A smooth coated tablet is easier to swallow and visually appealing, encouraging patients to adhere to their medication regimen.

3

Control Release

Film coatings can release the active ingredient at specific rates or locations in the gastrointestinal tract, improving therapeutic effectiveness.

4

Taste & Odor Masking

Coatings conceal unpleasant taste and smell of active ingredients, making medication more palatable.

5

Stability

Protect products from moisture, oxygen and light to improve stability and reduce the risk of degradation.



Film Coatings

What is a film coating?

Film coating is the application of a thin, even and continuous polymer film around a substrate, typically a tablet or multiparticulate.

Ingredients:

Each coating formulation has a unique set of properties, specially designed, depending on the substrate.

Polymer

Plasticizer

Opacifiers

Pigments

Others



Coating process:

Tablets are placed in a rotating drum while the coating solution is sprayed through atomizing nozzles. Hot air is simultaneously introduced to dry the coating.

To ensure the coating is applied correctly, several factors need to be optimized, including equipment, spray rate, temperature, inlet and outlet air.

Colorcon created a troubleshooting guide to help overcome common coating problems.



Film Coating Troubleshooting Chart

Your guide for increasing process efficiency and improving product quality



Logo Bridging

Coating spans across the tablet logo or breakline, making the logo unreadable or breakline not clearly visible



- **Low adhesion core ingredients**
Use high adhesion core materials
- **Poor logo design**
Use logo design optimized for film coating
- **Poorly plasticized film coating**
Select an optimally plasticized film coating from Colorcon
- **Low adhesion film coating**
Select a high adhesion film coating from Colorcon
- **Spray rate too high**
Decrease spray rate
- **Product temperature too low**
Increase product temperature
- **Atomization air pressure too low**
Increase atomization air pressure

Twinning

Two or more tablets are stuck together



- **Inappropriate tablet shape (flat surfaces)**
*Choose tablet design that eliminates flat surfaces**
- **Pan speed too low**
Increase pan speed
- **Atomization air pressure too low**
Increase atomization air pressure
- **Spray rate too high**
Decrease spray rate
- **Spray guns too close to bed**
Increase gun-to-bed distance
- **Insufficient drying**
Increase drying (through higher inlet temperature or higher inlet airflow rate)

Surface Erosion

The tablet surfaces are worn away or damaged during the coating run



- **Hygroscopic tablet core**
Reduce hygroscopic core materials, eg. superdisintegrant
- **High core friability**
Investigate core improvement
- **Logo placement or design**
Change logo design & placement
- **Low film strength**
Select a high strength film coating from Colorcon
- **Suspension solids concentration too low**
Increase suspension solids concentration (if possible)
- **Spray rate too low**
Increase spray rate
- **Pan speed too high**
Decrease pan speed
- **Punch design**
Improve punch design
- **Punch wear**
Check punches for wear or damage
- **Inappropriate baffle design for tablet shape**
Change baffle design

Edge Erosion

The edges of the tablets are worn away or damaged during the coating run



- **Sharp edges on tablets**
Change tablet shape/design
- **High core friability**
Investigate core improvement
- **Low film strength**
Select high film strength coating from Colorcon
- **Suspension solids concentration too low**
Increase suspension solids concentration (if possible)
- **Spray rate too low**
Increase spray rate
- **Pan speed too high**
Decrease pan speed
- **Incorrect coating pan fill**
Fill pan to correct volume
- **Worn tablet tooling (causes 'flashing')**
Replace tablet tooling
- **Inappropriate baffle design for tablet shape**
Change baffle design

Peeling

The coating peels away from the tablet surface



- **Core tablet erosion**
Improve tablet core: reduce hygroscopic ingredients, reduce friability, choose better core shape
- **Poor film coating formulation, eg. low film mechanical strength, poor adhesion to core, poorly plasticized**
Select an optimized film coating from Colorcon
- **Overheated tablet core**
Reduce pre-warming temperature/time

Breakage

Tablets are broken during the coating run



- **Tablets are too soft or too brittle**
Investigate core improvement
- **Tablets cap/laminate**
Change tablet compression profile
- **Poor tablet shape for coating**
Change tablet shape
- **Pan speed too high**
Decrease pan speed
- **Inappropriate baffle design for tablet shape**
Change baffle design
- **Spray rate too low**
Increase spray rate
- **Suspension solids concentration too low**
Increase suspension solids concentration (if possible)

Film Cracking

The coating is cracked, fractured or broken



- **Core and coating have different thermal expansion properties**
Reduce mineral type fillers in the core formulation, eg. calcium carbonate, calcium sulfate, magnesium carbonate
- **Lack of relaxation time between tablet compression and coating**
Extend time between tableting and coating

- **Poorly plasticized film coating**
Select an optimally plasticized film coating from Colorcon
- **Expansion of core due to heating**
Avoid high tablet bed temperatures

Spray Drying (Logo Filling)

Dried coating material creates a rough, uneven surface on the tablet and/or fills the logo or breakline, making the logo unreadable



- **Suspension solids concentration too high**
Decrease suspension solids concentration (if possible)
- **Atomization air pressure too high**
Decrease atomization air pressure
- **Drying air temperature too high**
Decrease drying air temperature
- **Spray guns too far from tablet bed**
Decrease gun-to-bed distance

- **Poor spray gun design or maintenance**
Replace or service gun
- **Turbulent airflow**
Minimize pan negative pressure
- **Aeration of coating suspension**
Optimize suspension preparation to avoid aeration

Picking and Sticking

Coating material pulled from the tablet surface and/or coating material deposited on the surface



- **Poor adhesion to core**
Use high adhesion core excipients
- **Poor film adhesion**
Select a high adhesion film coating from Colorcon
- **Low solids film coating formulation**
Select a high solids film coating from Colorcon
- **Spray rate too high**
Decrease spray rate
- **Drying air volume too low**
Increase airflow rate

- **Drying air temperature too low**
Increase drying temperature
- **Pan speed too low**
Increase pan speed
- **Atomization air pressure too low**
Increase atomization air pressure
- **Pan load too low**
Increase pan load
- **Poor spray uniformity**
Increase number of spray guns, fan width and/or gun-to-bed distance, suspension flow rate balance

Orange Peel Roughness

The entire surface of the coated tablets appears rough, like the surface of an orange



- **Film coating suspension viscosity too high**
Select a low viscosity film coating from Colorcon
- **Atomization air pressure too low**
Increase the atomization air pressure
- **Suspension solids concentration too high**
Decrease coating suspension solids concentration (if possible)

- **Spray rate too high**
Decrease spray rate
- **Poor spray gun performance**
Correct gun setup: gun design, gun spacing, gun-to-bed distance, fan width, suspension flow rate balance, or use a better spray gun

Color Variation

The color of individual tablets is uneven or non-uniform



- **Core ingredients (usually moisture sensitive) migrate (bleed) through the coating**
Use an isolating seal-coat
- **Pigments are poorly dispersed**
Select a fully formulated film coating from Colorcon
- **Core ingredients interact with film coating to cause color instability**
Select a different film coating from Colorcon

- **Liquid plasticizer migration**
Select a film coating with a solid plasticizer from Colorcon
- **Low opacity film coating**
Select a high opacity film coating from Colorcon
- **Core overwet during coating**
Increase tablet bed temperature

Tablet-To-Tablet Color Variation

The color of coated tablets is uneven within the batch



- **Poor tablet shape**
Optimize tablet shape for mixing
- **Suspension solids concentration too high**
Decrease suspension solids concentration (if possible)
- **Low opacity of film coating**
Select a high opacity film coating from Colorcon
- **Low film coat weight gain**
Increase weight gain of film coating
- **Pan speed too low**
Increase pan speed

- **Insufficient number of spray guns**
Increase number of spray guns
- **Pan load too low**
Increase pan load
- **Poor baffle design**
Improve baffle design
- **Poor spray gun design or setup**
Correct gun setup: gun design, gun spacing, gun-to-bed distance, fan width, suspension flow rate balance, or use a better spray gun

For more information, contact your Colorcon representative or call:

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Why Colorcon?

Here to support you at every stage:

60+ years and thousands of pharmaceutical projects make us the experts in solid oral dosage development and design. We work with our customers on pharmaceutical solutions for improved compliance and efficiency.

Global supply and technical support:

Over 40 global locations and 16 manufacturing sites producing superior quality ingredients and unparalleled technical support.

My Colorcon:

24/7 self-service portal brings unmatched convenience and assurance to every step of your customer journey.



**Coating
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Colorcon Academy

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