

How to successfully evaluate an alternative tablet film coating product

INTRODUCTION

Tablet film coating fulfils several important functions; they add colour to enhance the product appearance, enable consumers to differentiate one product from another, make the dosage form easier to swallow, mask unpalatable tastes and odours, protect active ingredient(s) from moisture, or alter release characteristics of actives upon ingestion. Costs aside, tablet film coatings procurement function is critical since it's the most noticeable physical representation of the dosage's integrity.

From time to time, pharmaceutical manufacturers look to new suppliers for new technologies, achieve process efficiencies that new suppliers bring, lower raw material costs, or just as a back-up plan for reducing supply discontinuities. It is therefore essential to have a defined set of criteria for selecting and evaluating suppliers and their offerings. In this note, I describe the tests that companies can use to successfully evaluate alternative film coatings suppliers. I divide the process into three stages: Supplier Evaluation, Quality/Regulatory Compliance & Technical Evaluation, and Product Evaluation.

Supplier Evaluation

Supplier evaluation involves verifying if a given company has the ability to meet your requirements. This is an important step since supplier non-performance, even the most basic or for the simplest items, can have serious consequences for your company. Some of the important parameters to consider are:

- Capacity (equipment scale, batch size, minimum order quantity);
- Safety/Health/Environmental risk;

- Financial solvency/business stability;
- REACH compliance;
- Delivery performance (distribution footprint & lead time); and
- Supply chain management.

For a long time, the film coatings supplier base was limited to two or three, mainly European and American companies. With the on-boarding of several small to medium suppliers, the situation is changing, bringing with it choice, innovation and flexibility for customers. Azelis now partners with Corel Pharma Chem, one the most established film coatings suppliers in India, to bring our UK and European customers innovative and cost-effective film coatings, covering all application areas (pharmaceutical, nutraceutical, immediate and modified release). Sold under the COLORCOAT™, NUTRACOAT™ and ACRYCOAT™ brands, these cost-effective coating systems are formulated using advanced technologies for ease of use, and consistent, problem-free application, even for challenging substrates.

Regulatory Compliance and Technical Evaluation

The next consideration is the supplier's quality and regulatory track record. We suggest buyers evaluate suppliers on the basis of the following criteria:

- cGMP compliance & other Quality Management Systems;
- Recalls & complaints policies;
- Change management policies;
- Material management controls;
- Quality agreement;
- Production facilities; and
- Documentation standard.

Technical competencies involve assessing a supplier in terms of their

DR. ENOSH MWESIGWA

Technical Product Manager
Azelis UK Ltd.

Enosh.mwesigwa@azelis.co.uk

laboratory capabilities, technical skill/staff qualifications, new product development capabilities and process development/understanding capabilities. We suggest obtaining feedback from previous customers and asking about the supplier's delivery performance, adherence to contract terms and ability to resolve issues. Film coatings are technically simple physical blends, however, their application is highly challenging and the availability of technical support is crucial to project success. This is why you should inquire about the technical support that's available, where the supplier's technical employees are based and the time it takes for them to respond to customer queries when they arise.

Product Evaluation

The final consideration is product assessment. The tables below summarise some of the tests that can be performed on products to assess and compare their suitability.

Having undertaken the technical assessment, the final aspect of the product evaluation step is to look at the comparative price of the material, in particular, the full cost of use. For film

ABOUT THE AUTHOR

Dr. Enosh Mwesigwa is a Technical Product Manager at Azelis, a leading global specialty ingredients distributor. He holds a PhD in Pharmaceuticals from University of London and has worked both in academia and industry.

Table 1
Tests for powders/formulations

	Purpose	Test
Odour	Odours can inform about the presence of volatile ingredients, impurities or signs of degradation. Caution: Some formulations may contain ammonia or solvents. Take extra care with such systems.	Record any distinctive odours and note if there are differences with existing product.
Description	Colour, texture & other observable characteristics are an indication of the quality of the powder.	Physical description, particle size, colour distribution/homogeneity, presence of fibres & other extraneous matter.
Dry Draw Down	Also known as Doctor Blade. It is a very simple and effective way to measure appearance and colour homogeneity of a film coating formulation.	Observe and make a note of any differences in appearance between samples.
Sieve analysis	Used to determine the particle size distribution of powdered coating formulation.	Record the percentage of different grain sizes contained within samples.
Bulk & tapped density	To assess the bulking properties (flowability, packing, handling, intermolecular interactions, etc.) of the powders.	Record the sample Unsettled apparent volume, Final tapped volume and Hausner Ratio.

Table 2
Tests for suspensions/dispersions

	Purpose	Test
pH	pH (and ionic content) provide valuable information about the chemical properties of the formulation and how it interacts with substrates.	Record the pH of the dispersion. How does it compare with other materials?
Viscosity	Viscosity of the dispersion influences the sprayability of the dispersion, process throughput as well as smoothness of the film obtained. The ideal dispersion viscosity should be < 400 mPas.	Use a rotational viscometer to record viscosity as a function of % solids content. Also, make a record of the time taken to hydrate the sample.
Wet Draw Down	Same as the Dry Draw Down.	Note the colour, presence of insoluble materials or contaminants.
Wet sieve test	Used to measure levels of insoluble or poorly dispersed material owing to its effectiveness at separating granular material from finer fractions.	Observe and record the amount of insoluble or poorly dispersed material.
Suspension characteristics	Suspension characteristics provide an indication on how well individual formulation ingredients are held in suspension.	Note and record the sedimentation rate, level of foaming, ease of dispersion of the sample.
Minimum Film Forming Temperature (MFFT)	This is a simple test that is used to determine the lowest temperature at which the coating will uniformly coalesce into a film. The MFFT gives an indication on how well a product is developed.	Make a record of the MFFT for each formulation.

Table 3
Tests for cast films

	Purpose	Test
Adhesion	In order to perform well as coatings, adhesion to the substrate is critical. This test allows you to assess this parameter.	There are several ways that can be used to measure adhesion (Scrape Adhesion, Pull-off or Instron). Make the appropriate observations.
Tensile strength	Mechanical strength is directly correlated with film aesthetics such as bridging, peeling and cracking.	Record the film's elongation and tensile strength and compare between samples.
Water vapour transmission rate (MVTR)	For moisture barrier coatings, this parameter describes how effective the film is at performing as a barrier to moisture.	Record the MVTR.

Table 4
Tests for coating process & coated substrates

	Purpose	Test
Coating parameters	Coating parameters (bed temperature, spray rate, atomisation pressure & spray gun nozzle size) determine how operationally efficient a given coating system is.	Compare and contrast recommended parameters, throughput and weight gains achieved for similar equipment loads.
Film colour/whiteness	For white or pigmented systems, a uniform coloration communicates to the consumer that the product is of high integrity.	Use an appropriate colour measuring tool (e.g Pantone® CAPSURE™ to measure colour differences in matched systems. Other measures such as the Berger Whiteness and CIE 82 can be used to assess whiteness.
Friability, disintegration & dissolution rate	Friability gives an indication about film coating mechanical properties while disintegration and dissolution rate provide an indication on how the coating system performs <i>in-vivo</i> .	Make a record of the friability, the disintegration time and dissolution time.

coatings, it is especially useful to examine the material's recommended weight gain as this single factor will influence the material needed for a comparable equipment load. By way of example, if we take two competing products A and B. Supposing product A is used at 5% weight gain but costs \$18 per unit while product B is more expensive at \$25 per unit but only requires a weight gain of 3%. For a comparative application process, Product B will be the cheaper by up to 20% since less material is required for each operation.

Tablet Film Coating Troubleshooting Guide

Most defects in coated tablets are deficiencies in the product and/or process that may, to different degrees, be detrimental to a product performance and/or undermine consumer's confidence.

Defects manifest as:

- Visual imperfections in a finished product;
- Product functionality deficiencies;
- Product instability; and
- Processability issues.

This guide provides a list of suggestions for addressing common problems encountered during tablet film coating.

Although operators make process adjustments during the course of tablet coating to resolve problems as they arise, the ideal situation is to build robustness into your process design proactively, so that the process design space can accommodate any formulation limitations (for both the core and coating), thus preventing any unanticipated issues downstream altogether.

Tablet Film Coating Defects

Sticking and Picking: Tablets stick together temporarily after leaving the spray zone but separate to leave grazes on the film surface due to removal of pieces of film.

Twinning: Tablets remain stuck together along large flat surfaces, usually in pairs.

Colour Differences: These defects manifest as a visible variations in the colours or shades of the film coating from one tablet to another.

Logo In-filling & Bridging: In-filling is when intaglios are filled out & blurred. Bridging is when coating fails to neatly adhere within the contours of intaglios.

Film Peeling: For film peeling defects, the coating peels off during or immediately after the coating process to leave unsightly blotches or naked patches.

Splitting & Film Cracking: Splitting is when tablets develop cracks around the edges of the tablet. Cracking involves the coating cracking across the crown of the tablet.



Scuffing: Dark marks on surface of white or pastel coloured coated tablets. Mainly a friction promoted interaction between titanium dioxide in coating & steel in pan wall.

Surface Roughness: Surface of the coated tablet has an apparent rough texture. In extreme cases, the surface is pitted & raised, much like an orange skin/peel.

Surface Erosion: Sections of tablet surfaces erode as cores tumble in the coating pan. The problem is exacerbated by the presence of intaglios/logos.

Discolouration: Manifests as unsightly specks on coating surface. Can involve migration of core ingredients into the film or interactions between core and coating.

Common film coating defects, likely causes and suggested solutions

Defect	Likely causes	Physical appearance	Suggested solutions
Sticking and Picking Picking and sticking involves tablets sticking together temporarily after leaving the spray zone and then separating. However, upon separating the tablets leave grazes on the surface as pieces of film are removed.	Tablets have flat surfaces, especially along the edges. Use of caplets, oblong or flat round cores. Coating formulation is very tacky. Sub-par drying conditions.		Consider modifying tooling for adequate curvature along edge of the tablets. Consult with Azelis or your existing supplier to select a non-tacky coating system. Increase pan speed to reduce dwell time within spray zone. Increase bed temperature. Decrease spray rate to reduce overwetting. Increase atomising air pressure for more fine spray droplets & more effective drying.
Twinning Tablets remain stuck together along large flat surfaces, usually in pairs.	Tablets have flat surfaces, especially along the edges. Use of caplets, oblong or flat round cores. Coating formulation is very tacky. Sub-par drying conditions.		Consider modifying tooling for adequate curvature along edge of the tablets. Consult with Azelis or your existing supplier to select a non-tacky coating system. Increase pan speed to reduce dwell time within spray zone. Decrease spray rate to reduce overwetting. Increase atomising air pressure for more fine spray droplets for more effective drying.
Colour Differences This defect manifests itself as a visible variation in the colour/shade of the film coating from one tablet to another.	Coating formulation lacks the necessary hiding power. Differences in tablet dwell time within spray zone leading to non-uniform coating distribution.		Use coating system with adequate hiding power. Consult with Azelis or your existing supplier to review colour options. Increase pan speed to increase the frequency of passes through spray zone or number of spray guns to widen the spray zone for greater surface coverage. Prime spray guns for uniform spray rates & cover.
Logo In-filling and Bridging In-filling is when intaglios are filled out & blurred while bridging is a failure of the coating to neatly adhere within the contours of intaglios, especially at higher weight gains.	Use of tablet core ingredients that reduce adhesion. Low porosity tablet core. Highly intricate logo design. Tacky coating formulation. Excessive foaming of coating dispersion. Sub-par drying conditions.		Increase levels of adhesion-promoting ingredients (e.g. hypromellose) in tablet core. Replace hydrophobic lubricants. Where possible, decrease compression force or use high porosity promoting fillers. Consult with Azelis or your existing supplier to select a non-tacky coating system. Use a suitable defoamer. Increasing bed temperature & lower spray rate.

Peeling

For film peeling defects, the coating peels off during or immediately after the coating process.

Tablets formulation ingredients do not promote sufficient adhesion.

Coating formulation does not yield film with sufficient adhesion or toughness to withstand edge damage or build up internal stresses.



Consider increasing levels of adhesion-promoting ingredients.
Reduce/replace levels of hydrophobic lubricants.
Where possible, decrease compression force or use high porosity promoting fillers such as cellulose.
Consult with Azelis or your existing supplier to select a coating system with inbuilt adhesion.
Consider adjusting bed temperature for an optimum surface adhesion & spreading.

Splitting

The tablet develops cracks/splits around the edges of the tablet.

Coating formulation lacks adhesion or toughness to withstand edge damage or build up internal stresses.
Presence of attrition factors in the coating drum.
Excessively high drying conditions.



Where possible, decrease compression force or use high porosity promoting fillers such as cellulose.
Consult with Azelis or your existing supplier to select a coating system with inbuilt adhesion & toughness.

Cracking

Cracking involves the coating cracking across the crown of the tablet.

Coating formulation lacks adhesion or toughness to withstand edge damage or build up internal stresses.
Presence of attrition factors in the coating drum.
Excessively high drying conditions.



Consult with Azelis or your existing supplier to select a coating system with inbuilt adhesion & toughness.

Scuffing

Dark spots or marks on the surface of white or pastel coloured coated tablets. Mainly a friction-promoted interaction between titanium dioxide in coating & stainless steel in the pan wall.

Large/dense tablets which abrade easily.
High content of titanium dioxide and/or lengthy coating operations.
Higher pan speeds which increase chances of tablets sliding in pan.
Low pan charge/load.



Minimise the use of high-density fillers such as dicalcium phosphate.
Avoid use of oblong/capsule shaped tablet cores.
Use alternatives to titanium dioxide.
Shorten the duration of the coating process.
Increase pan speed and/or pan load.
Ensure pan surface is clean.
Passivate the stainless steel surfaces of the coating pan that contact with the tablets.

Roughness

Surface of the coated tablet has a rough texture (apparent visibly and to the touch). In extreme cases, the surface is pitted & raised, much like an orange skin/peel.

Coating formulation is very viscous or does not atomise well.
Coating formulation does not atomise efficiently.
Overwetting of tablet bed.



Use low viscosity systems.
Consult Azelis or your existing supplier to select a film coating system that atomises efficiently.
Adjust atomising air pressure.
Check spray gun spray patterns.
Optimise drying conditions to minimise spray-drying effects.

Surface Erosion

Tablet surfaces appear eroded as cores tumble in the coating pan during the coating process. The problem is exacerbated by the presence of intaglios/logos.

Friable cores.
High spray rate.
Highly hygroscopic cores.
Unsuitable punch designs.
Coating formulation lacks adhesive strength.
Coating formulation lacks covering power.
High pan speed.



Use binders such as HPMC, include silica or reduce plastic ingredients such as starch in core to improve tablet hardness.
Where possible reduce levels of hygroscopic ingredients (e.g. cellulose, starch, or sorbitol).
Opt for punches with reduced curvature on upper & lower faces.
Optimise pan speed and/or spray rate.

Discolouration

A common defect in nutraceuticals. Manifests as unsightly specks on coating surface. Can involve migration of core ingredients into the film due to heat or interactions between core and coating.

Overwetting from excessive spray.
Transfer of moisture into core.
Interaction of coating and tablet ingredients.
Coating system lacks moisture barrier effects.
Temperature-related degradation of ingredients.



Speak to Azelis or your existing supplier to select a film coating system that is optimised for high solids application or has low reactivity.
Switch to a moisture barrier coating, such as Colorcoat™MB4W or similar.
Decrease spray rate or increase processing temperature or increase pan speed to reduce dwell time in spray zone.
Optimise spray patterns to avoid mis-sprays.

CONCLUSION

The target audience for this Technical Note is buyers and NPD professionals involved in purchasing film coatings products for pharmaceutical and nutraceuticals dosage forms. The guidance covers the most important tests for assessing new or existing products, and we believe when applied correctly, it can be a useful tool for making most of new product offerings.