

Guest Post: Colorcon



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Colorcon Coatings – Achieving the Perfect Finish

If an uncoated tablet is therapeutically effective, why bother film coating? It's an added step in production and often considered to be a specialized process requiring significant formulation and regulatory knowledge.

So why is it that the largest percentage of today's top selling solid oral dosage forms are film coated? There are sound quality and regulatory reasons.

A Positive Contribution to Product Quality

Film coatings protect solid dosage forms and add a superior and glossy product finish with color that provides differentiation and excellent brand quality. In packaging, film coated tablets reduce waste, enhance slip in production, help avoid cross contamination, and protect cores from environmental factors.

Meeting Regulatory Expectations

Today, regulatory agencies are focusing on guidance to help reduce medication errors and improve patient adherence. New FDA Guidance Documents (April 2016) call on Innovator, Generic, and OTC manufacturers to take steps to differentiate their oral dosage forms visually and to consider using film coatings to aid the patient in swallowing tablets. (1,2)

Many companies have opportunistically seized onto these newer expectations by including a carefully selected film coating for use on their product. Some manufacturers are now applying film coatings to previously uncoated tablets using fully formulated systems. They find that working with a reliable excipient supplier such as Colorcon helps them sort through the regulatory process. (3) Innovative manufacturers around the world are converting marketed product coatings to more efficient systems. This change provides not just a great tablet finish but reaps the rewards of manufacturing efficiencies.

First Time Right with Ready Formulated Film Coating Systems

When it comes to selecting the right film coating, one name is synonymous with first-in-class quality, complete with services that continue to set global standards. That brand is Opadry®, a complete film coating system from Colorcon.

The Opadry system is not a one-size fits all product, as our customers' products are diverse. The name itself stands for a family of customizable solutions where we carefully match the ingredients to the customers' color requirements, equipment capabilities, the tablet core, and their processing needs. As a fully formulated system, each Opadry is delivered ready-to-use, taking the confusion out of pigment and other ingredient choice complexity.

Fully Formulated Opadry Systems Help Lower Total Costs

Through the years, a variety of Opadry systems have been introduced that address the needs for film coating in the first place. For immediate release applications, these include the use of color for branding and differentiation, aesthetics, taste-masking, along with light, environmental and moisture protection.

All Opadry systems are high-efficiency products that contain a unique blend of polymer, plasticizer, and pigments needed to achieve the best result. Delivered as a ready-to-use dry powder, every Opadry offers the advantage of getting a product containing the right amount of excipients and pigments to ensure batch-to-batch consistency, time after time. As a complete package, a fully formulated Opadry reduces inventory management and Colorcon provides short lead times.

Opadry Means Innovation

The original Opadry brand has grown beyond the basic immediate release coating incorporating advanced polymers and novel pigments that:

- Reduce production time; Opadry II, Opadry QX
- Protect the core from environmental moisture; Opadry amb II
- Provide a unique high-gloss pearl finish; Opadry fx

Materials You Can Trust

All Opadry systems are developed using high-quality materials designed to meet global compendia requirements. Due to the complexity of pharmaceutical regulations worldwide, Colorcon applies its years of formulation expertise to deliver a system for the local market to meet the customer's specific goal. All ingredients used in Opadry products come from accredited sources supported through a global business continuity program. The result, no supply chain interruptions are experienced by the user. Regulatory filing information packages are also available from Colorcon, making the customer's application process that much easier.

Colorcon, from Core to Coating, Your Supplier of Choice

At Colorcon, we formulate, we innovate -- and we focus our coatings and excipients exclusively for pharmaceutical and nutritional oral solid dosages.

That's why, when you set out to select the right coating or excipient for your formulation, be sure to partner with the leading company that brings you innovative products plus specialized technical support when and where you need it. Be confident with your choice.

References:

1. FDA Guidance for Industry, Safety Considerations for Product Design to Minimize Medication Errors, (April 2016). <http://1.usa.gov/1SMYvSN>
2. FDA Guidance for Industry, Size Shape and Other Physical Attributes of Tablets and Capsules (June 2015). <https://www.federalregister.gov/articles/2015/06/19/2015-15076/size-shape-and-other-physical-attributes-of-generic-tablets-and-capsules-guidance-for-industry>
3. C. Miller, Beyond Keeping Up Appearances*The Medicine Maker (April 2016) pg. 44– Coat of Regulations