

An Immediate Release, Pearlescent, Film Coating System from Colorcon[®]

A distinctive product appearance offers many benefits to the producers and marketers of pharmaceutical tablets and nutritional supplements.¹ In response to the demand for solid oral dosage forms that are unique, elegant and will further enhance a distinctive tablet design, Colorcon offers Opadry[®] fx[™], special effects film coating systems.

Opadry fx systems are immediate release, special effects film coating formulations that create an exceptional solid oral dosage form while allowing manufacturers to capitalize on existing film coating expertise and equipment capacity. A distinctive coating system like Opadry fx can improve the brand identity of a product with the consumer and at the same time can add a tier of security against the act of tablet counterfeiting and the increasingly common practice of reimportation.²

Opadry fx systems are formulated by incorporating pearlescent pigments into high gloss, clear polymer systems from Colorcon. The results are film coated tablets that exhibit stimulating colors and lustrous effects. When a unique coating like Opadry fx is used in conjunction with a specific tablet shape, a debossed logo or a printed image, this film coating system will offer the manufacturer or marketer the opportunity to trademark the image.³

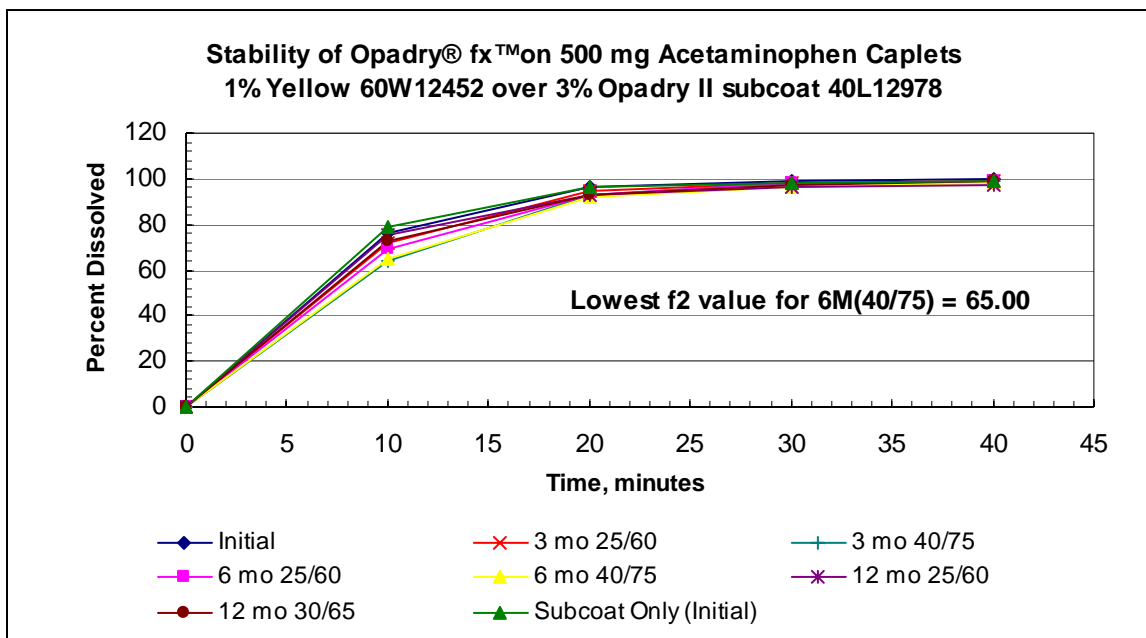
Figure 1. Tablets Coated with Opadry fx



IMMEDIATE RELEASE FILM COATING SYSTEM

Opadry fx systems are aesthetic, immediate release film coatings. Studies conducted on model drugs in tablet form show that Opadry fx coatings do not significantly change dissolution profiles.⁴ Further, the Opadry fx coated tablets maintain the immediate release dissolution profile when stored under standard ICH (International Conference on Harmonization) stability conditions as shown in Figure 2.

Figure 2. Dissolution Stability Profile for Paracetamol (APAP) Caplets Coated with Opadry II and Opadry fx Topcoat⁵



FILM PROPERTIES

Testing performed on a model Opadry fx system produced adhesion and tensile strength values that meet or exceed those of a standard Opadry® II formulation which is formulated with HPMC as the primary polymer.⁶ The oxygen transmission rate of an Opadry fx film is 100 times lower than that of a standard HPMC-based Opadry clear film coating. This property offers the active ingredients within a solid oral dosage form increased protection from environmental conditions.⁷ An additional study completed by Colorcon demonstrated that Opadry fx will inhibit the oxidation of ibuprofen in tablet form. The results of this study suggest that Opadry fx may protect other actives used in solid oral dosage forms against oxidation.⁸

APPLICATION

Creating a unique appearance with an Opadry fx film coating from Colorcon does not require any additional capital investment. To produce a tablet with a high gloss, pearlescent appearance, a fully formulated, white or pigmented subcoat of either an immediate release or enteric system from Colorcon is applied to a tablet. This color coating application is completed by means of standard film coating equipment and processing conditions.

Following the color coating, a top coating of Opadry fx is employed to impart the pearlescent effect to the tablet. Opadry fx is applied to the tablets in the same equipment and only minimal adjustments to the coating process parameters may be necessary.⁹ The addition of an Opadry fx film coating is simple and cost-effective!

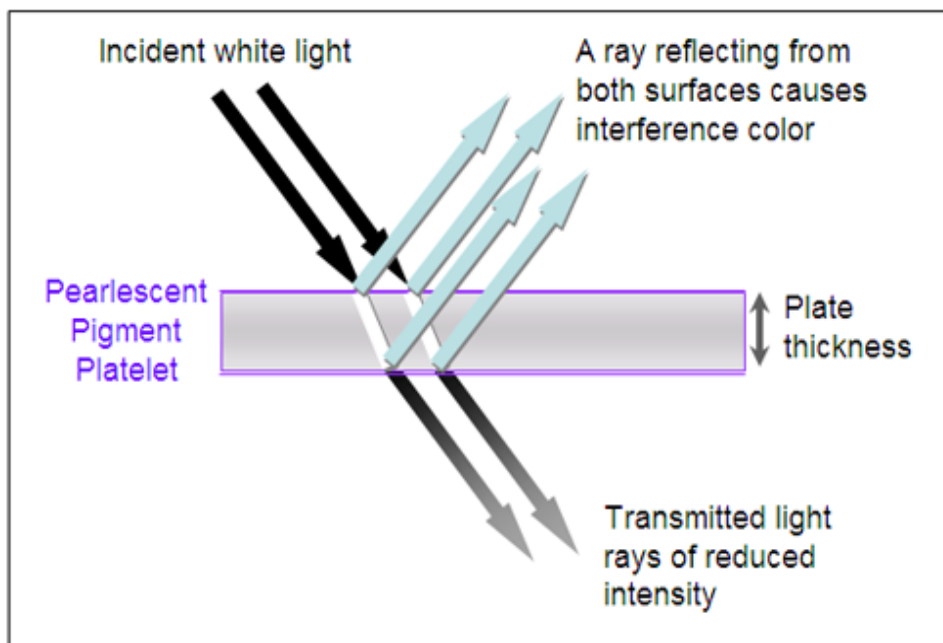
COLOR DEVELOPMENT

Opadry fx is a special effects film coating system due to the inclusion of specialized pearlescent pigments. Pearlescent pigments are comprised of small, transparent, platelet-shaped particles. At certain angles a ray of light is split by these pigment particles. A portion of the light is reflected from the top surface while another portion of light is reflected from the bottom surface.

The remainder of the light is transmitted through the particle. Since the two reflections travel different distances, the light waves are shifted partially out of phase. This shift results in a phenomenon known as optical interference and what is observed is referred to as the interference color.

Any transparent particle with a thickness equal to that of a wavelength of visible light is capable of producing an interference color. This is the same phenomenon that produces the colors observed on soap bubbles and snowflakes. For Opadry fx, the pharmaceutical grade pigments are manufactured in such a way as to produce platelets with precisely controlled thicknesses. The final color is determined by the individual plate thickness and the degree to which the material will bend incident light.¹⁰

Figure 3. How a Pearlescent Pigment Works

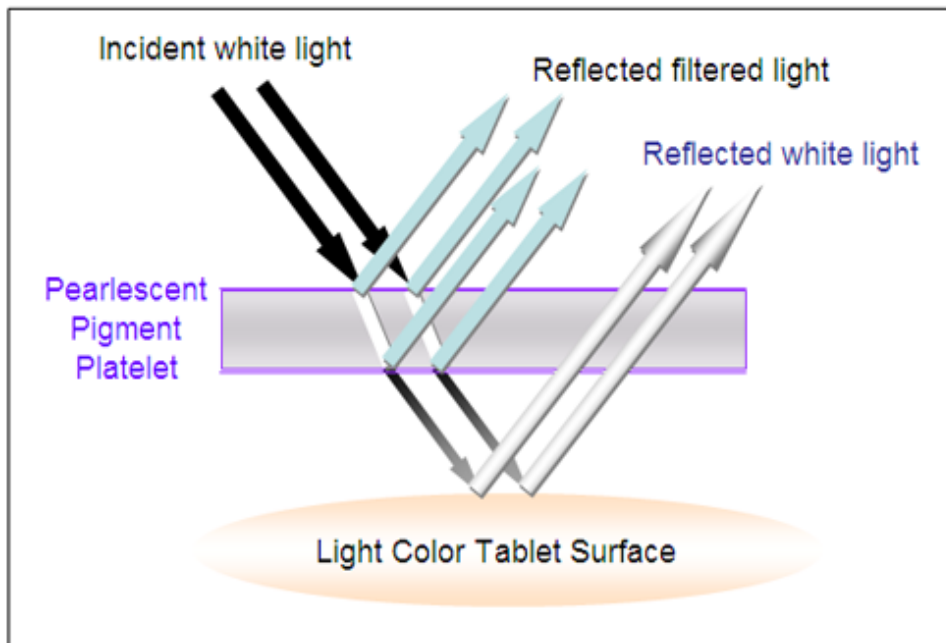


COLOR MATCHING AND CUSTOMIZED EFFECTS

Opadry fx is a high gloss film coating system that imparts a pearlescent effect. It is available formulated with blue, green, red, purple, orange, silver and yellow pigments from which a broader array of colors may be achieved. Opadry fx formulations are available in a choice of different colors to allow for complete customization of the finished, coated tablet. These colors can only be duplicated by knowing the specific pigment grade combination and the processing procedures used in the drug's manufacture.²

The final appearance of the Opadry fx is primarily dependent on the pigments utilized in the color coating applied prior to the application of the Opadry fx. When white or light colored subcoats are utilized, the light transmitted through the Opadry fx layer is reflected to the observer. The reflected light along with the reflection from the pearlescent pigments will dilute the resulting interference color. The result is a high gloss, yet subtle, pearlescent effect the tablet surface.

Figure 4a. Effect of Subcoat Color on the Degree of Pearlescence



With dark colored subcoats, most of the light transmitted through the Opadry fx layer is absorbed rather than reflected. The absence of a competing reflection allows the observer to view the pure interference color and the full effect of the pearlescent pigment along with the elegance of the high gloss polymer.

Figure 4b. Effect of Subcoat Color on the Degree of Pearlescence

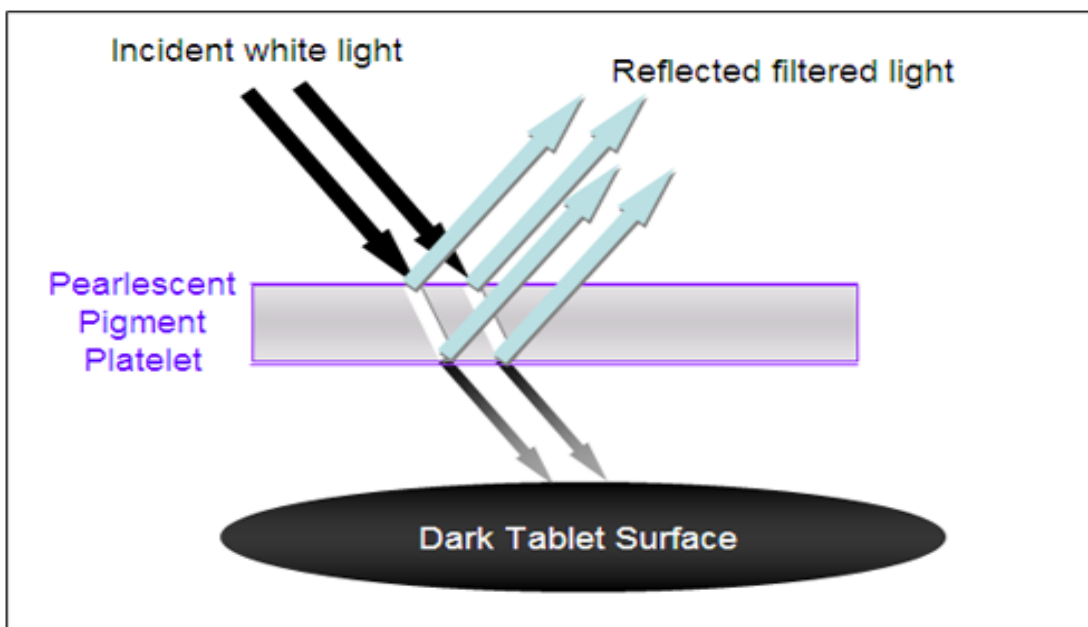
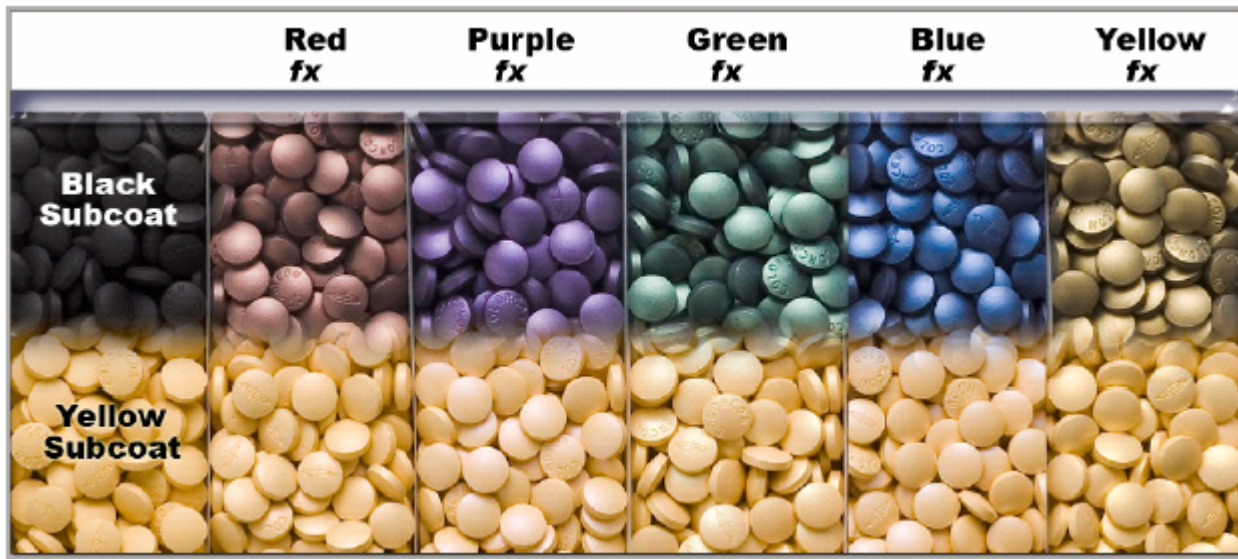
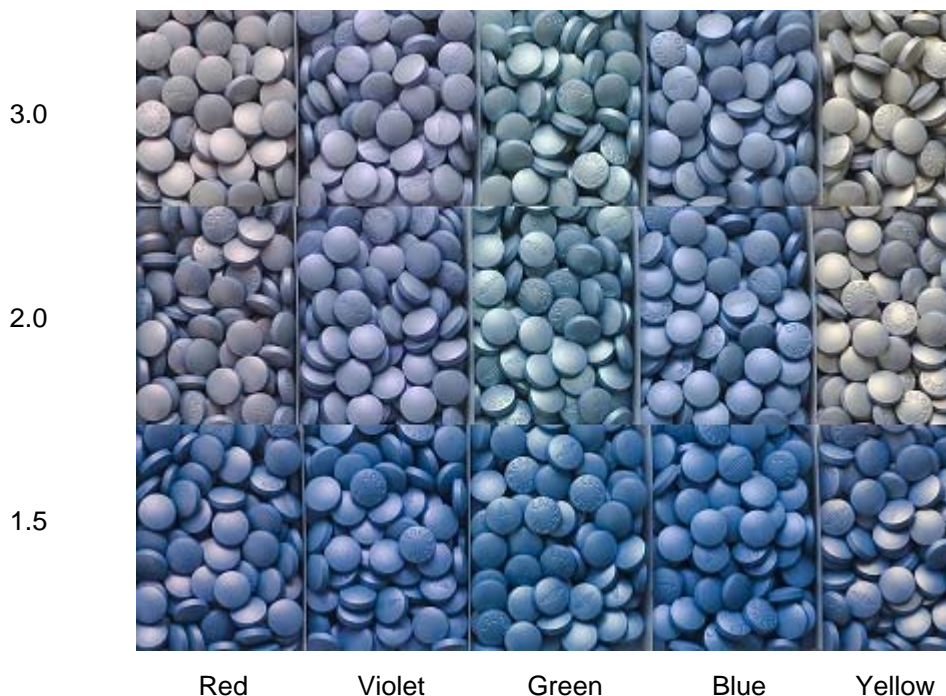


Figure 5. Visual Impact of Subcoat Choice on the Final Appearance of Opadry fx Coated Tablets



Beyond the impact of the choice in subcoat color and Opadry fx formulation, further customization of the final tablet is possible through variations in the film thickness or coating weight gain of the pearlescent film. Changes in the weight gain of the Opadry fx applied to the tablet will transform the perceived color. Figure 6 below displays tablets coated with a blue, pigmented, color coating. These tablets were then coated with five different Opadry fx color formulations to three distinct weight gains. Combinations of various subcoat colors, Opadry fx colors and Opadry fx weight gains offer nearly limitless possibilities in creating unique and elegant dosage forms.

Figure 6. The Effect of Increasing Weight Gain of Opadry fx on an Opadry II, Blue Subcoat



ACCEPTABLE FOR USE IN THE UNITED STATES AND EUROPE

The unpigmented base formula of the Opadry fx is comprised of ingredients that meet the regulatory requirements of the United States, Europe, Japan, India and China. The pearlescent pigments used in Opadry fx currently meet the regulatory requirements for use in the United States and Europe. Table 1 displays a current summary of the acceptability of Opadry fx for use in various regions of the world.¹² Ingredients derived from genetically modified organisms (GMOs) or animal sources are not present in Opadry fx.

Table 1. General Regulatory Acceptability by Region

Intended Use	US	Canada	EU	Japan	China	India
Pharmaceutical	Yes	No	Yes	No	No	No
Dietary Supplements	Yes	No	Yes	No	No	No

PRODUCT SUMMARY

Opadry fx is a fully formulated, pearlescent, film coating available in multiple colors and is applied using standard film coating equipment onto solid dosage forms. It is compatible with both printed and debossed logos.

Colorcon backs Opadry fx with world-class support to create a unique and elegant tablet image. Please feel free to contact your area's Colorcon Sales Manager or Area Technical Manager for technical assistance, including on-site coating trial support. Poster and publication reprints, parameter recommendations, regulatory summaries and other documentation to support the successful use of Opadry fx are all available from Colorcon.



REFERENCES

1. Colorcon engaged Paragon Research group to measure various solid oral dosage forms, including pearlescent, for preference by doctors, pharmacists and consumers.
2. More than Just a Pretty Color; David R. Schoneker, Pharmaceutical Executive, March 2005.
3. US Patent and Trade Mark Office, Title 15.
4. USP monograph for film coated paracetamol (APAP) and ibuprofen tablets.
5. The USP monograph for acetaminophen tablets states, "Tolerances-Not less than 80% (Q) of the labeled amount of C minutes."; 2003 USP/NF, The United States Pharmacopoeial Convention, Inc., p. 19.
6. Tests were performed on a standard clear HPMC film coating and Opadry fx 60W12452. The differences in the resulting values were statistically insignificant.
7. Taken from: Optical Properties, Film Properties, and Stability of Opadry fx Pearlescent Film Coating System; Franklin J. Gulian and Rita M. Steffenino; Colorcon, West Point, PA, USA; AAPS Annual Meeting and Exposition, Salt Lake City, October, 2003
8. Taken from: Oxidative Protection of Ibuprofen Using Opadry fx Special Effects Film Coating System; Franklin J. Gulian, Rita M. Steffenino, David M. Ferrizzi, and Thomas P. Farrell; Colorcon West Point, PA, USA; AAPS Annual Meeting and Expositions, Baltimore, November, 2004.
9. Opadry fx is typically reconstituted to 7.5% w/w solids. As this is likely to be a lower solids content than the base coat, processing parameters may need to be adjusted to ensure adequate drying depending on the equipment uses.
10. Encyclopedia of Polymer Science and Technology (Volume 10, 1969; published by John Wiley & Sons, Inc.; author L. M. Greenstein.)



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