

Opadry®AMB II

High Performance Moisture Barrier Film Coating



Aqueous Fully Formulated PEG-free Immediate Release System

- Proven protection from environmental moisture
- Superior coating productivity with ease-of-use
- High gloss finish with well defined logos



Colorcon®

Working Together for a Healthier World

High Performance Moisture Barrier Film Coating

Many active pharmaceutical ingredients and solid oral dosage tablets are sensitive to moisture potentially causing degradation or poor product performance. Immediate release (IR) film coating systems provide essential protection and are especially useful when tablets are removed from their original packaging.

Opadry® amb II, high performance moisture barrier film coating is the first fully formulated PVA-based immediate release system without polyethylene glycol (PEG) that delivers the three-fold advantage of high productivity, low impurity levels and a superior tablet finish.



Enhanced Product In-Use Integrity

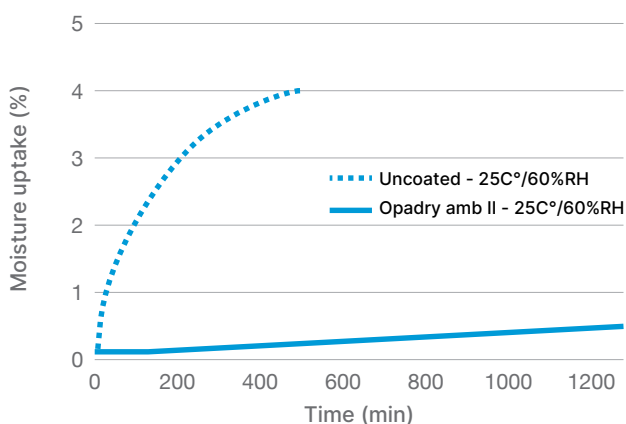


Guard your tablets from moisture over a longer period of time.

Proven Product Protection

The rate and level of moisture uptake provides a measureable indicator into the performance of moisture barrier film coatings. Opadry amb II films were characterized using a novel on-tablet testing method.¹ As shown in **Figure 1**, the rate of moisture uptake compared to uncoated tablets demonstrates the superior in-use functionality of this coating.

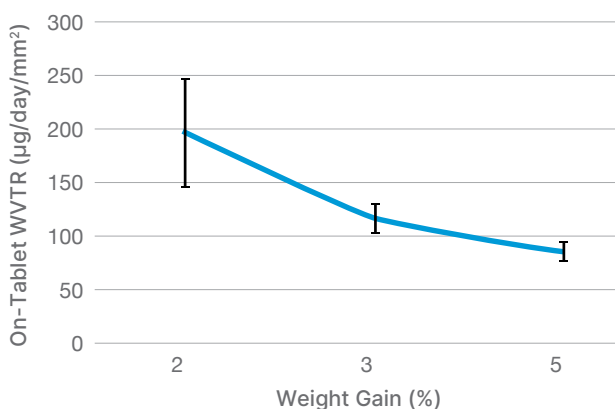
Fig 1. Moisture Uptake



Reliable Barrier

On-tablet analysis proves that coating with Opadry amb II at the recommended 4% weight gain offers the most reliable and consistent moisture barrier performance (See **Figure 2**).

Fig 2. Effect of Film Coating Weight Gain



Superior Coating Productivity

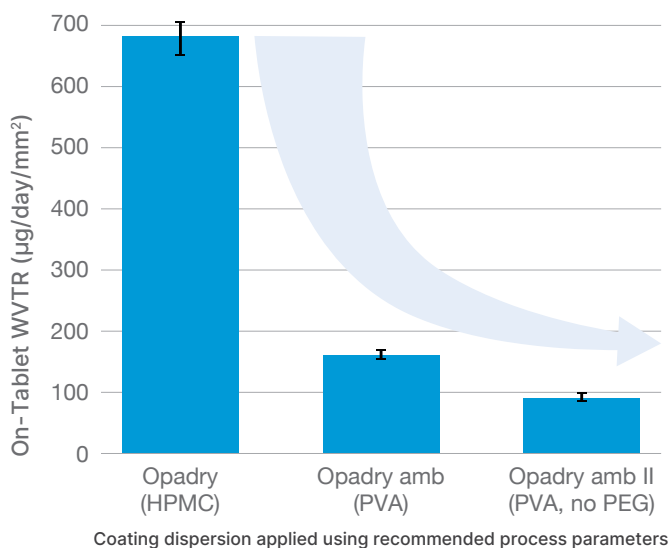
Opadry amb II provides the perfect balance of barrier protection, time savings in production and ease-of-use.

- One step dry powder - ready to use in 45 minutes
- High productivity - low viscosity



Faster coating and significantly more moisture protection with Opadry amb II

Fig 3. On-Tablet WVTR 40°C / 75% RH, 4% WG



Typical 48" Pan Coating

System	Avg. Spray rate (g/min)	% Solids	Coating Time (min)
Opadry	340	15	125.5
Opadry amb	172.5	20	185.5
Opadry amb II	275	20	116.4

Low Impurity Levels

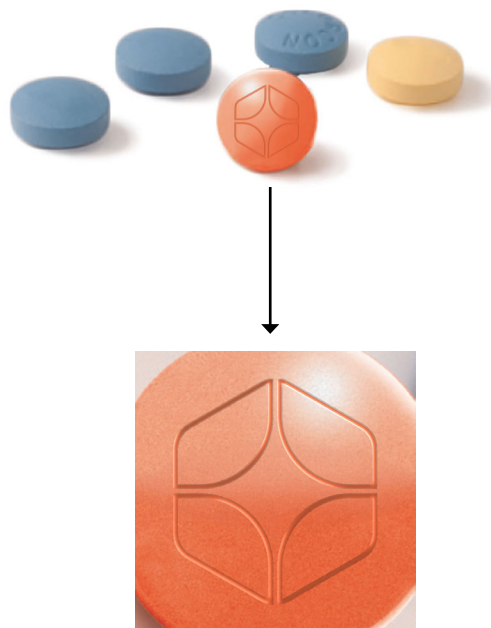
Opadry amb II is formulated without PEG to reduce potential interaction with sensitive drugs. Studies of the Opadry amb II powder show:

- Formic acid and formaldehyde residues exhibited no measurable increase after six months accelerated stability (40°C/75%RH)
- Peroxide levels remained undetectable after twelve months (30°C/65%RH)

Glossy Finish and Well-Defined Logo

Tablets coated with Opadry amb II create a high gloss finish with distinctly defined logos

- Available in clear and pigmented formulas
- Approved for pharmaceutical use



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Deliver high-performance products — with Colorcon

Choose Colorcon, leader in pharmaceutical solid oral dose solutions, as a formulation partner of choice in every phase of your product development.

Film Coatings:

- Optimized formulations specifically for your application and regulatory needs including customized colors and color matching
- Innovative products for mechanical integrity, gloss, pearlescence, and environmental protection
- Tablet design concepts, consulting and services to build a strong brand image and stand out from the competition.

Formulation Technologies:

- Full range of functional excipients
- Technologies for development and production of delayed/enteric release and extended/controlled release tablets and multiparticulates
- HyperStart® service and extensive applications data to provide starting formulations to save you development time and money
- Extensive formulation know-how and technical support to achieve the exact drug release profile desired

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