

FILM COATING

OPADRY[®] EC

Ethylcellulose Organic Coating System



Simplify Development and Modulate Drug Release

- Faster Formulation
- Adjustable Drug Release Profiles
- Reliable and Consistent Coating Performance



Formulated Barrier Membrane Coating

Opadry[®] EC is a controlled release film coating product, designed for organic solvent-coating of multiparticulates and tablets, for sustained release and taste-masking applications.

Release Performance is Controlled by Levels of Polymer and Pore-former

- Choice of 3 standard pore-former levels
- Combine pore-former formulations
- Apply coating at range of weight gains

Simplify Development and Modulate Drug Release

- Modifying film porosity provides controlled release of low, medium and high solubility drugs
- Stable film with high mechanical strength, suitable for moisture and/or heat sensitive drugs
- Achieve desired release profiles at low coating levels.

Additional formulation flexibility can be achieved using binary mixtures of the different pore-former formulations, with range from 0.0% to 20.6% pore-former level achievable. Plasticizer concentration remains constant when blending Opadry EC formulations.



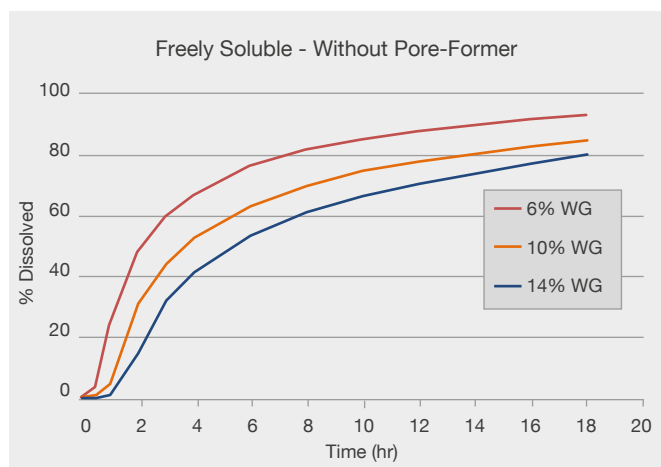
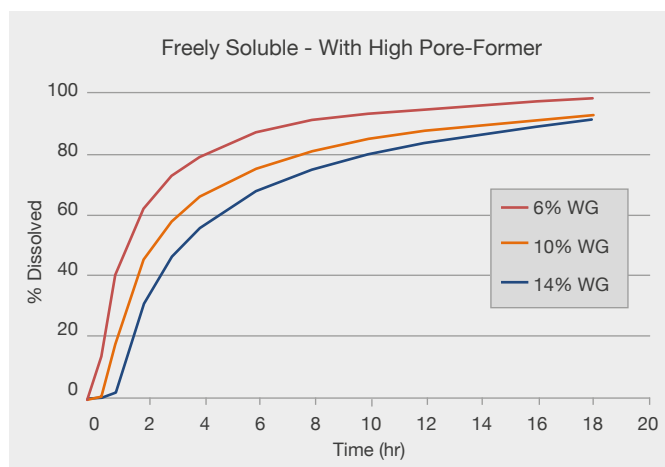
Tailor Drug Release Profiles

Adjusting the pore-former content and the applied coating weight gain modifies the barrier membrane porosity and thickness, and allows a range of release profiles to be achieved.

Case study using drug layered Suglets® sugar spheres, comprising either a freely soluble or slightly soluble model drug as the multiparticulate coating substrates.

Chlorpheniramine (CPM) release profiles were tailored by adjusting the pore-former content and the applied coating weight gain, resulting in modification of the barrier membrane porosity and thickness (as shown below)..

Barrier Membrane Porosity



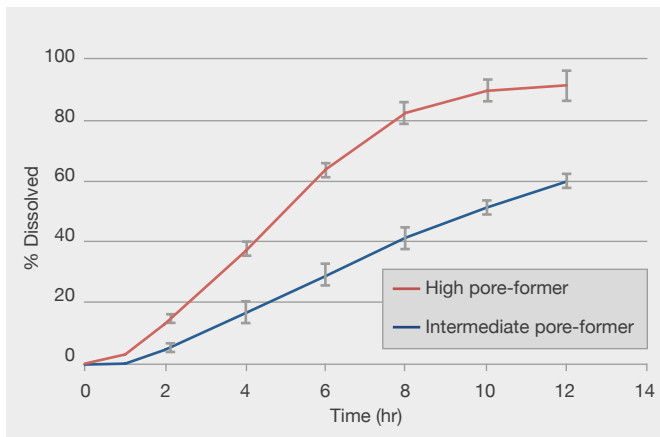
Model Drug	Solubility	Dose
Chlorpheniramine (CPM)	freely soluble (250 mg/ml)	30 mg/g dose
Theophylline	slightly soluble (8.3 mg/ml)	70 mg/g dose

Tailor Drug Release Profiles

Slightly Soluble Drug with Intermediate and High Level of Pore-Former

With coated theophylline spheres, the intermediate pore-former formulation provided greater T20 and T50 values compared to the high pore-former level.

In addition to the slower overall release profiles, the intermediate pore-former formulation had a linear ($R^2=0.993$) zero order release profile, providing a constant rate of drug release from 1 to 12 hours.



Time (hr) to reach:	Theophylline	
	Intermediate Pore-Former	High Pore-Former
T20	4.5	2.6
T50	9.7	5.0
T80	15.4 (extrapolated)	7.8

Simplify development and modulate drug release with Opadry[®] EC, the logical choice for reliable and consistent organic coating performance.

From Core to Coating Your Supplier of Choice

Reduce Complexity and Gain Reliability In-Use

Drug release profiles from ethylcellulose-coated multiparticulates can be modified by altering the membrane permeability through the inclusion of soluble pore-formers. Opadry EC incorporates a soluble pore-former, which allows formulators to tailor drug release profiles.

Consistency

- Colorcon quality ensuring the same product, every time
- Eliminates potential for operator error in pore-former addition

Ease-of-Use

- Fully formulated system
- No additional raw material components
- Reduced raw material quality control and supply chain management

Speed of Development and Improved Productivity

- Quick and easy way to evaluate range of release profiles
- Backed by Colorcon technical expertise and applications support

Regulatory

All ingredients in Opadry[®] EC are approved for Pharmaceutical use in the major global markets (conditionally for China and India).

From Core to Coating Your Supplier of Choice

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.

Contact your Colorcon representative or call:

North America +1-215-699-7733	Europe/Middle East/Africa +44-(0)-1322-293000	
Latin America +54-11-5556-7700	India +91-832-6727373	China +86-21-61982300

You can also visit our website at
www.colorcon.com



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