

FILM COATING

# OPADRY<sup>®</sup> 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<sup>®</sup> 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.



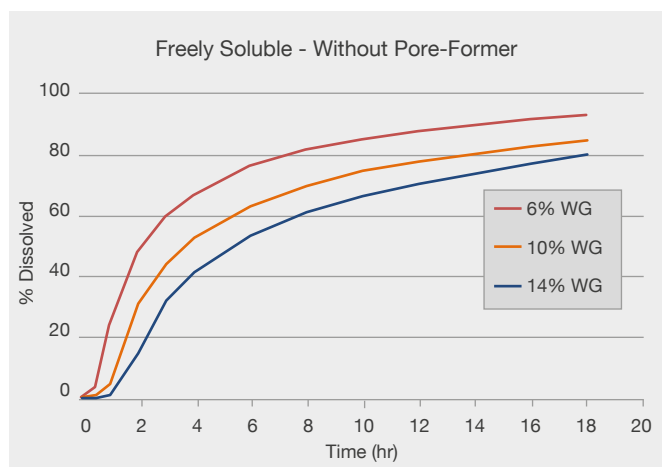
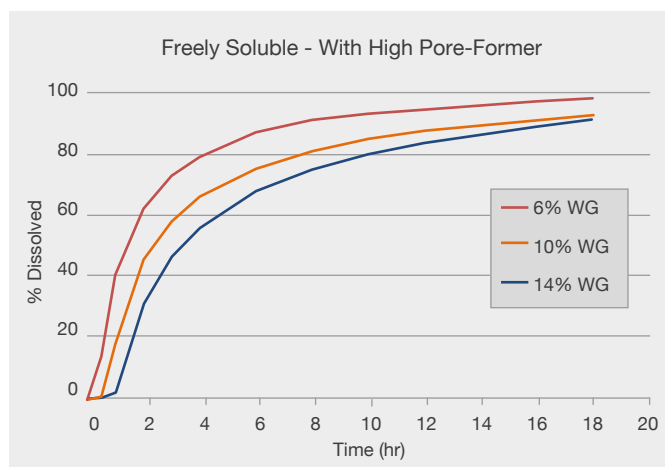
## Tailor Drug Release Profiles

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



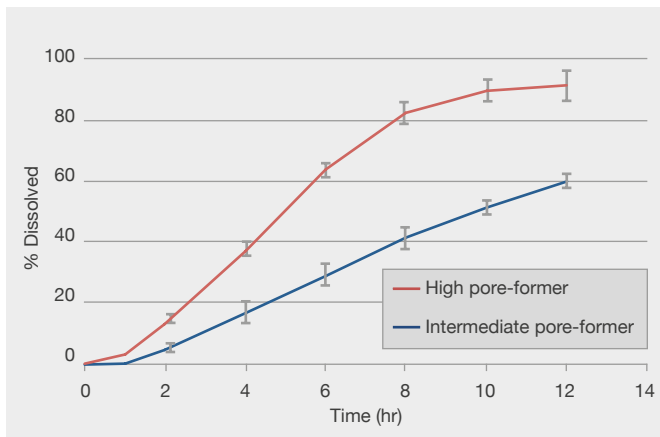
Model Drug	Solubility	Dose
Chlorpheniramine (CPM)	freely soluble (250 mg/ml)	30 mg/g dose
Theophylline	slightly soluble (8.3 mg/ml)	70 mg/g dose

## 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<sup>2</sup>=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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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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