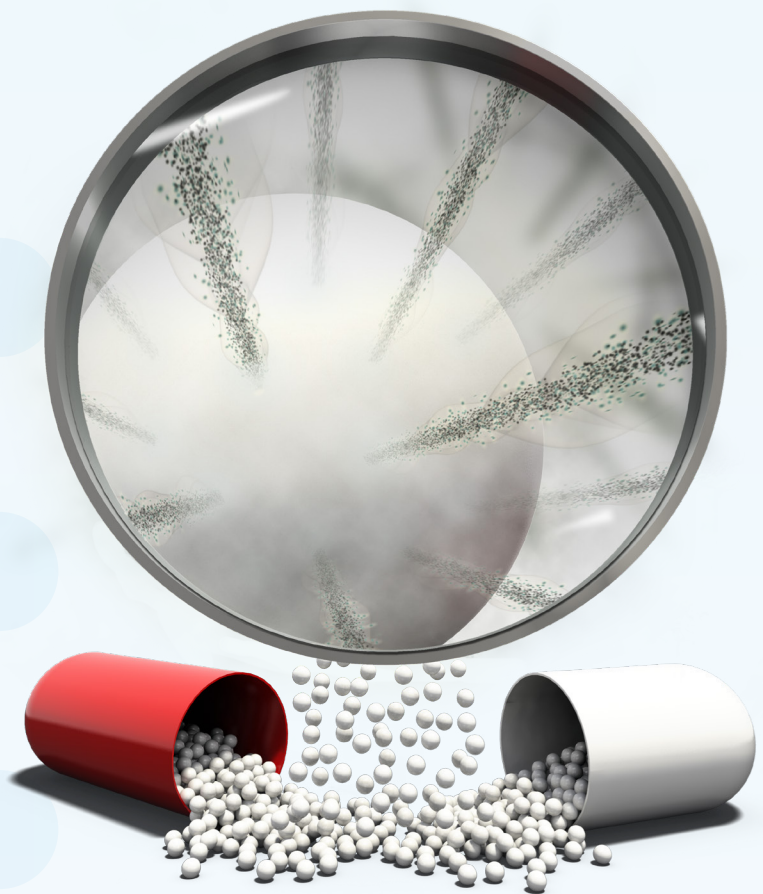


Simplify Development and Modulate Drug Release

Formulated Barrier Membrane Coating Corelease EC™ is a controlled release film coating product, designed for organic solvent-coating of multiparticulates and tablets, for sustained release and taste-masking applications

- Adjustable Drug Release Profiles
- Reliable and Consistent Coating Performance



Tailor Drug Release Profiles

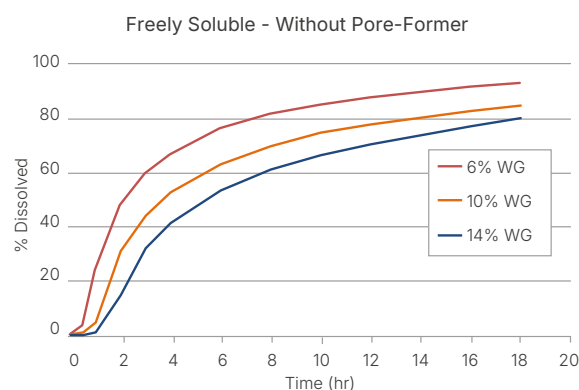
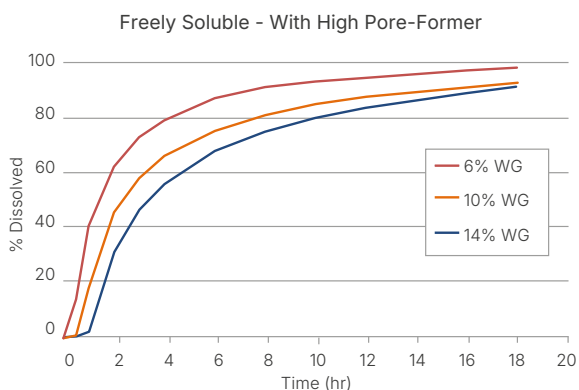
- Modifying film porosity provides controlled release of low, medium and high solubility drugs
- Stable film with high mechanical strength, suitable for moisture and/ or heat sensitive drugs
- Achieve desired release profiles at low coating levels.

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 Corelease EC formulations.

- 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).

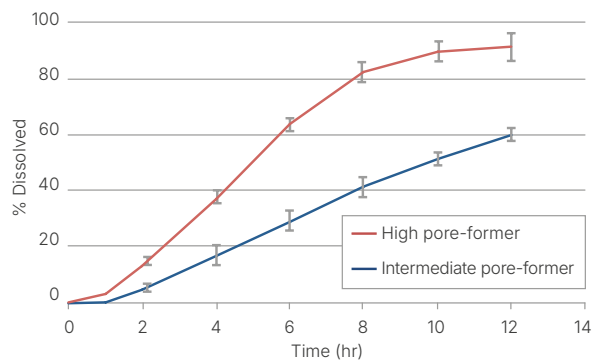
Barrier Membrane Porosity



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 (R2=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	30 mg/g dose
T50	9.7	70 mg/g dose
T80	15.4 (extrapolated)	7.8

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.

Corelease EC incorporates a soluble pore-former, which allows formulators to tailor drug release profiles. Formulations can be customized to meet individual needs.



Deliver high-performance products with Colorcon

Film Coatings

Optimized formulations to design a unique tablet brand and meet regulatory requirements with customized colors. Innovative coatings for mechanical integrity, gloss finish, and environmental protection.

Controlled Release Systems

Eliminate the complexity of drug product development and manufacturing through innovative controlled release formulated systems.

Specialty Excipients

Functional excipients designed for manufacturability and supported by comprehensive application data to streamline development and achieve robust final products.

Functional Packaging

Colorcon is a leading specialist in providing controlled atmosphere packaging with in-depth knowledge of moisture, oxygen and odor management for healthcare packaging.

With global technical support, unparalleled quality and regulatory expertise, and reliable supply, Colorcon is your trusted partner in controlled release to help you to streamline complex processes and achieve success.

Transforming Innovation into Solutions
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