

# AQUACOAT® ECD: CRITICAL FORMULATION ATTRIBUTES OF PORE FORMER

## Technical Memorandum

At DuPont, we aim to help our pharma customers with both every day challenges and future solutions. Armed with essential excipients and vital expertise, our broad portfolio is designed to deliver performance and cost advantages in various oral solid dosage forms.

### Pore former (water-soluble additives)

As ethyl cellulose is insoluble in water, films formed from Aquacoat® ECD may not be permeable enough to support all target release profiles. A pore former or water-soluble additive is included in the formulation to increase film permeability.

The pore former dissolves in the aqueous environment during the dissolution phase, leaving behind water filled channels that increase the drug's release rate<sup>1</sup>.

### Type and amount of pore former

Various water-soluble polymers have been evaluated for pore former functionality (Table 1).

Compatibility with Aquacoat® ECD and other observed characteristics should be taken into account when determining the suitability of these polymers as pore formers at different use levels and in different applications. Poly (vinyl alcohol)- Poly (ethylene glycol) graft copolymer (PVA-PEG graft copolymer) has been studied extensively for pore

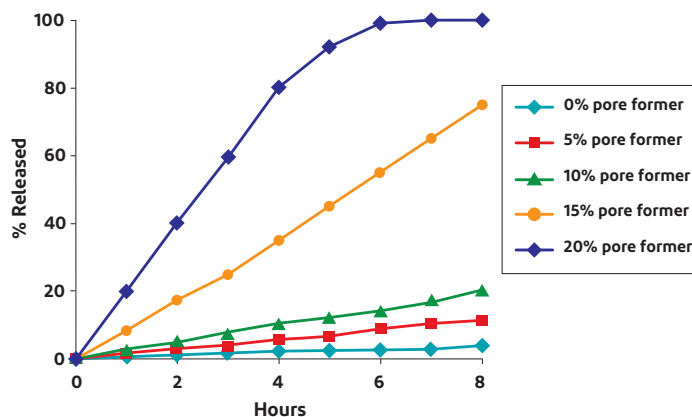
former functionality. The PVA-PEG graft copolymer has demonstrated good film-forming properties and is readily soluble in water, producing a relatively low viscosity coating solution. The PVA-PEG graft copolymer is compatible with Aquacoat® ECD at all concentrations and facilitates film coalescence during the coating process, producing stable films in long-term storage conditions. Optimizing both water-soluble additive levels and coating weight gain helps achieve the targeted release rate. The release rate of the drug is thus influenced by the amount of pore former added to the formulation: higher concentrations of pore former produce faster release rates due to the increase in film permeability (Figure 1). Water-soluble additives also improve

**Table 1. Commonly used pore formers**

Water-soluble additives category	List	Comments
Polymers	Poly (vinyl alcohol) - Poly (ethylene glycol) graft copolymer	Compatible with Aquacoat® ECD at all concentrations
	Polyvinylpyrrolidone K-30	Compatible with Aquacoat® ECD at all concentrations
	Hydroxypropyl methyl cellulose	Compatible at less than 15% w/w. Higher levels can cause aggregation and formation of inhomogeneous films
	Alginates	Compatible with Aquacoat® ECD at lower concentrations
	Carrageenans	Compatible with Aquacoat® ECD at all concentrations
Sugars	Maize starch	Compatible with Aquacoat® ECD at all concentrations
	Lactose	Compatible with Aquacoat® ECD but show some crystallization tendencies at accelerated storage conditions
	Sorbitol	
	Sucrose	
	Glucose	
	Mannitol	
Dextrose		

release rate reproducibility, compensating for variability in processing conditions where even a small change in film thickness can decrease the drug's release rate. This role is of special importance in drugs with low solubility that may be challenged by the hydrophobic nature of ethyl cellulose films. Here, the addition of a small amount of water-soluble additive helps preserve the desired release rate at the same coating level. The recommended concentration of pore former can range from 5-25% w/w based on ethyl cellulose solid content.

**Figure 1: PVA-PEG graft copolymer concentration effect on drug release rate**



Theophylline pellets coated with Aquacoat® ECD and various concentrations of PVA-PEG graft copolymer at a coating level of 20% w/w; dissolution medium pH 6.8 phosphate buffer

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