

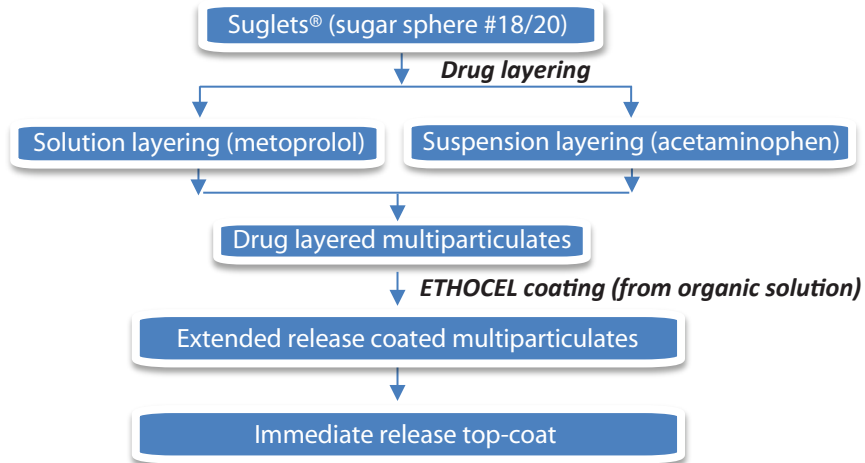
ETHOCEL™ Premium Ethylcellulose Polymers Quality by Design (QbD) Case Study

Technical Bulletin

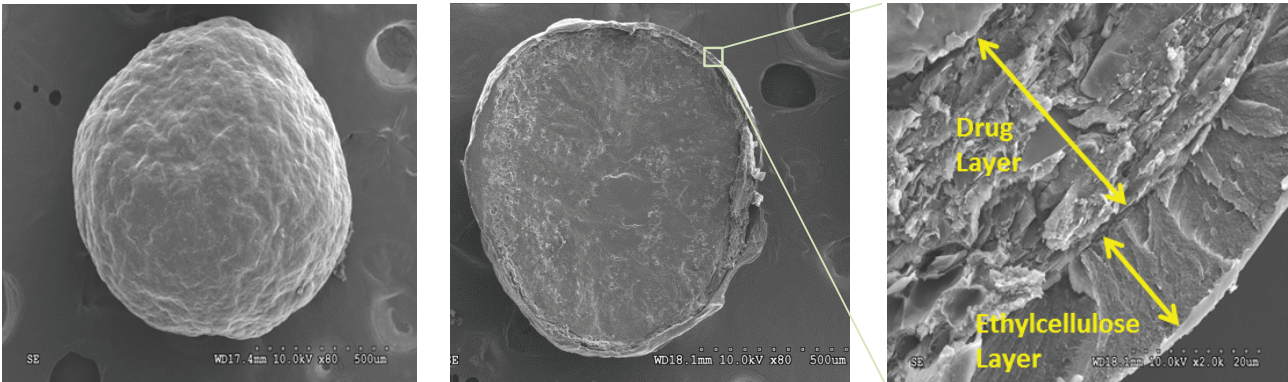


Objective: study the influence of viscosity variation of ETHOCEL (ethylcellulose) on drug release from acetaminophen (sparingly soluble) and metoprolol tartrate (freely soluble) multiparticulate dosage forms

Multiparticulate Dosage Development



SEM Images of ETHOCEL Coated Multiparticulate



Critical Attributes for ETHOCEL Coating

Formulation & Process Attributes

Formulation Attributes

- ETHOCEL viscosity grade
- Solvent selection
- Water as a co-solvent (elimination of static charge)
- Plasticizer level and type
- Coating solids %
- Type and level of pore-former

Process Attributes

- Dew point control
- Atomization pressure and spray rate
- Product temperature

Experimental Methods - Case Study

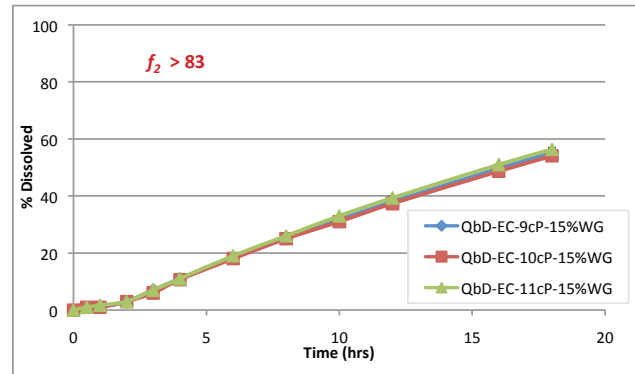
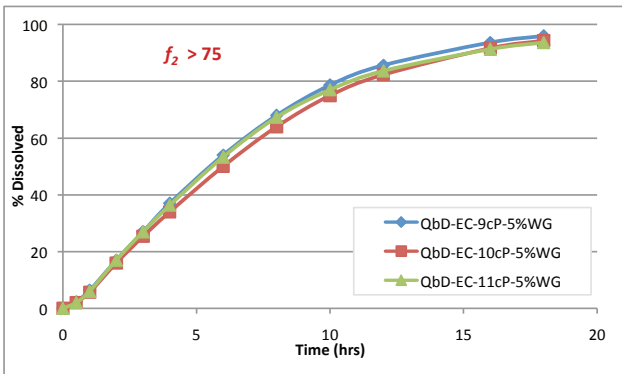
Extended Release Coating Parameters	Value
Solvent	Isopropyl alcohol : Water (90:10)
Solution Viscosity (cP)	70-85 cP
% Solids (w/w)	3% - 10% (7% solids for 10cP sample)
Current Ethocel Grade	10, 20, 100cP
Plasticizer	10% w/w (Dibutyl sebacate)
Weight Gain samples	2.5% to 15% WG

Application of ETHOCEL to Model Multiparticulate Dosage (ETHOCEL 10 cP, Viscosity Specification 9-11 cP)

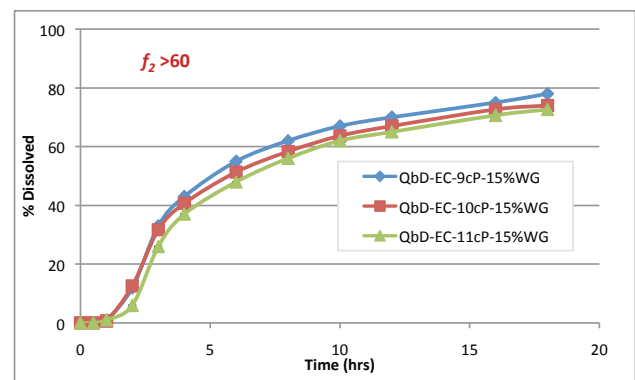
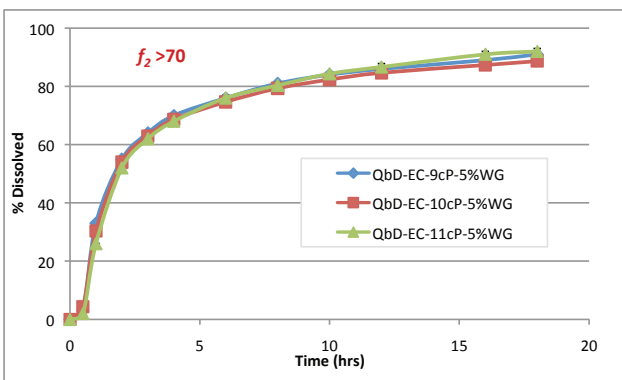
Processing Conditions: Bottom Spray Würster Coating (750g)

Process Parameter	Fluidizing Airflow (m ³ /hr)	Inlet Air Temp (°C)	Product Temp (°C)	Outlet Temp (°C)	Spray Rate (g/minute)	Atomizing Pressure (bar)
Value	45-50	38-40	30-31	28-30	5-7	1.3

Springly Soluble (Acetaminophen) Drug Release with ETHOCEL QbD Samples



Freely Soluble (Metoprolol Tartrate) Drug Release with ETHOCEL QbD Samples



Summary

- f_2 values were between 50 and 100 indicating that profiles can be considered similar within the viscosity specification for both sparingly and freely soluble drugs (acetaminophen and metoprolol tartrate)
- Data package available for ETHOCEL QbD samples: 7cP, 10 cP, 20 cP and 100 cP viscosity grades
- ETHOCEL QbD samples available to evaluate the effect of viscosity on drug release



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