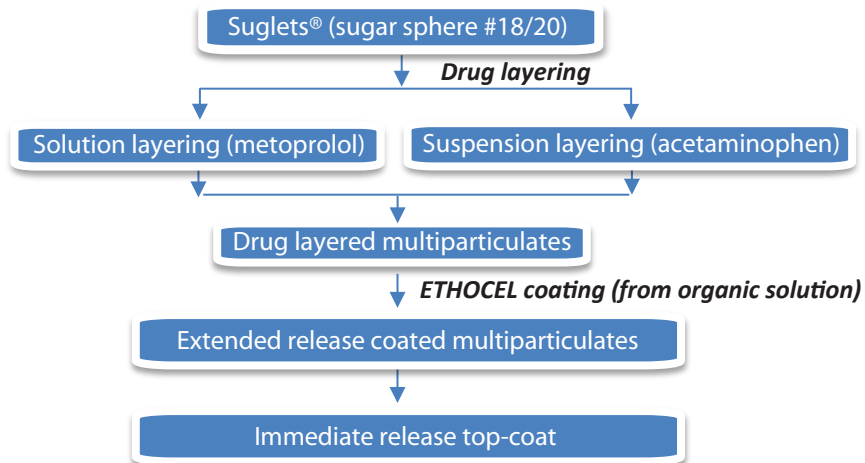


# ETHOCEL™ Premium Ethylcellulose Polymers Quality by Design (QbD) Case Study

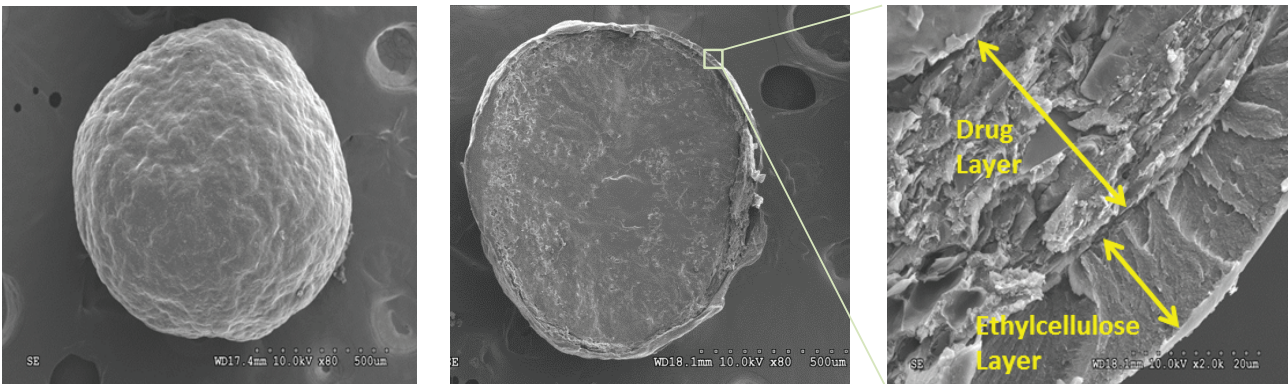


Objective: study the influence of viscosity variation of ETHOCEL (ethylcellulose) on drug release from acetaminophen (sparingly soluble) and metoprolol tartrate (freely soluble) multiparticulate dosage forms

## 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

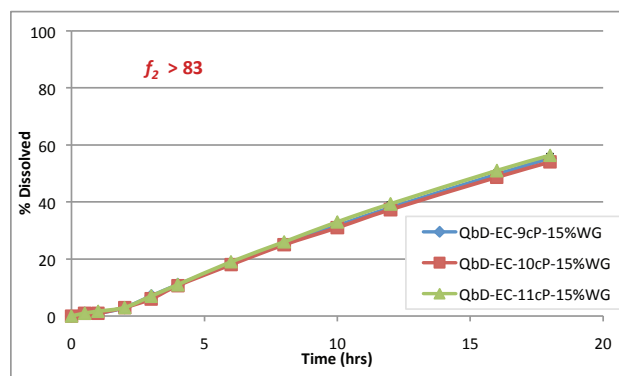
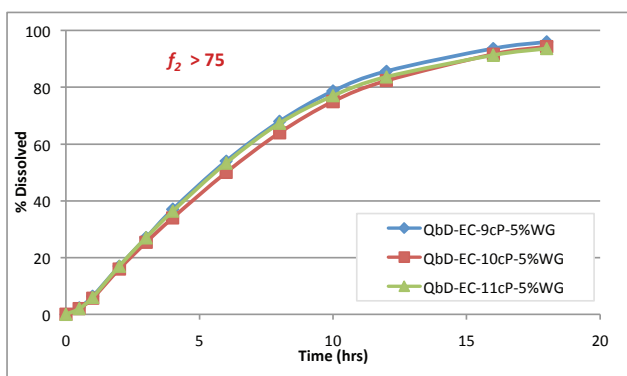
Extended Release Coating Parameters	Value
<b>Solvent</b>	Isopropyl alcohol : Water (90:10)
<b>Solution Viscosity (cP)</b>	70-85 cP
<b>% Solids (w/w)</b>	3% - 10% (7% solids for 10cP sample)
<b>Current Ethocel Grade</b>	10, 20, 100cP
<b>Plasticizer</b>	10% w/w (Dibutyl sebacate)
<b>Weight Gain samples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

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

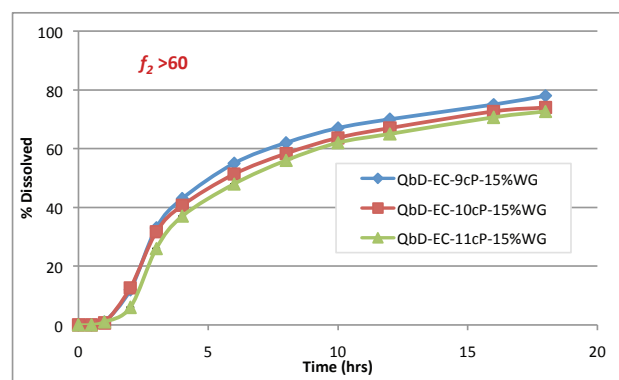
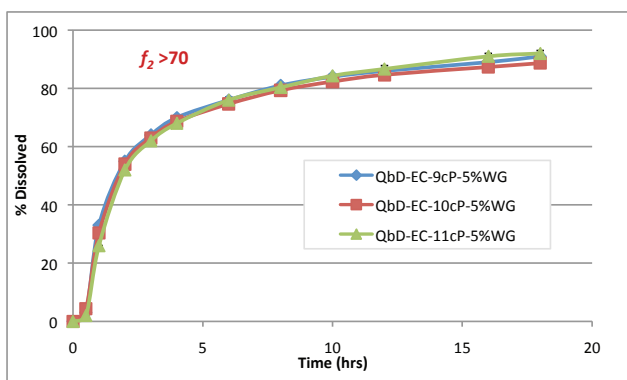
### Processing Conditions: Bottom Spray Würster Coating (750g)

Process Parameter	Fluidizing Airflow (m <sup>3</sup> /hr)	Inlet Air Temp (°C)	Product Temp (°C)	Outlet Temp (°C)	Spray Rate (g/minute)	Atomizing Pressure (bar)
<b>Value</b>	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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