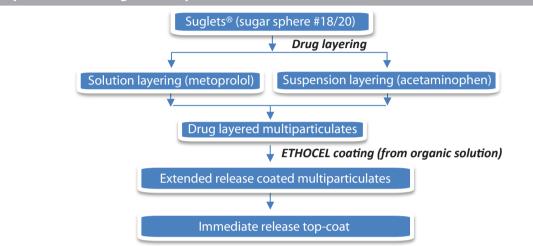
ETHOCEL[™]Premium Ethylcellulose Polymers Quality by Design (QbD) Case Study



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





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 |



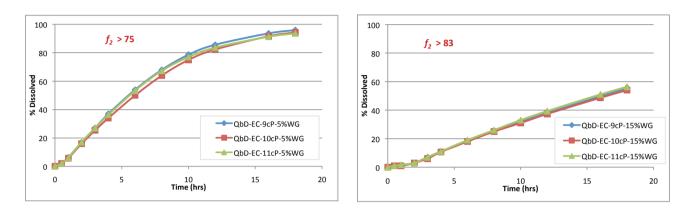
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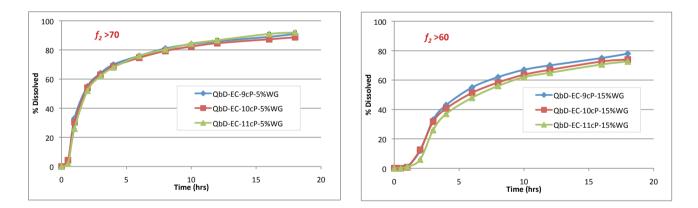
| Application of ETHOCEL to Model Multi | particulate Dosage (ETHOCEL 10 cP | , Viscosity Specification 9-11 cP) |
|---------------------------------------|-----------------------------------|------------------------------------|
| | | |

| 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 | | |

Sparingly 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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