

PTR-112

Aquarius™ Control ECD film coating system

Ethylcellulose Aqueous Dispersion, NF

Description

Control ECD is 30% w/w aqueous dispersion of ethyl cellulose. Ethyl cellulose is widely used as a coating polymer to achieve sustained release, taste masking and moisture protection.

Salient features

- Completely water based system
- Robust and stable dispersion
- Low viscosity
- Non-tacky
- Manufactured without ammonia

Advantages

- Choice of plasticizers
- Supports a solvent and ammonia free coating process
- Reduces environmental impact and improves product safety by eliminating use of hazardous solvents in film coating process.
- Easy to clean after coating
- Reproducible drug release results

Reconstitution and Prep Recommendations

The following steps are recommended for optimum processing.

Equipment:

Mixing vessel with 25 - 35% greater height than the liquid level. The diameter of the mixing vessel should be approximately 75 -100% of the height of the liquid.

- Variable speed mixer (100 - 2000 rpm)
- Propeller stirrer

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Preparation Guidelines:

Step 1: Dilute Control ECD dispersion to 15% solids content using purified water.

Step 2: Add suitable plasticizer, as needed (10 – 20% of the latex solid level), and mix for 30 - 60 minutes prior to adding other material such as HPMC or color, taking care to avoid excessive stirring speed.

Step 3: Pass the dispersion obtained in Step 2 through #100 (Optional but recommended).

Step 4: Spray the dispersion using suitable equipment to ensure good cascading or fluidization. Inlet air temperature should be so adjusted as to obtain the bed temperature of 32-36 °C.

Note:

- For most sustained release applications, a 30 percent weight dispersion of Control ECD and plasticizer can be used as the coating dispersion. For low weight addition coatings, a 15 percent weight dispersion is recommended.
- Coating suspensions made with Aquarius™ film coating systems should be stirred throughout the coating process.

Applications

- Controlled release drug delivery systems
- pH independent pore former
- Binder for wet granulation
- Moisture protection
- Taste masking

List of Ingredients

- Ethylcellulose 24 – 26%
- Cetyl alcohol 1.7 – 3.3%
- Sodium lauryl sulfate 0.9 – 1.7%
- Water 68 – 71%

Coating Parameters

Laboratory-scale Coating of Multiparticulates With Aquarius™ Control ECD Film Coating Systems

Coating Parameter	O'Hara Fluid Bed with Wurster Insert
Nozzle Orifice (mm)	1-1.2
Pellets (18-20 mesh) Loading (kg)	1
Fluidizing air volume (m ³ h ⁻¹)	75-85
(cfm)	45-50
Inlet air temperature (°C)	60
Product temperature (°C)	32-36
Exhaust air temperature (°C)	38-42
Atomizing air pressure (psi)	26-28
*Spray rate (g min ⁻¹)	8-10
Curing time (hr)	1-2

*Start slow until 1-2% weight gain is obtained, then ramp up to 8-10gm/min spray rate.