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
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

<table>
<thead>
<tr>
<th>Coating Parameter</th>
<th>O’Hara Fluid Bed with Wurster Insert</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nozzle Orifice (mm)</td>
<td>1-1.2</td>
</tr>
<tr>
<td>Pellets (18-20 mesh) Loading (kg)</td>
<td>1</td>
</tr>
<tr>
<td>Fluidizing air volume (m³ h⁻¹)</td>
<td>75-85</td>
</tr>
<tr>
<td>Inlet air temperature (°C)</td>
<td>60</td>
</tr>
<tr>
<td>Product temperature (°C)</td>
<td>32-36</td>
</tr>
<tr>
<td>Exhaust air temperature (°C)</td>
<td>38-42</td>
</tr>
<tr>
<td>Atomizing air pressure (psi)</td>
<td>26-28</td>
</tr>
<tr>
<td>*Spray rate (g min⁻¹)</td>
<td>8-10</td>
</tr>
<tr>
<td>Curing time (hr)</td>
<td>1-2</td>
</tr>
</tbody>
</table>

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