AQUEOUS COATING

Aquacoat® ECD

SUSTAINED RELEASE
MOISTURE BARRIER
TASTE MASKING
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Aquacoat ECD
ethylcellulose aqueous dispersion, NF

Product description

Aquacoat ECD is a 30 percent by weight aqueous dispersion of ethylcellulose polymer. Ethylcellulose is a hydrophobic coating material used in a variety of coatings applications to achieve sustained release, taste masking and moisture barrier/sealant.

Structure of ethylcellulose

Aquacoat ECD advantages

| Facilitates manufacture | • Completely water-based system, allows for solvent-free coating |
|                        | • Enables a faster coating rate for lower overall production time |
|                        | • Low viscosity and non-tacky |
|                        | • Easy application and clean up |
|                        | • No talc needed |
|                        | • Choice of plasticizer |
|                        | • No ammonia used |
| Functionality          | • Stable and reproducible release rates |
|                        | • Zero order release achievable |
|                        | • Custom release profiles |
|                        | • No logo bridging |
**Sustained release beads for capsules**

Aquacoat ECD offers excellent dissolution rate control stability and reproducibility that are pH independent. Aquacoat ECD is typically used on drug-layered nonpareils, microcrystalline cellulose beads and beads prepared by extrusion/spheronization for sustained release applications. The coated beads are typically delivered using gelatin capsules. Aquacoat ECD has been used in many sustained release applications including phenylpropanolamine HCl (PPA), conjugated estrogen, diltiazem, ibuprofen, chlorpheniramine maleate and theophylline.

**Sustained release tablets (compressed beads)**

Coated beads can also be formulated for compression into a tablet. FMC technical services can assist you in evaluating this option.

**Moisture barrier/sealant for powders, granules, tablets and capsules**

Aquacoat ECD forms a superior moisture barrier and will prevent bleed-through and discoloration of difficult products such as multivitamins. Aquacoat ECD does not cause bridging of logo indentations typical of polymer coatings. Where these benefits are required without sustained release, hydroxypropyl methyl cellulose (HPMC) may be added. A 50/50 mix of HPMC and Aquacoat ECD gives a high level of protection with an immediate release profile.

**Taste masking for powders, granules and tablets**

Aquacoat ECD is an effective taste masking agent for many applications. Contact FMC's technical services to find out more about our taste masking technologies.

**Wet granulation**

Aquacoat ECD can also be used in wet granulation where granulation and sustained release need to be achieved. Contact FMC's technical services to find out more about this application.
CUSTOM RELEASE PROFILES

When using Aquacoat ECD for sustained release you can tailor the release profile to suit specific applications. Tailored release profiles can be achieved by adjusting the coating level, the plasticizer type, the level of plasticizer, and by adding soluble polymers such as hydroxypropyl methylcellulose (HPMC) or polyethylene glycol (PEG). See figures 1 and 2 below:

**Figure 1** — Increasing the coating level slows the drug release rate

![Figure 1](image1.png)

PPA loaded nonpareils coated with Aquacoat ECD and DBS in a fluid bed.

**Figure 2** — Adding HPMC increases the drug release rate

![Figure 2](image2.png)

PPA loaded nonpareils with mixtures of Aquacoat ECD and HPMC plasticized with DBS.
PLASTICIZER VERSATILITY

Plasticizers should be used with Aquacoat ECD for most applications. Plasticizers are non-volatile, high-boiling liquids used to impart flexibility to otherwise hard or brittle polymeric materials.

Aquacoat ECD allows use of a variety of plasticizers, enabling you a tailored formulation for your specific drug and desired release profile. Recommended plasticizers include dibutyl sebacate (DBS), Myvacet® (acetylated monoglycerides), triacetin (GTA or glyceryl triacetate), acetyltriethyl citrate (ATEC) and triethyl citrate (TEC).

Plasticizers soften and swell the polymer latex spheres which aids deformation and coalescence, and lowers the film forming and glass transition temperatures. The glass transition temperatures for Aquacoat ECD (or, $T_g$, which is the temperature at which the polymer undergoes marked changes in physical properties), with various levels of plasticizer addition, are given below.

For most applications, we recommend that plasticizers be added at 24 percent of the latex solids level*.

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* grams plasticizer/grams solid x 100 = 24%
COATING STABILITY

Aquacoat ECD gives reproducible drug release profiles that are pH independent. Figure 4 shows typical release profiles for phenylpropanolamine hydrochloride (PPA•HCl) beads before and after storage at room temperature and at 35°C. With proper coating and curing, consistent release profiles can be achieved on both highly soluble drugs like PPA•HCl and less soluble drugs like theophylline.

Figure 4 — Stability of coating

PPA loaded nonpareils coated with Aquacoat ECD and using DBS.
HOW TO USE THIS COATING

About this coating
Aquacoat ECD coated on a tablet provides a smooth tablet surface onto which print can be applied and be printed on. Logo definition can be retained for even hard-to-coat logos.

Equipment
Aquacoat ECD is typically coated onto beads for sustained release applications. The preferred equipment is a bottom spray fluid bed coater with Wurster insert. However, top spray and tangential spray fluid beds and modified coating pans can also be used for bead coating. Side-vented and conventional coating pans can be used for tablet coating when using Aquacoat ECD for taste masking or as a moisture barrier.

Coating preparation
For most sustained release applications, a 30 percent weight dispersion of Aquacoat ECD and plasticizer can be used as the coating dispersion. For low weight addition coatings, a 15 percent weight dispersion is recommended. The high solids content results in faster coating times and lower energy costs for water evaporation. Stir Aquacoat ECD upon opening as minor settling may occur during storage. Plasticizer should be added and allowed to mix for 30 minutes before adding other materials such as HPMC or color. Use moderate mixing speeds to avoid air inclusion. A propeller blade will give the best results. An example of coating conditions for phenylpropanolamine hydrochloride beads is given in the Applications Example section of this brochure.

Aquacoat ECD is normally applied at 5 to 10 percent of the tablet weight or 8 to 15 percent of the bead weight for sustained release applications and 1 to 2 percent for a barrier coat. For sustained release applications, the precise level of coating applied is one of the parameters which may be used to achieve the desired release rate.

Drying and curing
After spraying, allow the beads or tablets to rotate in the coater. Maintain the bed temperature for an additional 15 to 30 minutes to assure the beads or tablets are dry in order to avoid bead or tablet sticking problems.

For sustained release applications, additional heating is necessary to cure the polymer coating. This is a necessary step for aqueous polymer coatings to insure reproducible release profiles. We recommend curing at 60°C for two hours. This can be done in a tray dryer or in the fluid bed column. For fluid bed column drying, please contact our technical service experts to assist you.

Adding color
Aquacoat ECD is compatible with most alcohol and propylene glycol based color dispersions. It is recommended that the plasticizer be added first and mixed for 30 minutes before adding the color. Color can also be added as a separate coating on top of the Aquacoat ECD.
Aquacoat ECD should be stored at room temperature (20°C to 25°C) and is stable for two years at those conditions. It is available in 15 kg and 50 kg containers for convenient handling, storage and dispensing.

### Product specifications

<table>
<thead>
<tr>
<th>Component</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total solids</td>
<td>29-32%</td>
</tr>
<tr>
<td>Ethylcellulose</td>
<td>24.5-29.5%</td>
</tr>
<tr>
<td>Sodium lauryl sulfate</td>
<td>0.9-1.7%</td>
</tr>
<tr>
<td>Cetyl alcohol</td>
<td>1.7-3.3%</td>
</tr>
<tr>
<td>Hydrogen peroxide</td>
<td>NMT 50 ppm</td>
</tr>
<tr>
<td>Heavy metals</td>
<td>NMT 10 ppm</td>
</tr>
<tr>
<td>Total aerobic microbial count</td>
<td>NMT 100 cfu/g</td>
</tr>
<tr>
<td>Total yeast and mold count</td>
<td>NMT 20 cfu/g</td>
</tr>
<tr>
<td>pH</td>
<td>4.0-7.0</td>
</tr>
<tr>
<td>Particle size</td>
<td>Submicron, 85% of particles &lt;0.5 µm</td>
</tr>
<tr>
<td>Viscosity</td>
<td>NMT 150 cp</td>
</tr>
</tbody>
</table>

NMT - Not more than
Aquacoat ECD is sold as a 30 percent by weight dispersion.

### Storage and stability of Aquacoat ECD

Aquacoat ECD should be stored at room temperature (20°C to 25°C) and is stable for two years at those conditions. It is available in 15 kg and 50 kg containers for convenient handling, storage and dispensing.
APPLICATION EXAMPLE

The following describes the conditions and equipment used for a sustained release coating of Aquacoat ECD on 1 mm drug-loaded beads.

Preparation

- Weigh the appropriate amounts of Aquacoat ECD, plasticizer and water.
- Mix the Aquacoat ECD at a moderate speed with a propeller mixer.
- Add the plasticizer slowly to the Aquacoat ECD while mixing. Mix for 30 minutes. Add the water and mix for an additional 10 minutes.
- Maintain moderate mixing while applying the coating.

Formulation

<table>
<thead>
<tr>
<th>Suspension (grams)</th>
<th>Solids (grams)</th>
<th>Percent (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aquacoat ECD</td>
<td>425.0</td>
<td>131.8</td>
</tr>
<tr>
<td>Plasticizer (DBS NF)</td>
<td>31.6</td>
<td>31.6</td>
</tr>
<tr>
<td>Water</td>
<td>88.0</td>
<td></td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>544.6</strong></td>
<td><strong>163.4</strong></td>
</tr>
</tbody>
</table>

Equipment

- Coater: Fluid bed coater with Wurster insert
- Column: 100 mm bottom/150 mm top
- Insert: 50 mm diameter
- Partition setting: 10 mm
- Nozzle orifice: 1 mm
- Pump: Peristaltic pump

Coating conditions

- Product charge: 1 kg of 16/20 mesh size drug-loaded beads
- Application rate: 8-10 mL/min.*
- Atomizing air pressure: 25 psi
- Temperature, inlet: 60°C
- Temperature, outlet: 39-41°C
- Bed temperature: 32-35°C
- Relative humidity of inlet air: 40%
- Coating level (theoretical): 10%
- Spray time: 42 min.
- Drying time post coating: 15 min.
- Oven curing: 2 hours at 60°C (needed for sustained release applications)

*Use 4-5 mL/min. at start for highly water soluble substrates. Apply a 2% coating by weight at this rate, then proceed with an 8-10 mL/min. rate to complete the coating run.
CONTACT FMC FOR ASSISTANCE

If you’d like a sample, have a question or would like to request assistance with a trial, please reference the back cover for the telephone, fax and e-mail for your region.

We will be delighted to assist you in discovering and utilizing the many advantages of Aquacoat ECD.
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