

Preparation & Use Guidelines

Opadry[®] EC is a controlled release film coating product, based on ethylcellulose, for the solvent-coating of multiparticulates and tablets. Opadry EC provides customized release profiles by varying levels of polymer and pore-former and the weight gain applied. Organic solution preparation is one-step, quick and easy.

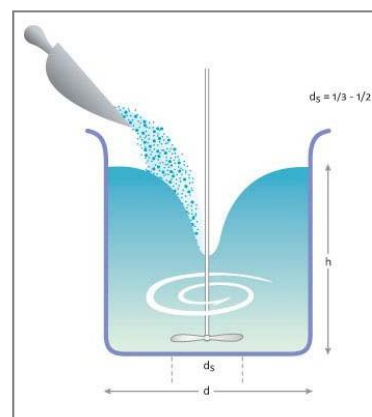
MATERIALS

- Opadry EC powder
- Hydro-alcoholic co-solvent solution **90:10 alcohol:water** (ethanol or isopropanol recommended)

EQUIPMENT

- Variable-speed mixer capable of producing and maintaining a vortex.
- Propeller stirrer with a diameter equivalent to 1/3 - 1/2 the diameter of the mixing vessel (Figure 1).
- Mixing vessel suitable to contain a liquid volume 15-25% greater than the total suspension being prepared. The liquid height should be equal to, or greater than, the vessel diameter. Vessel should have a suitable cover.

Figure 1



SOLUTION HANDLING

- Opadry EC solution should be prepared in a well ventilated area.
- Once prepared, the Opadry EC solution should be tightly covered to minimize solvent evaporation.
- Opadry EC solution can be pumped directly from the preparation vessel, if desired.
- All spray gun parts and tubing used must be solvent-resistant.

MIXING PROCEDURE

Determine the amount of Opadry EC and solvents required, based on the quantity of multiparticulates or tablets to be coated, and the target coating weight gain. Opadry EC coating solutions are recommended to be prepared at 6% solids w/w (in isopropanol), or 8% solids w/w (in ethanol).

- Weigh out required quantity of isopropanol or ethanol and water into the mixing vessel.
- Weight out required quantity of Opadry EC film coating system powder.
- Position the propeller in the center and as close to the bottom of the vessel as possible. Stir the liquid vigorously to form the strongest possible vortex.

- To prevent lump formation, take care to slowly add the Opadry EC powder to the center of the liquid vortex. Note that Opadry EC dispersion will require slower addition than other Opadry coating systems.
- Once all the Opadry EC has been added, reduce the mixer speed to eliminate the vortex while maintaining gentle stirring.
- Continue stirring for 45 minutes until all particles dissolve, the coating solution will then be ready for use.
- Continuous gentle stirring throughout coating process is recommended.
- Cover vessel tightly if solution will not be used immediately.

The responsibility for choice of solvents lies with the end-user to confirm specific country regulations prior to use.

Follow all solvent manufacturer recommendations and associated Material Safety Data Sheets for the safe handling practices for your solvent of choice.

USE GUIDELINES

- Recommended coating weight gains of Opadry EC will depend on a number of factors including coating substrate, API solubility and pore former inclusion level, but are typically between 10% and 40%.
- To determine actual weight gain, laboratory coating trials should be conducted.
- Your Colorcon Area Technical Manager (ATM) can assist you in optimizing the solvent type, solution solids levels, coating weight gain and process parameters to meet your required drug release profile.

CLEANING GUIDELINES

- For best results, clean equipment shortly after the end of the coating run.
- Clean the fluid delivery tubes and spray system by pumping a mixture of 90:10 alcohol:water for 2-3 minutes, then wash with cleaning solutions or deionized water.
- Opadry EC residue remaining on the coating equipment can easily be removed using a cleaning agent or deionized water. For pan coatings, if equipped, fill the coating pan with cleaning solution and allow the pan to rotate through the solution for 30 minutes.
- Spray equipment (guns and hoses) should be fully disassembled and can be soaked in the cleaning solution for 30 minutes.
- When cleaning spray guns, it is important to make sure connections are free of residual coating material that can block the orifice and restrict flow. A thin soft brush or swab can be passed through the tip of the gun to ensure all the coating material is removed. Avoid using hard bristles because these can damage the gun parts.
- All equipment should be rinsed with deionized water after cleaning.

Please contact your local Colorcon Technical Representative if you require any further information.

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