

Reconstitution

Opadry® EZ, easy swallow film coating systems are quick and easy to prepare. Simply pour the Opadry EZ powder into water and mix for 45 minutes with a propeller stirrer as described below. *

It is recommended that this coating suspension is reconstituted at up to 8% solids w/w and applied to a minimum weight gain of 1.4 mg/cm² (1%) or 2.9 mg/cm² (2%). Your Colorcon Area Technical Manager (ATM) can assist you to optimize the solid levels for this dispersion according to the atomizing capabilities of your equipment.

MATERIALS

- Opadry EZ film coating system.
- Water, deionized or distilled preferred, ambient temperature (maximum 30 °C).

EQUIPMENT

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

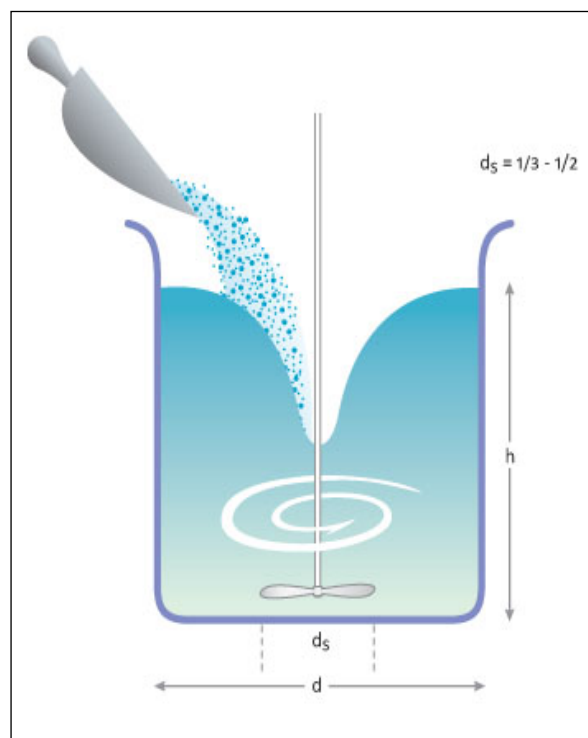
*MIXING PROCEDURE

1. Weigh necessary quantity of Opadry EZ film coating system.
2. Weigh necessary quantity of water into the mixing vessel.
3. With the propeller in the center and as close to the bottom of the vessel as possible, stir the water to form a vortex without drawing air into the liquid.
4. Steadily add the Opadry EZ powder to the vortex, avoiding powder flotation on the liquid surface. If required, increase the stirrer speed to maintain the vortex.
5. After all the Opadry EZ powder has been added, reduce the mixer speed to nearly eliminate the vortex. Mix for 45 minutes.

SUSPENSION HANDLING

The prepared Opadry EZ dispersion can be pumped directly from the preparation vessel if desired. We recommend that the Opadry EZ dispersion be gently agitated during the coating process.

Figure 1



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For more information, contact your Colorcon representative or call:

North America
+1-215-699-7733

Europe/Middle East/Africa
+44-(0)-1322-293000

Asia Pacific
+65-6438-0318

Latin America
+54-11-5556-7700

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