

Preparation and Use Guidelines

Acryl-EZE® II, aqueous acrylic enteric system, is a fully formulated, dry system dispersible in water, for the application of an enteric film coating to solid dosage forms such as tablets, granules and beads. Combining the benefits of a fully formulated coating system with a globally accepted enteric polymer (EUDRAGIT® L 100-55*), Acryl-EZE II provides consistent, reproducible enteric protection. The coating system can be pigmented to meet marketing requirements and provides consistent, reproducible enteric protection and drug release.

Acryl-EZE II is designed for easy preparation, processing and clean up. The coating suspension is reconstituted to 20% solids concentration. For Acryl-EZE II the recommended weight gain (WG) to obtain enteric protection on a 330mg biconvex tablet is 6% - 12% WG (7-14mg/cm²), depending on the physicochemical properties of the core. For multiparticulates (MP) a 20% - 40% WG (4-9mg/cm²) is recommended depending on MP size. A sub-coat may be required to separate the active pharmaceutical ingredient from the enteric polymer or to strengthen the dosage form prior to enteric coating. The recommended sub-coat formulas are Opadry® 03K for tablets and Opadry 03A for multiparticulates. A top-coat may be required for additional gloss.

MATERIALS

- Acryl-EZE II formulated powder.
- Simethicone emulsion (0.2% w/w with respect to Acryl-EZE II)
- Distilled/deionized water at ambient temperature (20-35°C).

EQUIPMENT

- Variable-speed mixer capable of producing and maintaining a vigorous vortex.**
- Mixing vessel, to contain a liquid volume 20% greater than the total suspension being prepared, to take account of the slight initial foaming and mixing.
- 250 micron (60 mesh) sieve.

MIXING PROCEDURE**

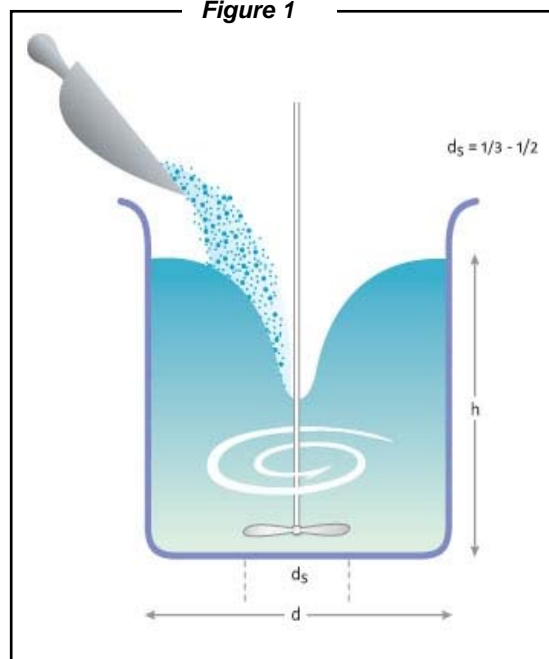
- Determine the amount of Acryl-EZE II (to 20% w/w solids), and water required, based on the quantity of product to be coated and the target coating weight.

Example: To coat 10kg of tablets to a nominal 8% wt. gain:

- 800g Acryl-EZE II
- 3200g water (ambient temperature)

- Weigh the water into the mixing vessel.

Figure 1



- Using a propeller stirrer, stir the water to form a vigorous vortex (Figure 1). Optionally, weigh the antifoam emulsion and add to the water and allow to disperse. Weigh the Acryl-EZE II and add to the center of the liquid vortex in a slow steady stream, avoiding clumping and maintaining a vortex. Continue mixing for 20 minutes (Note: Only 10 minutes mixing required if using high shear).
- Pass the dispersion through a 250 micron sieve prior to the coating process. Ensure the dispersion is continuously stirred during the coating process. The dispersion should be used the same day it is prepared, although Colorcon's microbial data shows suspension stability of up to 72 hours under controlled conditions.

ACRYL-EZE II CLEANUP GUIDELINES

- For best results, clean equipment shortly after the end of the coating run.
- Acryl-EZE II residue remaining on the coating equipment can easily be removed using a mild sodium bicarbonate solution (pH > 5.5). Sodium bicarbonate (NaHCO₃) is regarded as an essentially non-toxic and non-irritant material. Additionally, it is GRAS listed and has compendia status within the USP, BP, JP and PhEur.
- Coating pans can be cleaned with a solution of NaHCO₃ and deionized water. If equipped, fill the pan reservoir with cleaning solution and allow the pan to rotate through the solution for 30 minutes.
- Spray equipment (guns and hoses) should be disassembled and can be soaked in the cleaning solution for 30 minutes.
- When cleaning spray guns, it is important to make sure the passages 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 insure all the coating material is removed. Avoid using hard substances because these can damage the gun parts.
- All equipment should be rinsed with deionized water after cleaning.

* Methacrylic acid copolymer type C

** Note: High shear mixing may also be used to prepare the Acryl-EZE II dispersion. High shear mixers that do not generate heat are most suitable for the shorter 10-minute dispersion process and antifoam emulsion (0.2% with respect to Acryl-EZE II) is required for successful dispersion preparation.

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