

Preparation and Use Guidelines

Acryl-EZE®, 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 L100-55*), Acryl-EZE 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 is designed for easy preparation, processing and clean up. The coating suspension is reconstituted to 20%ww solids. Recommended weight gains of Acryl-EZE are 7% - 10% for enteric performance, depending on the physicochemical properties of the core. 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. A recommended sub-coat formula is Opadry® 03K19229. A top-coat may be required for additional gloss or to aid in printing.

Materials

- Acryl-EZE formulated powder.
- 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.

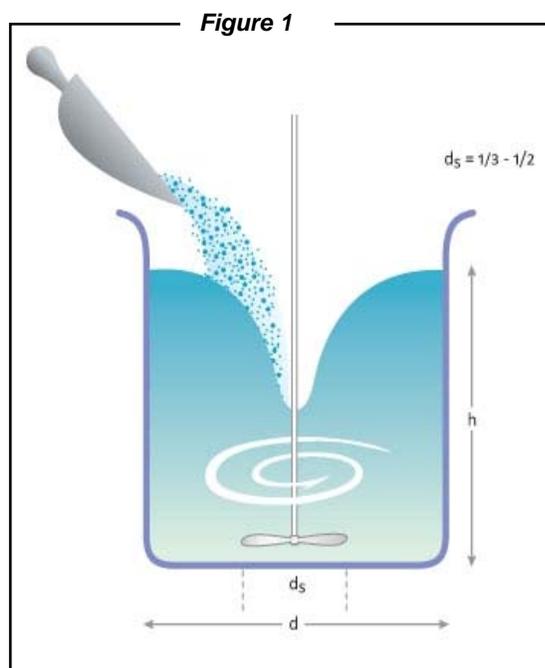
MIXING PROCEDURE**

- Determine the amount of Acryl-EZE (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
- 3200g water (ambient temperature)

- Weigh the water into the mixing vessel.
- Using a propeller stirrer, stir the water to form a vigorous vortex. If applicable, weigh the antifoam emulsion and add to the water. Weigh the Acryl-EZE 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). (Figure 1)



- Pass the dispersion through a 250 micron sieve prior to the coating process. Ensure the dispersion is continuously stirred during the coating process. The suspension 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 CLEANUP GUIDELINES

- For best results, clean equipment shortly after the end of the coating run.
- Acryl-EZE residue remaining on the coating equipment can easily be removed using a mild (greater than pH 5.5) sodium bicarbonate solution. Sodium bicarbonate (NaHCO_3) 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 NaHCO_3 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 dispersion. High shear mixers that do not generate heat are most suitable for the shorter 10-minute dispersion process and antifoam emulsion (0.5% with respect to Acryl-EZE) is required for successful dispersion preparation.

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