

Preparation and Use Guidelines

Acryl-EZE® LF, Label Friendly Aqueous Acrylic Enteric System, is a two-step, pigmented, delayed release film coating system. Acryl-EZE LF combines the acrylic film forming polymer* with Acryl-EZE LF Emulsion, containing a mix of plasticizer, detackifier and anti-foam.

Acryl-EZE LF formulations are reconstituted at 20% solids. Recommended weight gains of Acryl-EZE LF are 8% - 12% for enteric performance, depending on the physiochemical 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® 03K19339. A top-coat may be required for additional gloss or to aid in printing.

Materials

- Acryl-EZE LF formulated powder
- Acryl-EZE® LF Emulsion
- 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

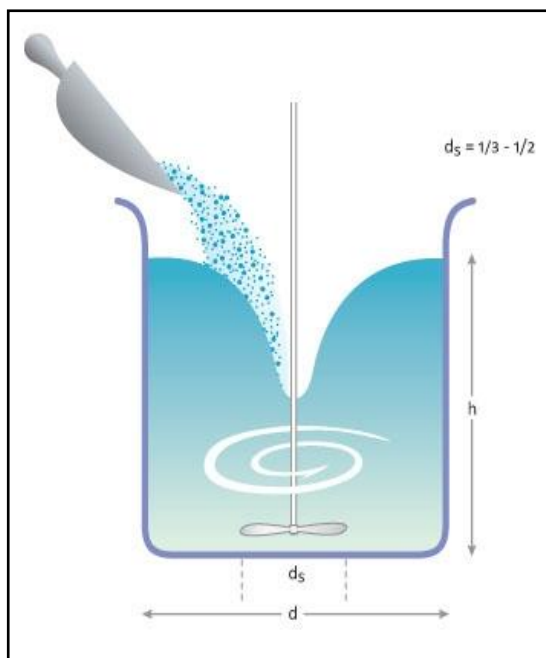
MIXING PROCEDURE**

- Determine the amount of Acryl-EZE LF powder. Acryl-EZE LF Emulsion and water are required to achieve a 20% solids dispersion based on the quantity of the product to be coated and the target coating weight.

Example: To coat 1.0 kg of tablets to a nominal 10% wt. gain:

- 80 g Acryl-EZE LF
- 98 g Acryl-EZE LF Emulsion
- 322 g water (ambient temperature).

Please note: Acryl-EZE LF Emulsion appears as a semi-solid and could be used directly without modification.



- Weigh the water into the mixing vessel.
- Using a propeller stirrer, stir the water to form a vigorous vortex. Weigh the Acryl-EZE LF Emulsion and add to the water. Weigh the Acryl-EZE LF powder and add to the centre 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).
- Ensure the dispersion is continuously stirred during the coating process. The suspension should be used the same day it is prepared.

ACRYL-EZE CLEANUP GUIDELINES

- For best results, clean equipment shortly after the end of the coating run.
- Acryl-EZE LF 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 LF dispersion. High shear mixers that do not generate heat are most suitable for the shorter 10-minute dispersion process.

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