

## Preparation and Use Guidelines

Acryl-EZE® 93A, aqueous acrylic enteric system, is a two-step, pigmented, delayed release film coating system specifically designed to provide enteric protection in elevated pH environments. Acryl-EZE 93A offers the formulator flexibility to select the plasticizer type and level, depending on the physicochemical properties of the pharmaceutical active or substrate.

Combining the benefits of a pigmented coating system with a globally accepted enteric polymer (Eudragit L100-55\*), Acryl-EZE 93A formulations are easily dispersed in water, for the application of a delayed release film coating to solid dosage forms such as tablets, granules and beads. The coating system can be color matched to meet marketing requirements and provides consistent, reproducible enteric protection and drug release profiles.

Acryl-EZE 93A formulations are reconstituted to 20%ww solids. Recommended weight gains of Acryl-EZE 93A are 8% - 12% 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 93A formulated powder.
- Distilled/deionized water at ambient temperature (20-35°C).
- Antifoam: simethicone or simethicone emulsion
- Plasticizer: triethyl citrate (TEC), polyethylene glycol (PEG) 8000, or triacetin.

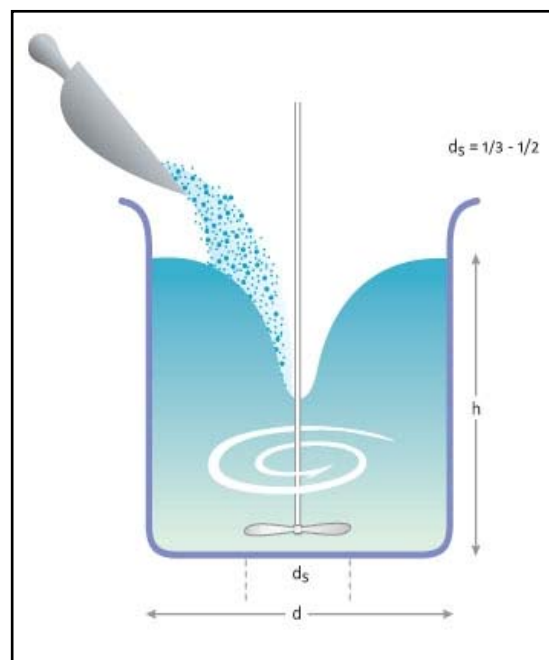
### Equipment

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

### MIXING PROCEDURE\*\*

- Determine the amount of Acryl-EZE 93A powder (to 20% w/w solids), plasticizer, water and antifoam required, based on the quantity of tablets to be coated and the target coating weight.

Figure 1



- Antifoam: 0.1%w/w with respect to Acryl-EZE 93A powder.
- Plasticizer: PEG 8000 (7-8% w/w), TEC (10-12% w/w) or Triacetin (12-13% w/w) with respect to Acryl-EZE 93A powder.

**Example:** To coat 1.0 kg of tablets to a nominal 8% wt. gain using 10% triethyl citrate:

- 80.0g Acryl-EZE 93A powder
- 8.0g TEC
- 320.0g Water
- 0.08g Simethicone

- Weigh the water into the mixing vessel.
- Using a propeller stirrer, stir the water to form a vigorous vortex.
- Weigh the antifoam and add it to the water.
- Mix for 5 minutes.
- Weigh the plasticizer and add it to the water/antifoam mixture.
- Mix for 5 minutes.
- Weigh the Acryl-EZE 93A powder and add to the center of the liquid vortex in a slow steady stream, avoiding clumping and maintaining a vortex. (Figure 1) After all of the powder is added, decrease the stirring speed to eliminate the vortex and maintain sufficient mixing.
- Continue mixing for 30 minutes
- Pass the dispersion through a 250 micron (60 mesh) screen 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.

## 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 ( $\text{NaHCO}_3$ ) 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  $\text{NaHCO}_3$  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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