



ACRYL-EZE®
Aqueous Acrylic Enteric System

Technical Data Sheet

Preparation & Use Guidelines

Acryl-EZE 93A

Acryl-EZE® 93A series is a two-step, pigmented, aqueous, delayed release film coating system specifically designed to provide enteric protection in elevated gastric pH environments. Acryl-EZE 93A series 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 dispersible 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 the enteric coating provides consistent, reproducible delayed release profiles.

Use Guidelines

- Acryl-EZE 93A formulations are reconstituted to 20% w/w solids dispersion.
- The coating system is pigmented to meet marketing requirements and provides consistent, reproducible enteric protection and drug release.
- Recommended weight gains of Acryl-EZE 93A coatings are 8% to 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 subcoat formula is Opadry®, 03K19229.
- A top-coat may be required for additional gloss or to aid in printing.

Preparation Guidelines

Materials

- Acryl-EZE 93A formulated powder.
- Distilled/deionised 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 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.
 - 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 1.0kg of tablets to 8% weight 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.
- Weigh the plasticizer and add it to the water.
- Mix for 5 minutes.
- Weigh the Acryl-EZE 93A powder and add it to the center of the liquid vortex in a slow steady stream, avoiding clumping and maintaining a vortex. 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 Clean Up 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 deionised water after cleaning.

Please contact your local Colorcon Technical Representative if you require any further information.

World Headquarters

Colorcon

415 Moyer Blvd., P.O. Box 24, West Point, PA 19486-0024

Tel: 215-699-7733 Fax: 215-661-2605 Web Site @<http://www.colorcon.com> E.mail: modified_release@colorcon.com

Locations	Telephone	Facsimile	Locations	Telephone	Facsimile
<i>United States</i>			<i>Asia/Pacific</i>		
Santa Ana, California	714-549-0631	714-549-4921	Singapore	65-6438-0318	65-6438-0178
Indianapolis, Indiana	317-545-6211	317-545-6218	Nishiyama, Japan	81-5-4465-2711	81-5-4465-2730
Humacao, Puerto Rico	787-852-3815	787-852-0030	Shanghai, China	86-21-5442-2222	86-21-5442-2229
Quebec, Canada	514-337-8341	514-337-9159	Goa, India	91-832-288-3434	91-832-288-3440
			Seoul, Korea	82-2-2057-2713	82-2-2057-2179
<i>Europe</i>			<i>Latin America</i>		
Dartford, Kent, England	44-1322-293000	44-1322-627200	Buenos Aires, Argentina	54-11-4552-1565	54-11-4552-3997
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Budapest, Hungary	36-1-200-8000	36-1-200-8010	Caracas, Venezuela	58-212-442-4819	58-212-442-8724
Barcelona, Spain	34-9-3589-3756	34-9-3589-3792			
Istanbul, Turkey	90-216-465-0360	90-216-465-0361			

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