ACRYL-EZE®

Aqueous Acrylic Enteric System

Acryl-EZE®, aqueous acrylic enteric system, is a fully formulated, dry enteric coating 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.

Table 1. Analytical Stability Results on Formulated Powder

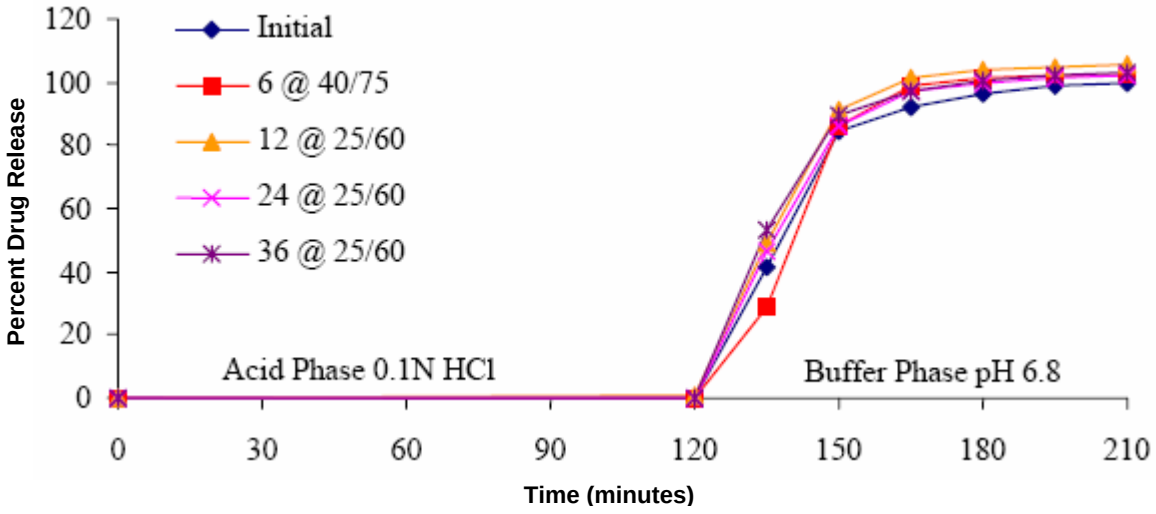
Formula number: 93O18359 Color: White Batch size: 80kg

Study Time	Powder Properties	Dispersion Properties			Color Difference
	Overall Appearance	Particle Size (D_{90})	pH	Viscosity (mPa·s)	DE index
Initial	Baseline	24.17	5.6	13	N/A
Storage Conditions 25ºC/60% RH in polyethylene double bag, with desiccant, inside fibre drum					
12 mth	No change	25.45	5.6	12	0.38
24 mth	No change	25.43	5.3	19	0.24
36 mth	No change	49.31	5.4	11	0.29
Storage Conditions 40ºC/60% RH in polyethylene double bag, with desiccant, inside fibre drum					
1 mth	No change	25.32	5.6	13	0.11
3 mth	No change	21.43	5.6	14	0.18
6 mth	No change	51.41	5.6	14	0.83

Enteric testing was then performed on tablets which were coated with the Acryl-EZE samples that were removed from the stability chambers at various intervals. Samples were tested at initial, 12, 24 and 36 months at 25ºC/60%RH, and 1,3 and 6 months at 40ºC/75%RH.

325mg acetylsalicylic acid tablets were sub-coated with a 2%wt. gain (2.3mg/cm2) of Opadry® II, high performance film coating system, Y-30-18037 and 8%wt. gain (9.2mg/cm2) of Acryl-EZE.

Figure 1. Analytical Results on Tablets Coated with Powder from Stability Testing



Specifications:

ACID PHASE: 0-120 minutes; not more than 10% dissolved

BUFFER PHASE: 120-210 minutes; not less than 80% dissolved.

The results show excellent stability of the ready formulated Acryl-EZE powder and also that the enteric properties are reproducible following storage of the powder at 36 months ambient and 6 months accelerated stability conditions.

For more information, contact your Colorcon representative or call:

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