

Product Information

Acryl-EZE®, aqueous acrylic enteric system, is 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.

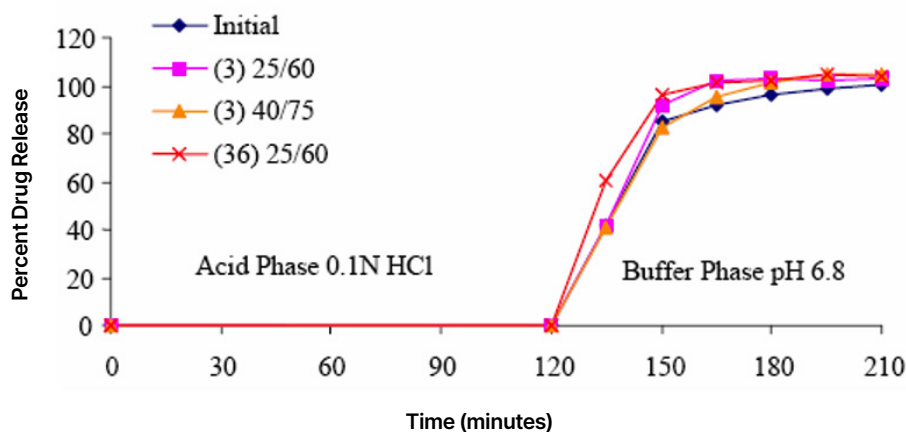
Enteric coated product stability

The following data demonstrates the enteric integrity and reproducibility of Acryl-EZE enteric-coated acetylsalicylic acid tablets under ambient and accelerated stability conditions.

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.

The tablets were then packaged into HDPE bottles, with cotton and desiccant, then heat sealed before placing on stability. Samples were tested at initial, 3 months following storage at 25°C/60% relative humidity (RH) and 40°C/75% relative humidity (RH), and 36 months at 25°C/60% relative humidity.

Figure 1. USP Delayed Release Acetylsalicylic Acid Tablet Dissolution Results



Specification

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

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

Table 1. Analytical Results

Analytical Tests	Specification	Initial	3 months		36 months
			25C / 60% RH	40C / 75% RH	25C / 60% RH
Free Salicylic Acid Content (%)	< 3.0%	0.0	0.1	0.2	0.8
Acetylsalicylic Acid Assay (%)	95-105%	98	103	101	99
Tablet Breaking Force (kp)	Report value	10.2	11.6	12.3	12.6

Acryl-eze®

Aqueous Acrylic Enteric System

Results exceed all USP requirements for delayed release acetylsalicylic acid tablets.

Similar results were obtained with other model formulations of Acryl-EZE. For further information please contact your local Colorcon Technical Contact.

* Methacrylic acid copolymer type C.

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