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.

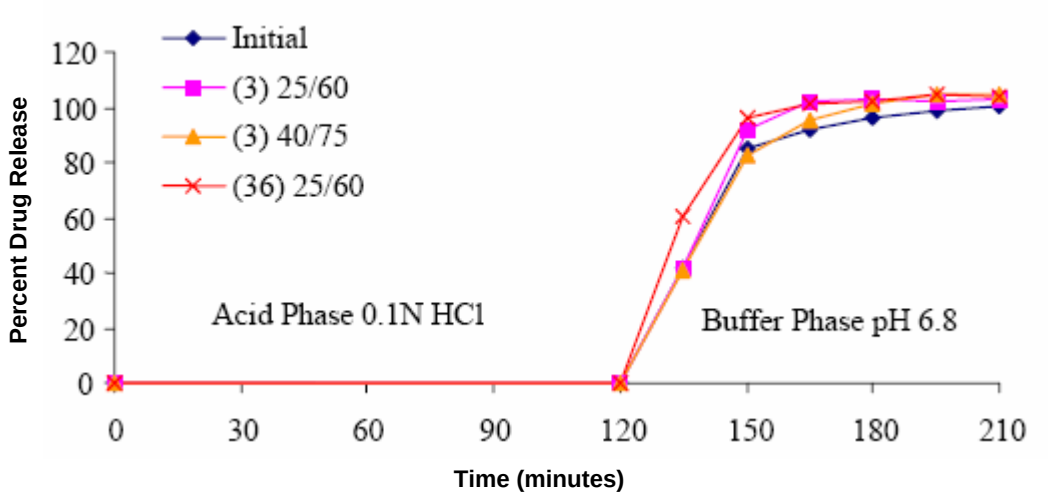
Enteric coated product stability

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 25ºC/60% relative humidity (RH) and 40ºC/75% relative humidity (RH), and 36 months at 25ºC/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

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.

For more information, contact your Colorcon representative or call:

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