Acryl-EZE®
Aqueous Acrylic Enteric System

Colorcon®

Simultaneous Application of a Two-part Delayed Release Coating in a Single Pass Continuous Coating Process

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Introduction

The objective of this study was to evaluate the application of both a seal-coating and an aqueous enteric coating to acetylsalicylic acid (Aspirin) tablets in a single pass continuous method.

Methods

Acetylsalicylic acid tablets 325 mg were used as the substrate; with the two-part fully formulated coating system consisting of an Opadry® clear seal-coat, and a pigmented enteric coating system, Acryl-EZE® (both from Colorcon Inc., USA), prepared at 10% and 20% solids concentration respectively.

The coating was conducted in a DRIACONTI-T continuous cycled coating machine (Driam GmbH, Germany) (Figure 1).

Figure 1. Driaconti-T Pharma Coating Machine

The coating machine is equipped with a rotating, perforated 100 cm diameter drum. The drum is divided into 7 individual coating chambers, using 30 cm high separating walls, spaced 22 cm apart. Tablets are fed into the first coating chamber from a pre-warming hopper, where the required quantity of tablets are heated to the desired temperature prior to coating. The “mini-batches” are then transferred from chamber to chamber, as the required amount of film coating for each segment has been applied. To facilitate batch-wise tablet movement through the length of the pan, a pneumatically controlled flap is built into each of the separating walls. When activated, the flap opens fully across the width of the individual chambers to form a helical configuration, passing tablets from one chamber to the next within one complete pan rotation. The flap is then closed and the next spray sequence begins. The seal-coat was applied at 10% solids concentration to a 2% weight gain (WG) in chambers 1 and 2 (1% WG per chamber). The enteric coat was applied at 20% solids concentration to a 10% WG in chambers 3-7 (2% WG per chamber) as shown in Figure 2.

Figure 2. Schematic of the Driaconti-T Coating Process

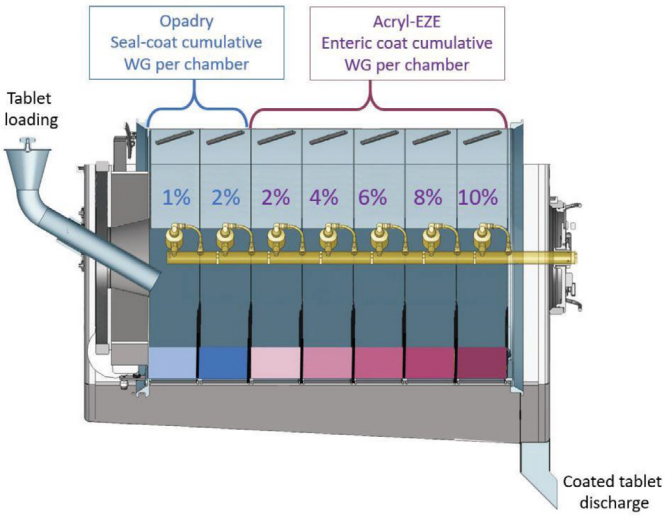


Table 1. Coating Process Parameters

Parameter	Setting
Spray rate (g/min/chamber)	45
Tablet load per chamber (kg)	18
Process air volume (m3/hr)	3,600
Inlet temperature (°C)	54-55
Exhaust temperature (°C)	39-42
Product temperature (°C)	39-43
Atomizing air pressure (bar)	1.1
Pattern air pressure (bar)	0.7
Pan speed (rmp)	8.0
Coating time per cycle (min)	40.0
Product transfer time per cycle (min)	1.0
Total tablet throughput rate (kg/hr)	26.0

At the completion of the 7 full cycles of coating, the process was stopped and tablets were sampled from each of the chambers to assess coated tablet properties. The coating process parameters are shown in Table 1.

Tablet samples from chambers 3-7 were tested for % acid uptake using a modified disintegration method: tablets were weighed before and after 2 hours exposure to 0.1N HCl. Samples taken from chambers 5-7 were also tested according to USP Aspirin Delayed Release Tablets monograph.

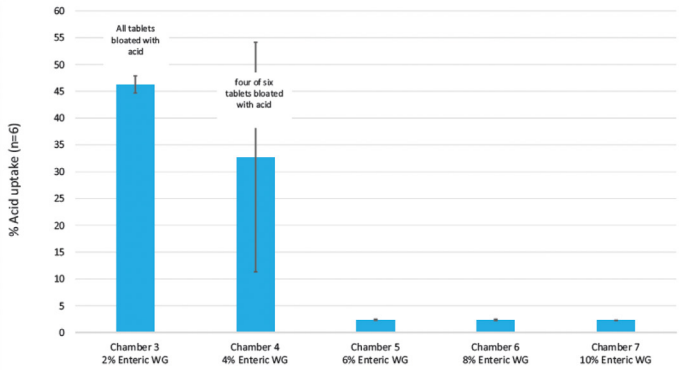
Results

Figure 3. Final Coated Tablet Appearance

The process resulted in a tablet coating throughput rate of 26.4 kg/h. Coated tablets, sampled from each chamber at the end of the trial, were smooth, uniform in color and free of visual defects (Figure 3).

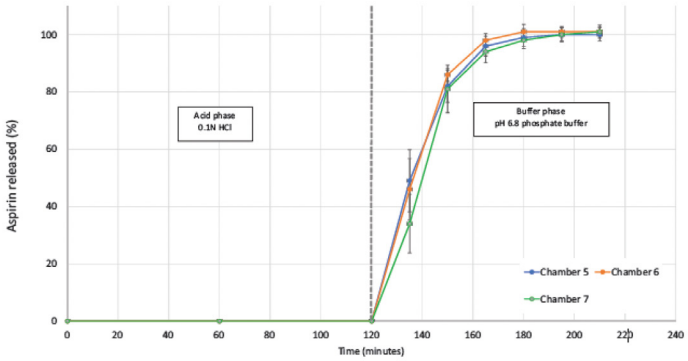
Following a two-hour disintegration test in 0.1N HCl, samples from chambers 5, 6 and 7 (6%, 8% and 10% WG of Acryl-EZE) exhibited no signs of defect and acid uptake values less than 2.4% (Figure 4).

Figure 4. Acid Uptake Values for Tablets Sampled from Chambers 3-7



USP dissolution testing confirmed robust enteric coating performance with no drug release in 0.1N HCl from samples ≥ 6% WG, and greater than 90% released within 45 minutes in pH 6.8 buffer (Figure 5).

Figure 5. Dissolution Profiles for Tablets Sampled from Chambers 5-7



Conclusions

The unique segmented chamber design of the DRIACONTI-T coater was used to sequentially apply two separate coating systems, with different solids concentrations and functionality, in a single continuous coating process. The Acryl-EZE coating formulation provided enteric protection lower than the initially targeted 10% WG; thus, offering the opportunity to further increase production throughput rates by optimizing the coating weight gain in each chamber.

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