Investigation of a New Semi-continuous Coating Process Using a Fully Formulated Enteric Coating System

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Purpose

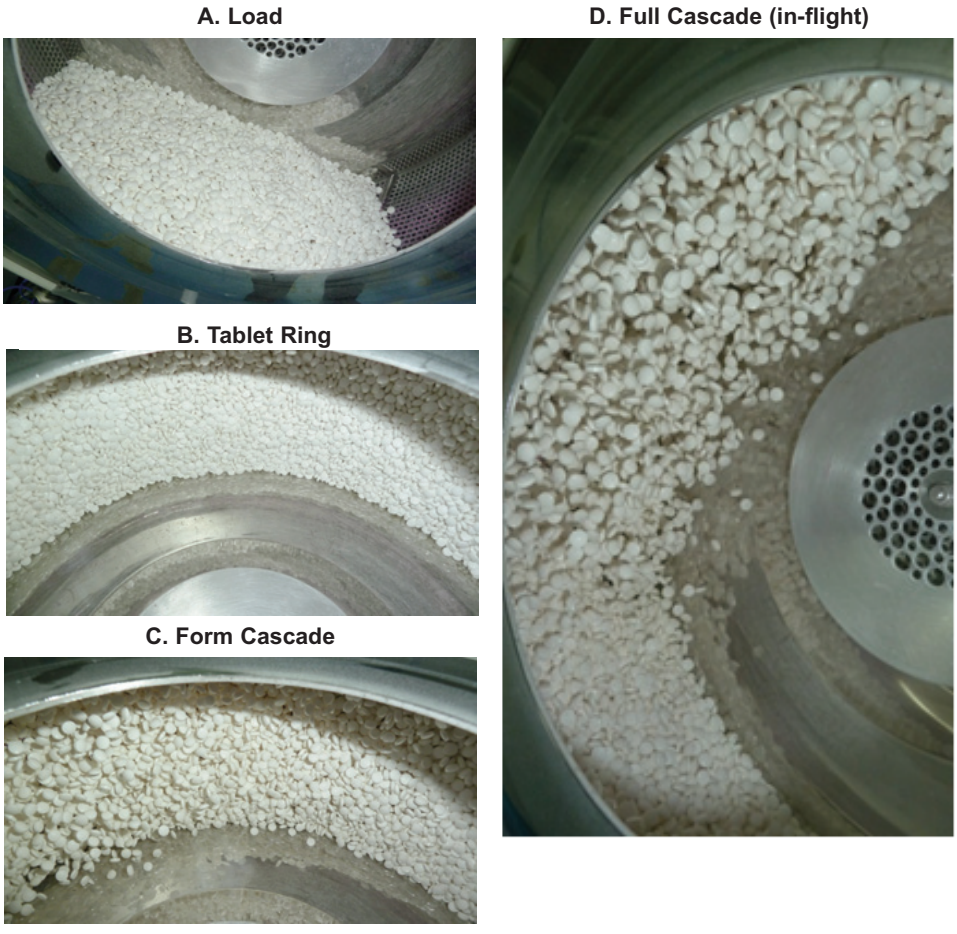
The Omega™ (GEA Pharma Systems) coater is the final unit operation in a continuous solid oral dose manufacturing process. This new type of coater subjects tablets to a cascading tablet movement enabling greater fluid application rates (higher coating build-rates) than traditional coating pans. The functionality of enteric coatings is greatly dependent on weight gain and coating uniformity which makes this type of coating ideal for assessment of this new coating process. In traditional coating pans, fast coating application rates often result in poor coating uniformity requiring a higher weight gain of coating to achieve enteric protection. The objective of this study was to evaluate the suitability of the Omega novel semi-continuous coating process for the rapid application of an aqueous enteric coating system used as a model functional coating.

Methods

Aspirin tablets 325mg were used as the coating substrate. The coating was a fully formulated aqueous enteric coating system, Acryl-EZE® aqueous acrylic enteric system, (Colorcon Inc), prepared at 20% solids concentration. The coating trial was conducted with a batch size of 3kg and final target weight gain (WG) of 12% w/w.

In the Omega coater the tablet charge, under the influence of radial air knives, is induced to form a stable cascade inside a perforated drum rotating at high speed (Figure 1).

Figure 1. Stages of tablet motion in the Omega coater



A conventional spray nozzle is directed upwards into the cascade of "in-flight" tablets where substantially their full surface area is available to receive the coating on each pass. A high spray rate relative to the tablet charge is matched by high specific airflows. Filling and discharge is automated and rapid.

The Omega coater can be operated as single or multiple modules - typically two when matched to a GEA continuous tableting line applying immediate release coatings (Figure 2).

Figure 2. Omega coater twin-wheel manufacturing unit

In this study, tablets were automatically fed into a single coating module with automated discharge at the completion of each coating cycle in a semi-continuous process. The single coating chamber configuration is shown in Figure 3.

Figure 3. Single coating chamber configuration

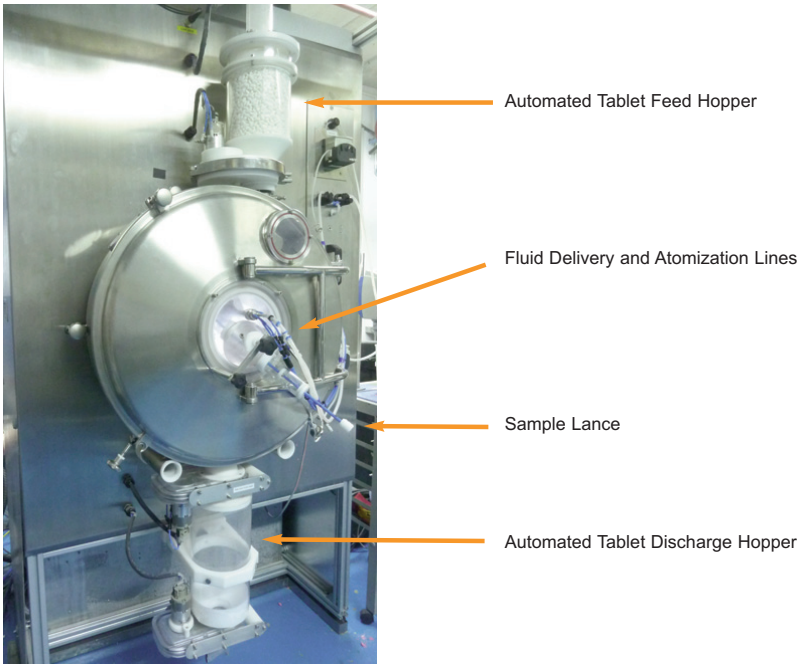


Table 1. The process parameters used for the enteric coating trial are shown in Table 1.

Trial parameter description		Unit	Value
Tablet core	Dimensions	mm	10.5 x 4.9 Round
	Weight	mg	388.0
	Surface area	mm²	252.0
Process loading	Wheel size	mm	Ø440 x160
	Fill weight	g	3000.0
	Number of tablets		7732.0
	Surface area	cm²	19484.5
Handling Time	Loading / Discharge time	sec	90.0
	Preheat time	sec	15.0
	Drying time	sec	15.0
	Total	sec	120.0
Spray parameters	Solids concentration	%	20.0
	Quantity applied	g	1800.0
	Spray rate	g/min	60.0
	Dry film density	g/cm³	1.6
	Spray time	min	30.0
	Film build rate	microns/min	3.8
	Film thickness	microns	115
Output	Theoretical weight gain	%	12.0
	Output	kg/hr	5.6
Spray Pattern	Atomizing air	bar	1.5
	Pattern air	bar	1.0
Tablet Motion	Wheel speed	rpm	95/92
	Knife 1	m/bar	220.0
	Knife 2	m/bar	220.0
Drying	Flow rate	m³/hr	220.0
	Temp	°C	80.0

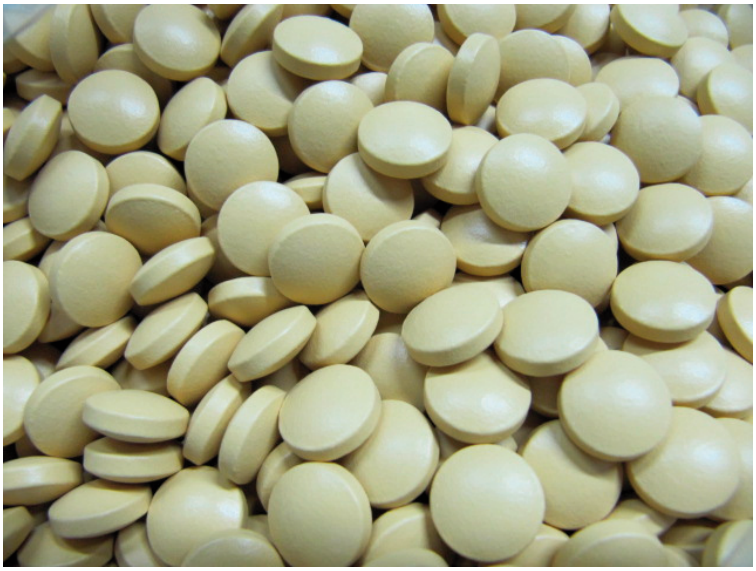
Coated tablet samples were withdrawn from the process at 5%, 6%, 8% and 10% applied WG.

Enteric performance was evaluated using USP dissolution apparatus 1 at 100 rpm. Enteric coated tablets (n=6) were tested in 0.1N HCl for 2 hours then immediately transferred into pH 6.8 phosphate buffer for dissolution and drug release testing.

Results

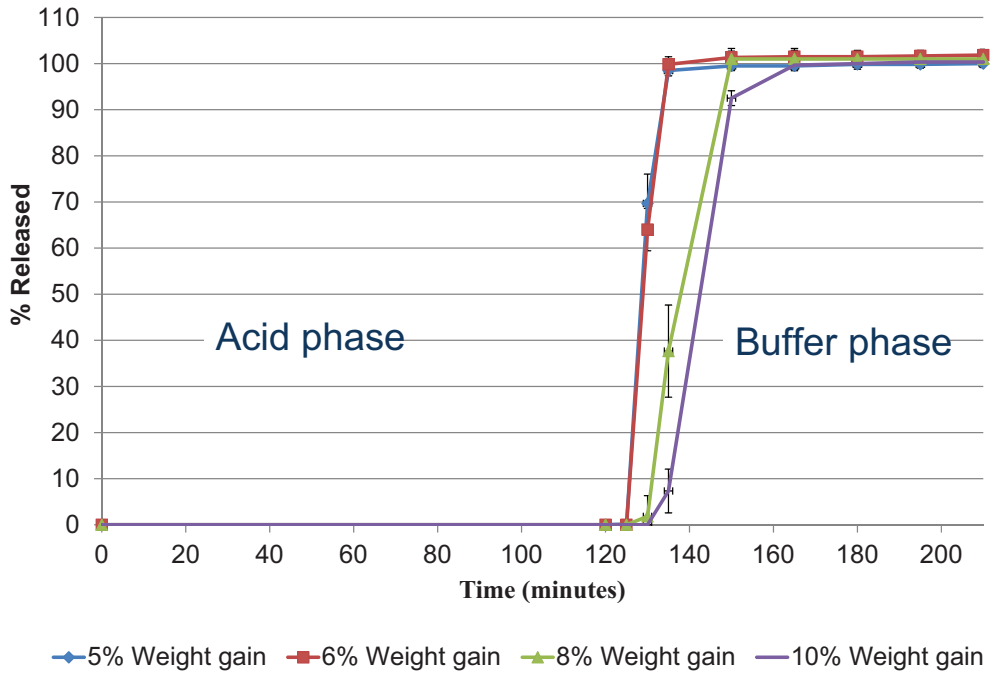
The enteric coated tablets were smooth and glossy and free of any apparent defects. The color uniformity of the tablets was very good as would be expected at the higher weight gains sampled for enteric testing (Figure 4).

Figure 4. Coated tablet appearance



Dissolution testing demonstrated robust enteric coating performance with samples from 5% WG exhibiting no drug release in pH 1.2, and greater than 90% released within 45 minutes in pH 6.8 buffer (Figure 5).

Figure 5. Comparison of APAP granule dissolution profiles for 80:20 at 25% weight gain with and without heat treatment (a) full profile:0–45 minutes, (b) initial release profile: 0–6 minutes.



Slight differences in the rate of drug release were observed in buffer phase depending on the applied coating WG. As expected, higher WG resulted in slightly slower release initially, but all samples reached > 90% release within 20 minutes. The total coating time to reach 12% WG was 30 minutes. Passing enteric results were achieved in 12.5 minutes of coating at 5% WG indicating excellent coating uniformity. This early protection and the absence of any visible tablet edge defects indicated low tablet stress in this dynamic process.

Conclusions

The results indicate that the Omega semi-continuous coating process can achieve uniform application of functional coatings at low weight gains in a very short process time. The Omega coater would also be ideal for the application of immediate release aesthetic coatings where color uniformity would be achieved at even lower weight gains. Another significant advantage of this coater is that development batches in this unit are effectively completed at commercial scale expediting transfer to manufacturing. The Acryl-EZE, fully formulated enteric coating system was found to be well suited for use in this new coating technology.

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