Enhanced Intra Tablet Enteric Coating Uniformity in the ConsiGma™ Coating Process

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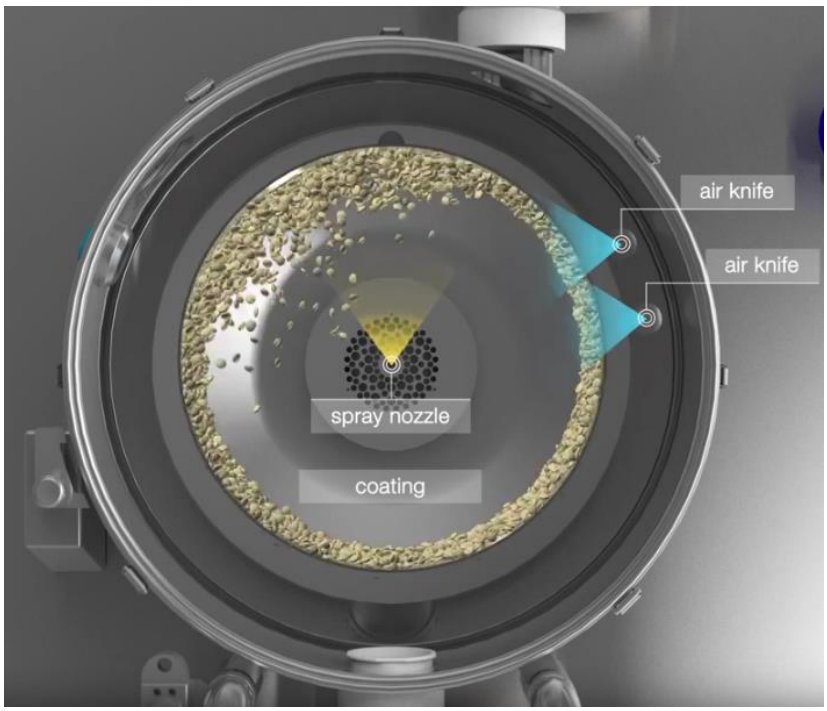
Purpose

The ConsiGma™ coater (GEA Pharma Systems) is the final operation in a continuous solid oral dose manufacturing process. In this new type of coater, tablets repeatedly and rapidly move through the spray zone in a falling motion; they are not preferentially oriented on one side (face, edge, end) of the tablet, toward the spray (Figure 1).

Figure 1: Tablet Motion in the ConsiGma Coater



In traditional coating pans, it has been demonstrated that the coating is always thicker on the face as compared to the edge or end of the tablet since they are closely packed and not able to freely rotate as they pass through the spray zone.[1]

The objective of this study was to compare intra-tablet coating uniformity between the ConsiGma and traditional batch pan coating processes. An enteric coating was chosen for this study as its functionality is highly dependent on weight gain (film thickness) and both inter and intra-tablet coating uniformity.

Methods

Aspirin tablets (325 mg) were used as the tablet core substrate. The coating was a fully formulated aqueous enteric coating system, Acryl-EZE® (Colorcon Inc.), prepared at 20% solids concentration.

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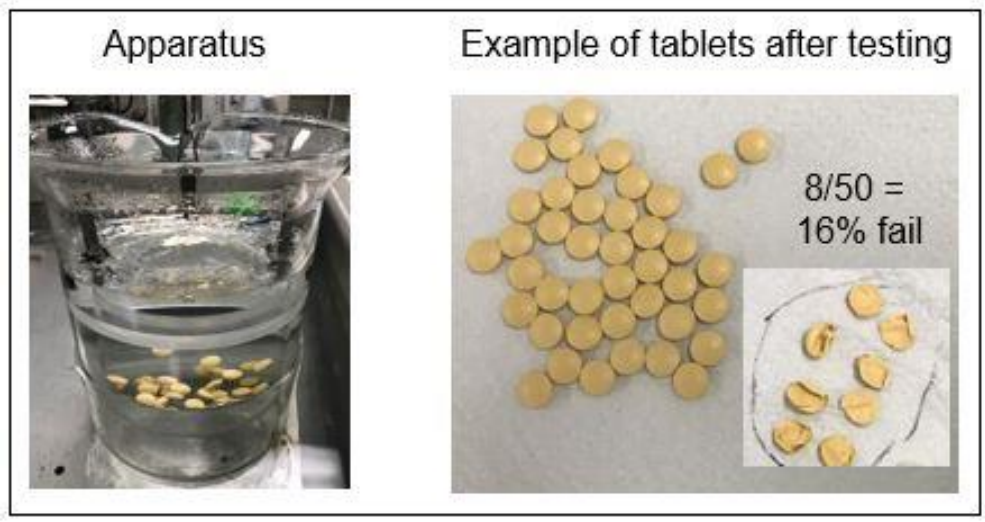
Six coating trials were conducted in the ConsiGma machine with a batch size of 3 kg and final target weight gains (WG) of 7, 8, 9, 10, 11 and 12%. One coating trial was conducted in a 24" fully perforated, side-vented coating pan (Labcoat II, O'Hara Technologies) with a batch size of 16.0 kg and a final target of 12% WG. This batch was sampled in-process at 8, 9, 10, 11 and 12% WG.

Acid resistance for all samples was tested using a modified disintegration apparatus that subjected 50 tablets, per sample, to 2 hours in 0.1N HCl (37°C). After removal from the acid, individual tablets were inspected for any signs of bloating, peeling or disintegration (Figure 2).

Figure 2: Acid Resistance Test Apparatus and Example Results



Samples were also tested for dissolution according to USP Aspirin Delayed Release Tablets monograph.

Scanning electron microscopy (SEM) was used to assess the intra-tablet coating thickness and uniformity from cross sections of tablets, coated in either the ConsiGma or traditional batch process.

Results

The coating processes were free of any issues. The ConsiGma coater process times ranged from 17.5 minutes (7% WG) to 30 minutes (12% WG) for the 3 kg batches. The single coating trial in the traditional coating pan was completed in 160 minutes. All coated tablet samples were visually smooth, uniform and free of defects irrespective of the coating process used (Figure 3).

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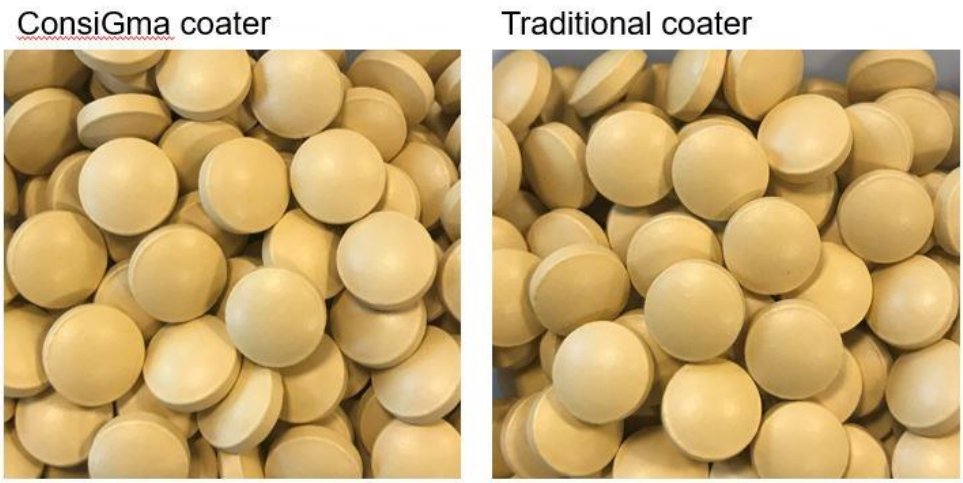
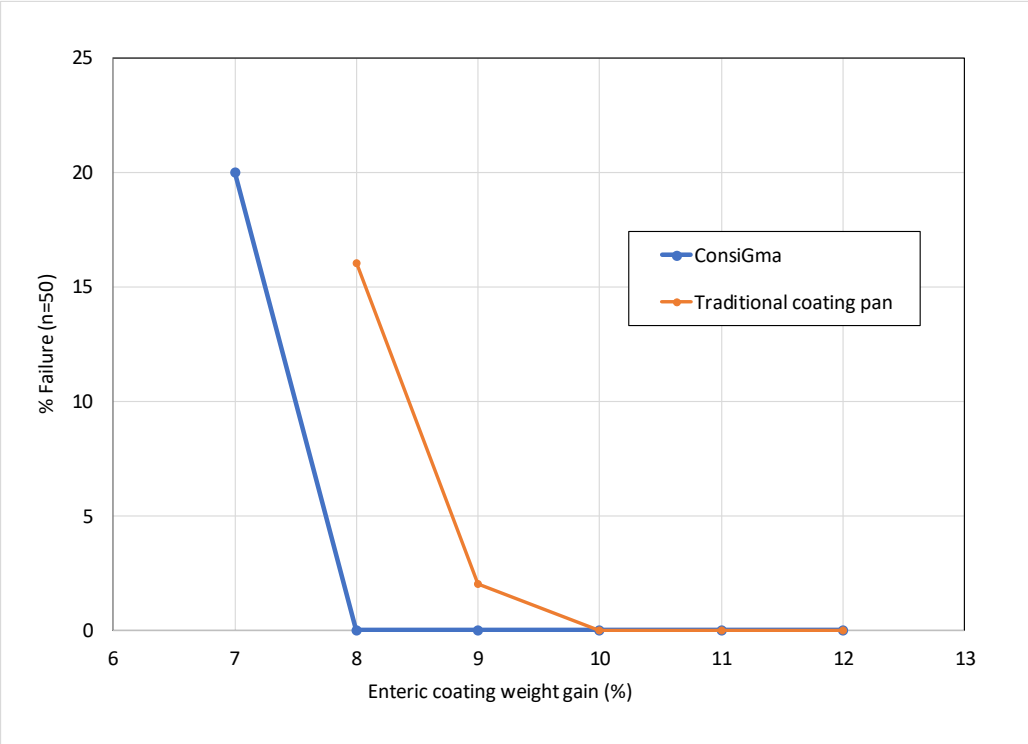
Figure 3: Coated Tablet Appearance (12% WG)



The ConsiGma coated tablets passed acid resistance testing at 8% WG compared to the traditionally coated tablets that passed at 10% WG (Figure 4).

Figure 4: Acid Resistance Results



SEM revealed the enteric coating thickness was more uniform around all surfaces of the ConsiGma coated tablets, compared to the traditional coating process where the coating thickness on the edges and ends of the tablet was much thinner (Figure 5 and Table 1). These thin areas of coating are likely to be responsible for the need to increase the amount of coating required to pass the acid resistance testing.

Figure 5: SEM Cross Section of Coated Tablets

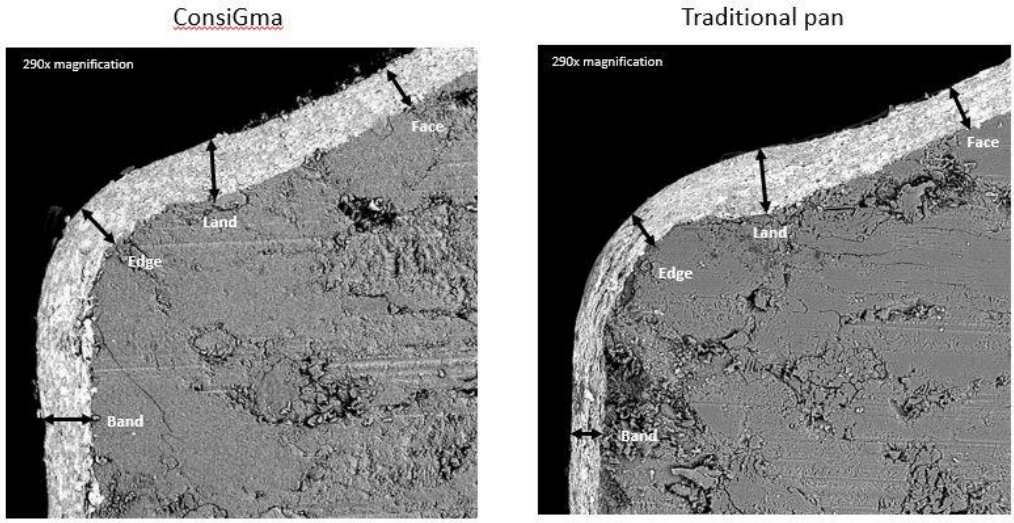
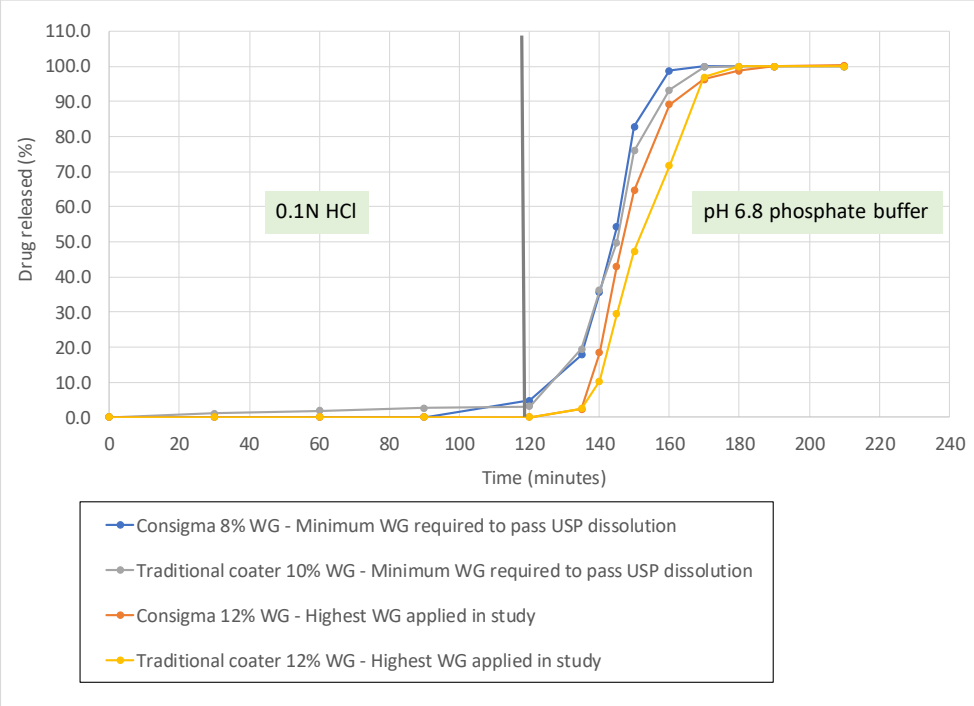


Table 1: Coating Thickness Measurements

Coating Location	ConsiGma	Traditional Coating Pan
	Coating thickness (microns)	
Face	104.0	88.1
Land	117.0	122.0
Edge	94.7	61.1
End	101.0	62.9
Average	104.2	83.5
St. dev.	9.4	28.5
% RSD	9.0	34.1

ConsiGma coated tablets ≥ 8% WG and traditionally coated tablets ≥ 10% WG passed USP delayed release dissolution testing (Figure 6).

Figure 6: Dissolution Profiles



Conclusions

This study indicated that the ConsiGma coating process can achieve uniform application of functional coatings in a very short process time. The unique method of presenting tablets to the spray zone resulted in excellent inter and intra-tablet coating uniformity in comparison to the traditional batch coater. The Acryl-EZE, fully formulated enteric coating system was found to be well suited for use in this new coating process technology.

References

1. Wilson KE, Crossman E. The Influence of Tablet Shape and Pan Speed on Intra-Tablet Film Coating Uniformity. Drug Development and Industrial Pharmacy 23 (12), 1239-1243 (1997)

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