Investigation into a High Productivity Sugar Coating Formulation and Processing

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Purpose

Sugar coating is a traditional method of producing elegantly coated tablets. However, it can be a challenging coating process as there are multiple complex steps involved. Seal-coating with organic solvent is often required to protect the cores from over-wetting during the ladling process. Additionally, the ladling process is manual and operator dependent, often taking days to complete. These issues also limit operator and equipment flexibility and can lead to batch-to-batch variability. This study evaluates a developmental aqueous sugar film coating system, that can be applied using automated film spraying equipment, in both conventional and perforated coating pans. The system consists of three coating formulations: a bulk coat to round tablet edges, a pigmented coat to add color, and a clear coat for a high gloss finish.

Methods

The developmental bulk sugar film coating was applied at a solids contents of 35 % w/w onto 10 mm standard biconvex round placebo tablets in fully perforated and conventional solid coating pans. Pilot and production scale fully perforated coating trials were performed in O'Hara Labcoat IIX fitted with a 24″ pan (O'Hara Technologies, Ontario, CA), and an Manesty Accela-Cota 150 outfitted with a 48″ pan (Bosch, UK). Solid conventional pan coating trials were performed in a Skerman 16″ coating pan. All coating processes were automated and the dispersions sprayed continuously using the conditions described in Table 1.

Surface gloss of the coated tablets was measured using a Tricor Surface Analysis System.

Table 1: Coating Parameters for Bulk Coat in Pilot and Production Scale Fully Perforated and Solid Conventional Coating Pans

Parameter	Labcoat IIX – 24″ (Pilot)	Accela-cota 150 – 48″ (Production)	Skerman – 16″ (Conventional)
Batch Size (kg)	15	100	1
Pan Type	Fully Perforated	Fully Perforated	Solid
Bed Temperature (°C)	48	52	39
Spray Rate (g/min)	60	200	10
Air Flow (cfm / m^3/hr)	265 / 450	1236 / 2100	59 / 100
Atomization Air Pressure (psi / bar)	35 / 2.4	57 / 4.0	22 / 1.5
Pattern Air Pressure (psi / bar)	25 / 1.7	42.7 / 3	22 / 1.5
No. of Guns	2	3	1

Ibuprofen tablets (200 mg, 10 mm, deep biconvex) were coated with bulk, pigmented, and gloss sugar film coatings at 30%, 20% and 8% solids with coating weight gains of 44%, 3%, and 1% weight gain respectively, using the O'Hara Labcoat I fitted with a 15″ fully perforated pan. The coating process conditions are described in Table 2. The disintegration time was evaluated in deionized water using a Vankel disintegration tester following USP methods.[1]

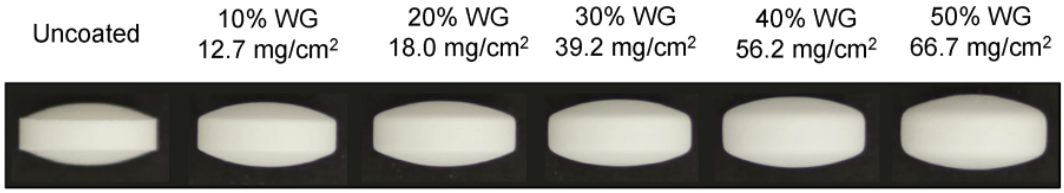
Table 2: Coating Parameters for Bulk, Pigmented and Clear Coat of Developmental Aqueous Sugar Film Coating onto Ibuprofen Tablet Cores in a Lab Scale Fully Perforated Coating Pan

Parameter	Bulking	Pigmented	Clear
Batch size (kg)	2.2	2.2	2.2
Weight gain (%)	44	3	1
Solids (%)	30	20	8
Spray rate (g/min)	28	20	16
Total coating time (min)	119	17	17
Bed temperature (°C)	42	42	42
Air volume [CFM / (m^3/hr)]	175 / 300	175 / 300	175 / 300
Atomization air pressure (psi / bar)	35 / 2.4	25 / 1.7	25 / 1.7
Pattern air pressure (psi / bar)	22 / 1.6	22 / 1.6	22 / 1.6

Results

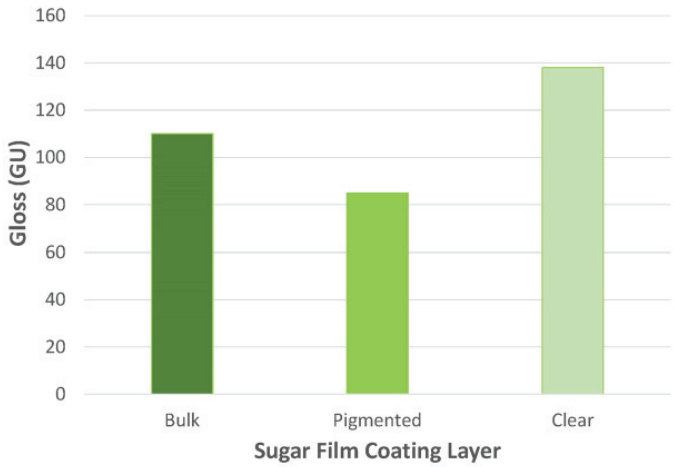
The bulk coat was applied directly onto the placebo tablets with controlled processing conditions, circumventing the need for an organic seal-coat. Due to the controlled and automated process, no defects such as over wetting or tablet sticking were observed in any of the coating trials, regardless of scale or equipment. Figure 1 shows the rounding of the tablet as the bulking coat was applied, with the most rounding being apparent above 30% weight gain.

Figure 1: Profile of Tablet Rounding as a Function of Developmental Aqueous Sugar Film Coating Theoretical Weight Gain



The bulk and pigmented coating provided a high surface gloss as shown in Figure 2. The application of the clear top-coat provided an exceptionally high gloss finish of 138 GU, with a very elegant final appearance.

Figure 2: Surface Gloss Units (GU) of Placebo Tablets Coated with Bulk, Pigmented and Clear Developmental Aqueous Sugar Film Coating



The final sugar film coated ibuprofen tablets had an extremely high gloss of 147 GU and an elegant appearance, as shown in Figure 3. The disintegration time as a function of coating weight gain is shown in Figure 4. Even at a 48% WG of coating the tablets had a fast disintegration time of 10.8 ± 0.8 minutes in deionized water.

The gloss and disintegration time are comparable to previously reported results for ibuprofen tablets coated using a traditional sugar coating ladling process; gloss value of 163 GU and disintegration time of 10.0 min.[2] There were two major differences between the sugar film coating process and the traditional sugar coating process. The traditional process required an organic solvent based shellac coating to protect the cores, with the total processing time of 6.25 hours. In comparison, the aqueous sugar film coating process did not require a seal-coat, resulting in a much shorter coating time of 2.55 hours. A comparison of the gloss and coating process time can be seen in Figure 5.

Figure 3: Image of Deep Biconvex, Aqueous Sugar Film Coated Ibuprofen

Figure 4: Disintegration Time of Deep Biconvex, Aqueous Sugar Film Coated Ibuprofen in Deionized Water

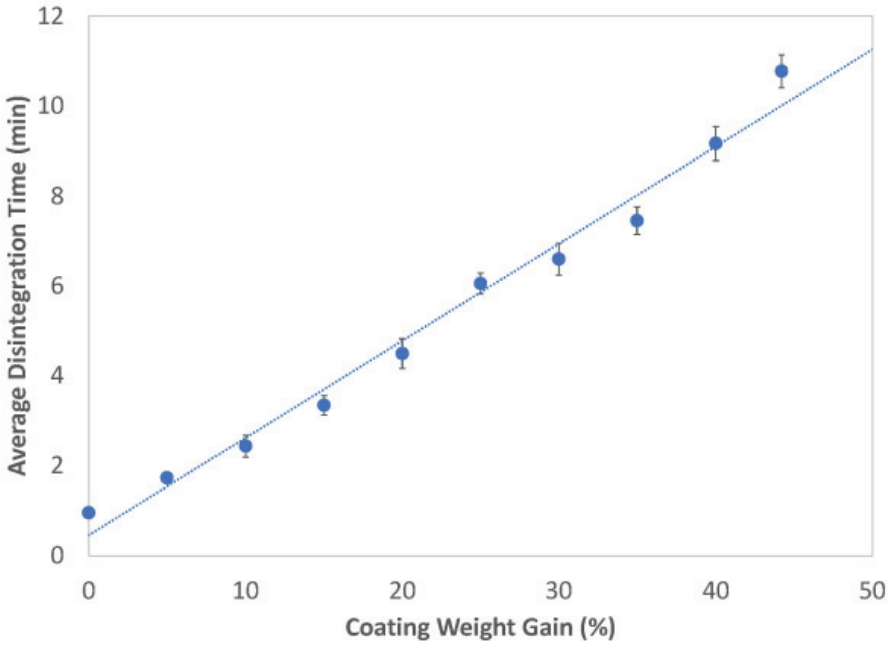
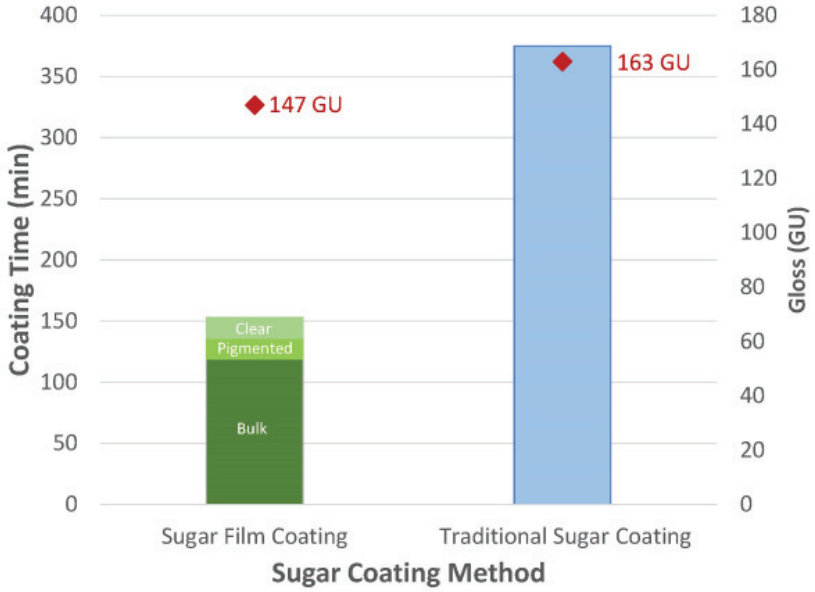


Figure 5: Comparison of Gloss and Processing Time Required for Sugar Film Coating and Traditional Sugar Coating



Conclusions

The developmental aqueous sugar film coating system resulted in a tablet appearance similar to traditionally sugar coated tablets, achieved using a more efficient and simplified coating process. The bulk, pigmented, and clear coating systems were applied continuously with an automated film coating process. As there was no need for an organic seal-coat, the overall coating process time was significantly decreased (over 40%) and there was a reduced risk of batch-to-batch variability and operator dependency.

References

1. *United States Pharmacopeia and National Formulary* (USP 40-NF 35 S1). Rockville, MD: United States Pharmacopeia Convention; 2017:584.
2. Steffenino, R. Vesey C. Enhanced Aesthetic and Functional Stability of Opaglos® 2 High Gloss Film Coating System vs. Sugar Coating on Ibuprofen. AAPS 2002.

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