Application of a Developmental, High Productivity Film Coating in the GEA ConsiGma™ Coater

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The developmental film coating from this study was commercially launched in April 2016 as:

Opadry® QX
Quick and FleXible Film Coating System

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Purpose

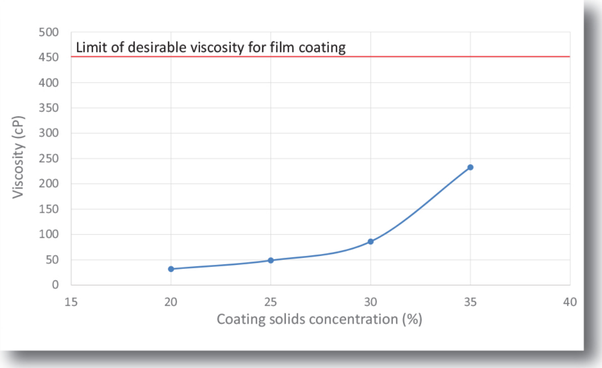
The objective of this study was to evaluate the rapid application of a developmental, low viscosity aqueous film coating system in a novel semi-continuous coating machine. The ConsiGma (GEA Pharma Systems) Coater is the final operation in a continuous solid oral dose manufacturing process. The design of this coater subjects tablets to a cascading tablet movement enabling greater fluid application rates (higher coating build-rates) than traditional coating pans

Methods

Materials

Placebo 250 mg round tablets were used as the coating substrate. The coating system was a developmental, pigmented formulation innovated by Colorcon and based on Kollicoat® IR (polyvinyl alcohol-polyethylene glycol graft copolymer) (BASF, Florham Park, NJ). This system is designed for faster applications at up to 35% w/w dispersion solids concentration. The coating dispersion exhibits a very low viscosity in water with significantly higher dispersion solids concentrations possible when compared to currently available fully formulated film coating systems (Figure 1).

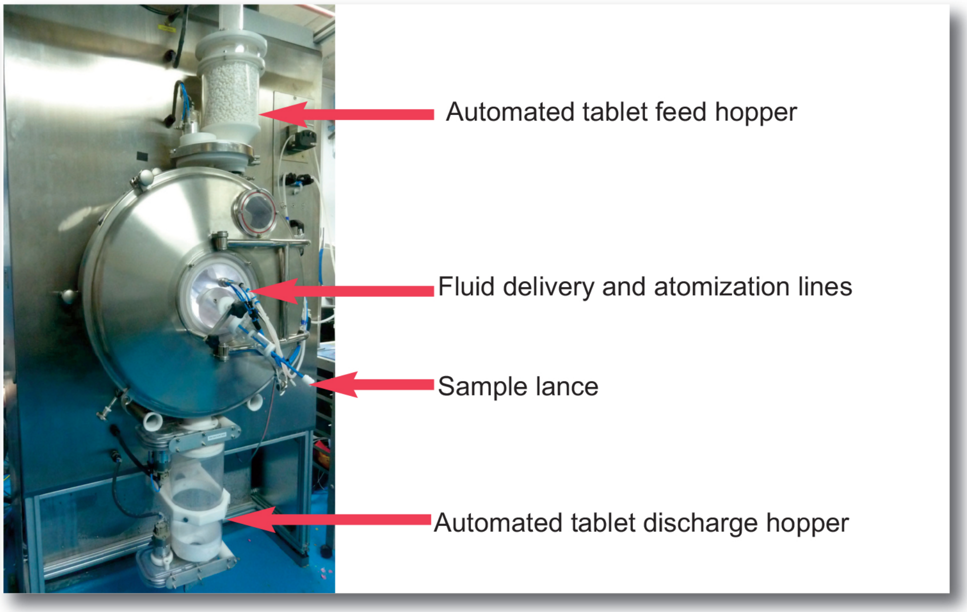
Figure 1: Developmental Coating Formulation Viscosity Profile



Equipment and Process

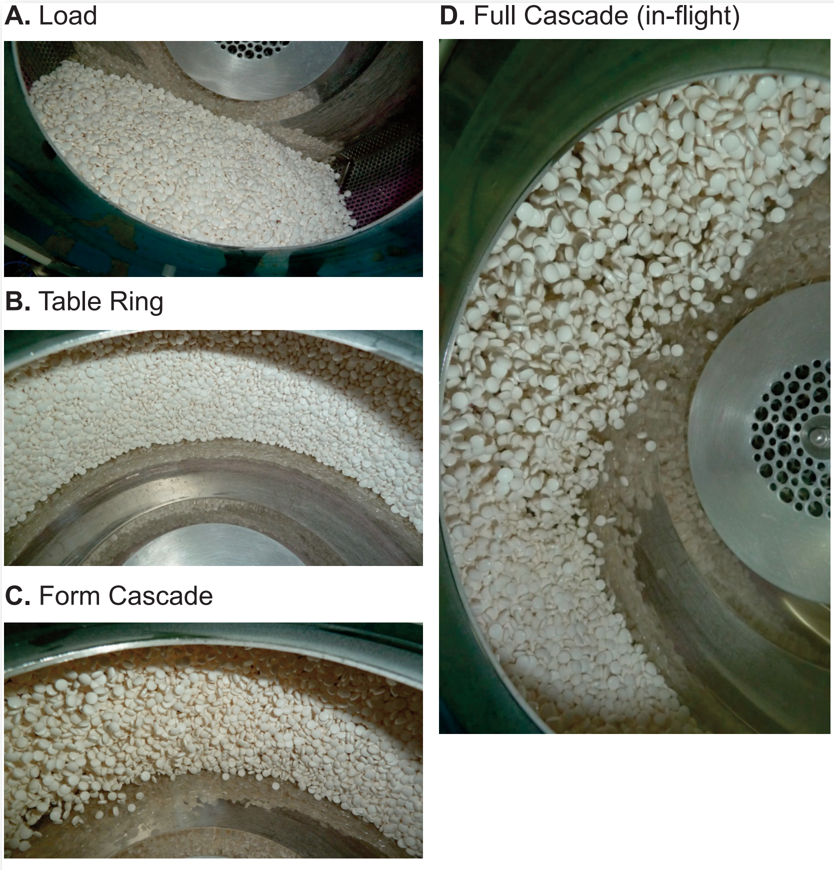
The coater consists of two modules operating in tandem with each module autonomously loading, coating, and discharging product in rapid succession. In this study, tablets were automatically fed into a single coating chamber with automated discharge at the completion of each coating cycle; a semi-continuous process. The single coating chamber configuration is shown in Figure 2.

Figure 2: Single Coating Chamber Configuration



In the ConsiGma 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 3).

Figure 3: Stages of Tablet Motion in the ConsiGma Coater



A conventional spray nozzle is directed upwards into the cascade of "in-flight" tablets where essentially 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.

Coating trials were conducted with a batch size of 3 kg and a target weight gain (WG) of 3%. Four coating trials were conducted at 25% or 30% w/w solids concentration, inlet air temperature of 80°C and spray rates of either 50 g/min or 80 g/min (Table 1).

Table 1: Coating Trial Settings

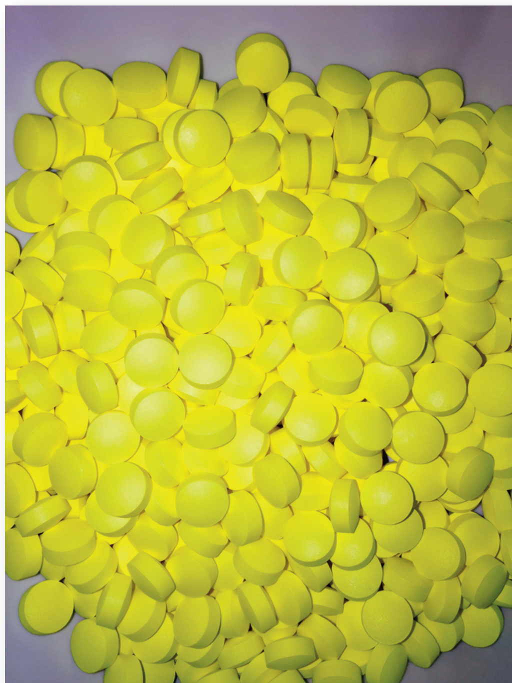
Trial #	Solids conc. (%)	Spray rate (g/min)	Coating suspension (g)	Coating time (min)	Load / discharge / preheat / dry (min)	Total throughput rate (kg/hr)	Total system (twin wheel) output (kg/hr)
1	25	50	400	8	0.5	21	42
2	25	80	400	5	0.5	33	66
3	30	50	333	6.7	0.5	27	54
4	30	80	333	4.2	0.5	43	86

Samples taken at the end of each trial were assessed visually and tested for color uniformity (Model 600, Datacolor, Lawrenceville, NJ), surface roughness using an optical scanning profilometer (Model PS50, Nanovea, Irvine, CA) and gloss (Model 805A Surface Analysis System, Tricor Systems, Elgin, IL).

Results

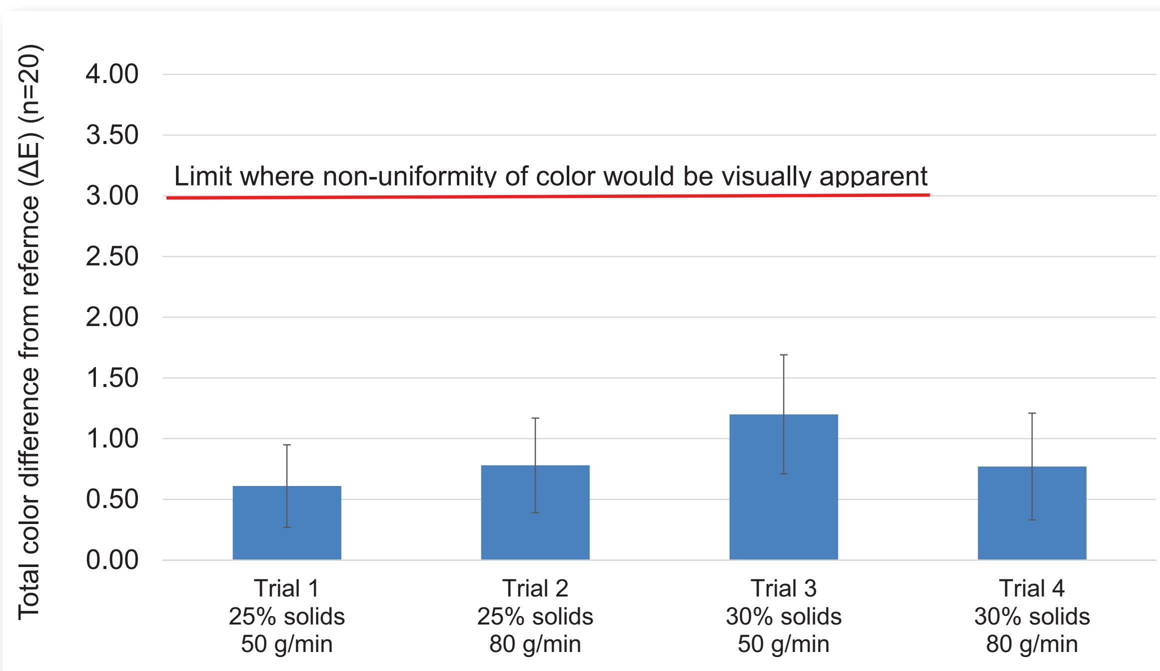
The coated tablets from each of the trials were smooth and free of any apparent defects. Even the tablets coated at 30% w/w solids concentration and the highest spray rate were visually elegant (Figure 4).

Figure 4: Coated Tablet Appearance (Trial 4)



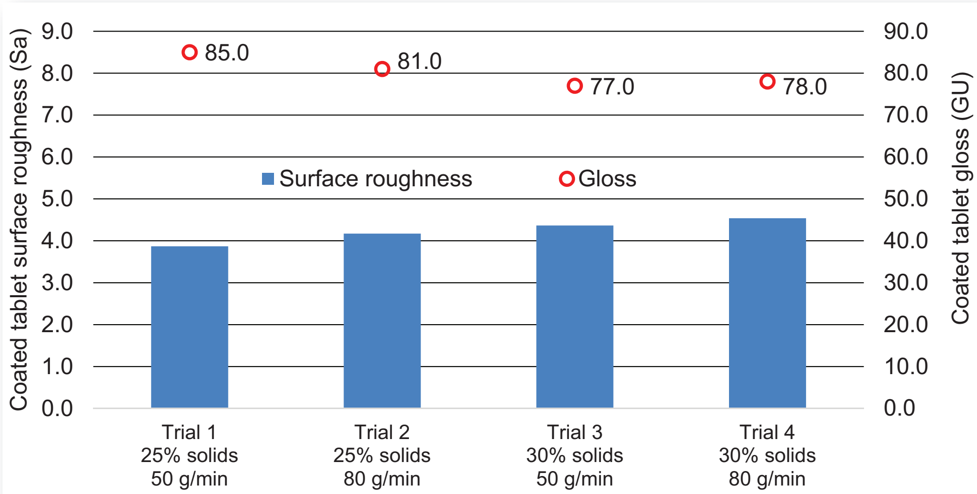
Color uniformity was excellent for all trials with color difference values averaging <1.5ΔE (Figure 5).

Figure 5: Color Development Uniformity



Instrumental testing confirmed the excellent visual appearance with surface roughness (Sa) values averaging < 4.5 and gloss units (GU) between 77 and 85 (Figure 6).

Figure 6: Coated Tablet Gloss and Surface Roughness



The overall process was very efficient. Coated tablet throughput rates increased from 21 kg/hr to 43 kg/hr as the solids concentration of the coating was increased from 25% to 30% w/w and spray rates increased from 50 g/min to 80 g/min. In the standard twin wheel configuration, this allows throughput rates as high as 86 kg/hour.

Conclusions

The developmental film coating was applied at solids concentrations as high as 30% w/w. The resultant coated tablets exhibited excellent appearance and color uniformity. The increased solids concentration allowed the ConsiGma Coater to achieve higher throughputs than with traditional coating materials (two to three times without optimization). Another significant advantage of this coater is that development or experimental batches conducted in this unit are effectively completed at commercial scale expediting transfer to manufacturing.

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