Examination of Coating Process Adaptability Using Opadry® QX in the GEA ConsiGma™ Coater

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Purpose

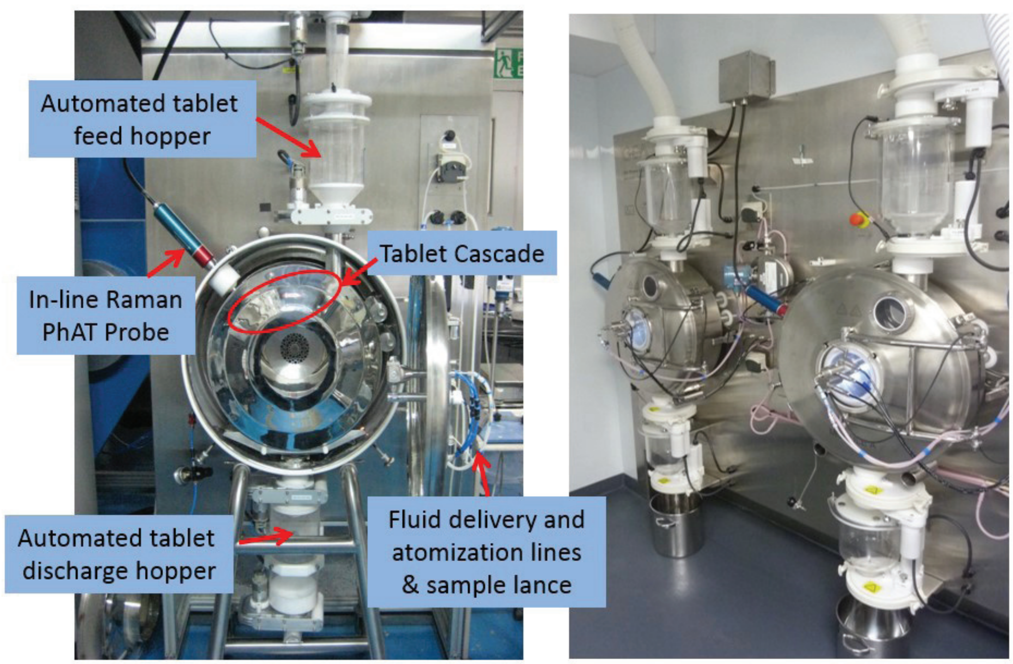
A novel tablet coating technology was developed to support a 10-100 kg/hr continuous tableting line, coating small 3-6 kg sub-lots very rapidly with a high degree of accuracy. The objective of this study was to evaluate critical process parameters (CPP) and their effect on coated tablet critical quality attributes (CQAs) using this novel low viscosity aqueous film coating system, in a semi-continuous coating machine. Additionally, a Raman Spectroscopic probe was employed to provide real-time quantifiable measurement of coating application rates.

Methods

Equipment

The GEA ConsiGma coater consists of two coating chambers operating in tandem, with each chamber 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 through a semi-continuous process. The coating chamber configurations are shown in Figure 1.

Figure 1: GEA ConsiGma Coater Configurations



In the ConsiGma Coater the tablet charge (3.0 kg), under the influence of radial air knives, is induced to form a stable cascade inside a perforated drum rotating at high speed. A conventional spray nozzle is directed upward into the cascade of "inflight" tablets, where 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.

Materials

Round shape, 250 mg, placebo tablets were used as the coating substrate (3 kg batch size). The coating formulation was Opadry® QX, quick and flexible film coating (Colorcon Inc.) which exhibits novel low viscosity (Figure 2) and enables application at higher solids concentrations (up to 35%) compared to traditional coatings.

The coating trials (19 total) were conducted in the ConsiGma coater (GEA Pharma Systems). A Design of Experiment (DOE) strategy was used to vary inlet temperature, spray rate and coating solids concentrations over a wide range as shown in Table 1.

Figure 2: Opadry QX Viscosity Profile

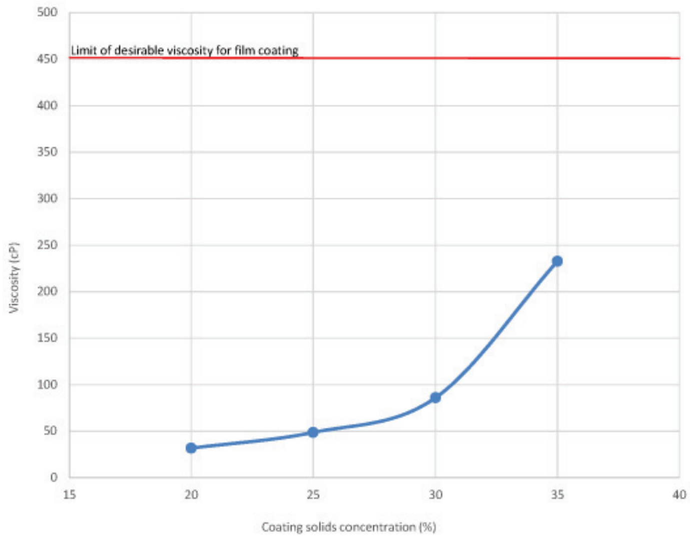
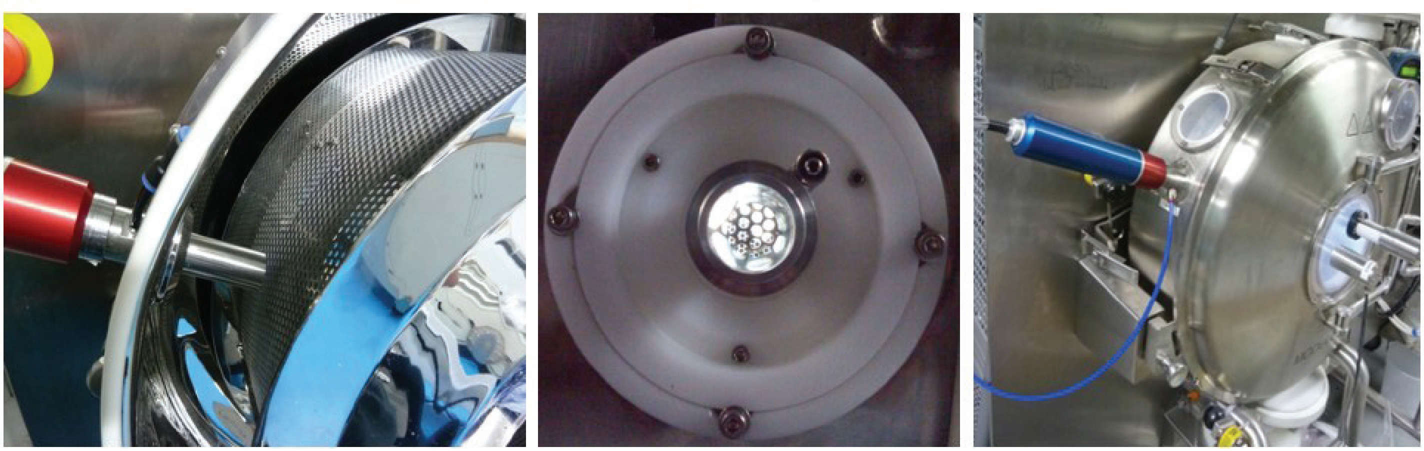


Table 1. Design of Experiment Parameters

Trial no.	Solids concentration (w/w %)	Inlet temp (°C)	Spray rate (g/min)	Total spray time (min)
1	27.5	90	60	5.5
2	27.5	75	80	4.1
3	35.0	90	80	3.2
4	20.0	60	80	5.6
5	20.0	75	60	7.5
6	35.0	60	40	6.4
7	27.5	75	40	8.2
8	27.5	60	60	5.5
9	20.0	90	80	5.6
10	27.5	75	60	5.5
11	27.5	75	60	5.5
12	27.5	75	60	5.5
13	35.0	60	80	3.2
14	20.0	90	40	11.3
15	35.0	75	60	4.3
16	35.0	90	40	6.4
17	20.0	60	40	11.3
18	30.0	75	60	5.0
19	30.0	90	80	3.8

Tablets were sampled from the process at 1%, 2% and 3% theoretical weight gain (WG) and assessed instrumentally for color development and uniformity, surface roughness, gloss and coating weight variation. A large volumetric focal volume Raman (PhAT) probe (Kaiser Optical Systems Inc.) was focused inside the coater (Figure 3) to non-destructively measure % WG during each coating cycle and then correlated to an off-line primary gravimetric method.

Figure 3. Raman PhAT Probe Placement within Coater



Coater Open with PhAT probe inserted into the Omega Coater (looking into cascade)

PhAT probe port view. Coater mesh is observed

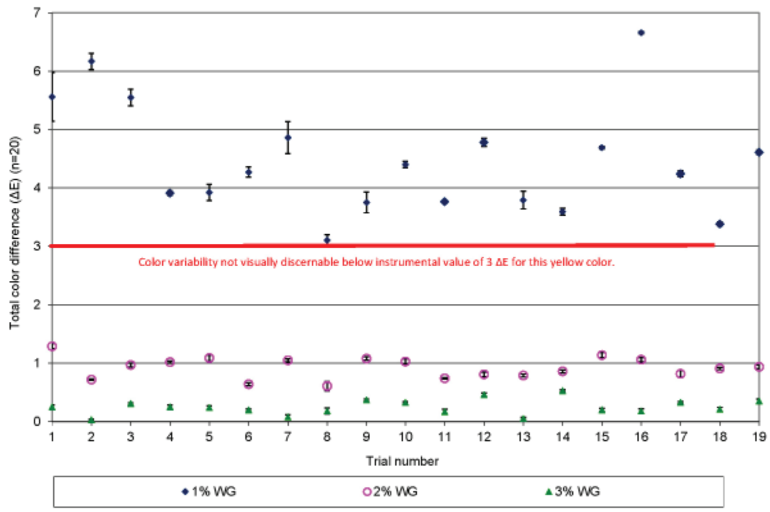
Coater Closed with PhAT probe in place looking into cascade

Results

Depending on the spray rate and wide solids concentration settings, a 3% WG of coating was applied in as little as 3 min of actual spray time, or as long as 11 min. Allowing for loading, preheating and unloading operations, total cycle times ranged from 5.5 min to 13.5 min. In the twin wheel configuration, this would equate to flexibility in production rates from 30 kg/hr to more than 70 kg/hr.

For all trials, color uniformity improved with increasing weight gain of coating, with color difference values reaching <1.5 ΔE from 2.0% WG (Figure 4). The data clearly illustrate the excellent mixing efficiency and increased exposure of tablets to the spray zone using this coating technology.

Figure 4: Color Difference from Reference Target at 1%, 2% and 3% Theoretical WG



Coatings were visually smooth and glossy, with instrumental surface roughness averaging <5.5 Sa and gloss between 70 and 85 GU, for all but the wettest conditions (trials at the lowest solids and fastest application rates), where some increase in roughness was seen (up to 7.0 Sa). Contour plots were developed over the full range of coating temperature conditions, showing the wide range of solids concentrations and spray rates resulting in acceptable surface roughness values <6.0 Sa (areas shaded blue and green in Figure 5). Coated tablet gloss values ranged from 66 GU to 84 GU across all trials and generally followed surface roughness trends.

Figure 5: Color Difference from Reference Target at 1%, 2% and 3% Theoretical WG

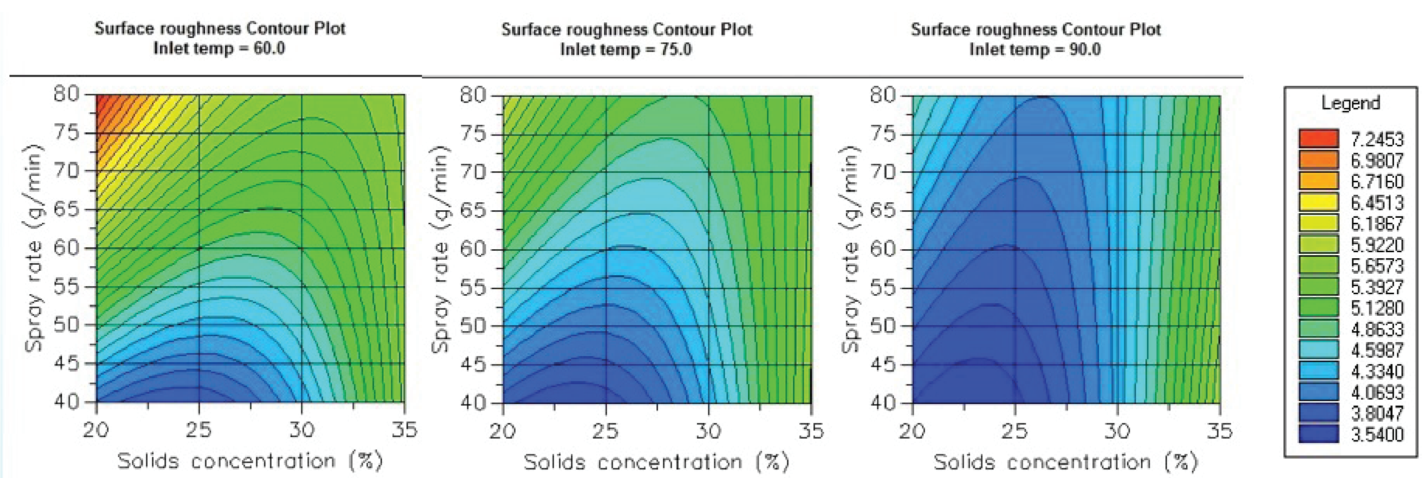


Figure 6: Example of Raw Raman Spectral Changes Over Coating Time (Single Trial)

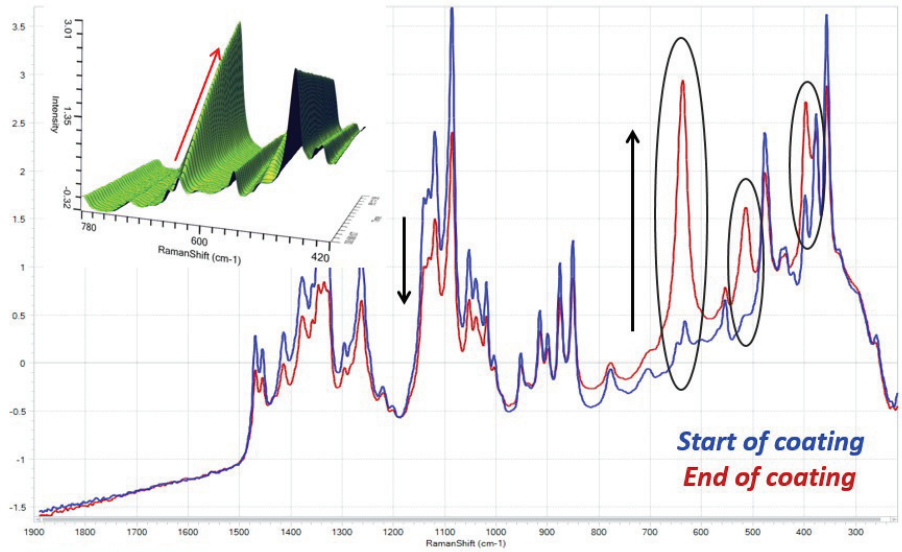
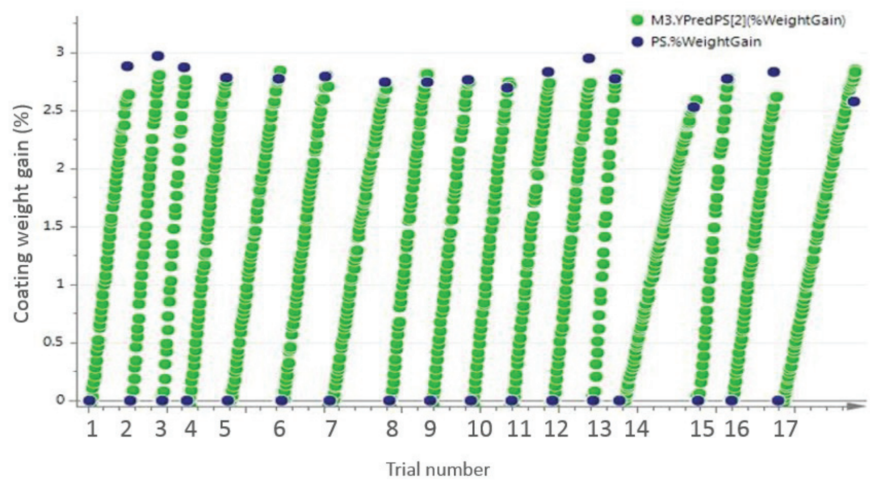


Figure 7: Raman Time Series Prediction Plot



Conclusions

Opadry QX was successfully applied in the semi-continuous ConsiGma coater. The flexibility of Opadry QX to be applied over a wide range of solids concentrations (up to 35%), along with fast attainment of coating uniformity in the ConsiGma process, allows wide adaptability to meet continuous tableting line throughput requirements. Due to the novel design of the ConsiGma process and speed of coating, the entire 19 trial DOE was completed in one day, in effect at production scale. On-line Raman spectroscopy successfully allowed for real-time monitoring of coating build rates and was used to quickly identify any process deviations.

For more information, contact your Colorcon representative or call:

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