

PTR-120

# evaluation of complementary technologies: aquarius™ genesis film coating system, an ultra-high-speed high gloss film coating system in the GEA ConsiGma\* coater

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## introduction

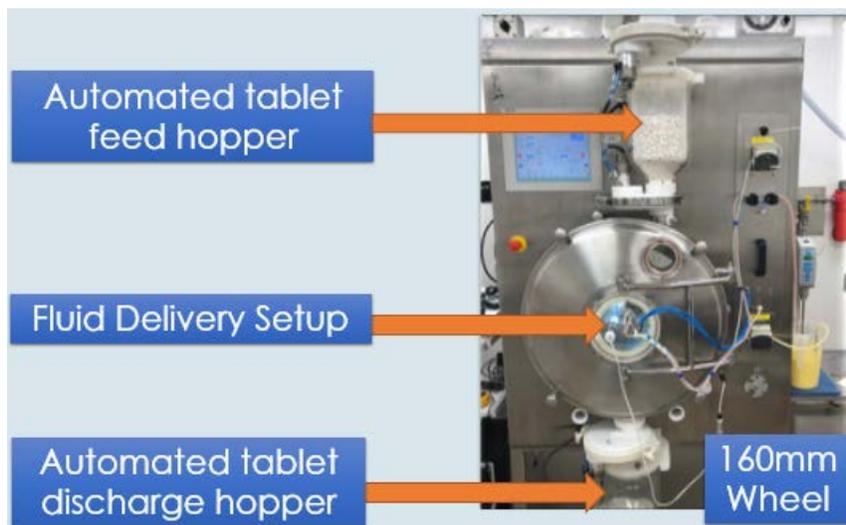
The purpose of this study was to evaluate the attainable coating speed of Aquarius™ Genesis, a high productivity, ultra-high solids coating system designed to achieve high gloss and improved aesthetics in a high speed semi-continuous ConsiGma\* coater (GEA Systems). This coating technology was developed to coat small 3–6 kg lots very rapidly with a high degree of efficiency on a continuous processing line (10–100 kg/hr).

## methods

Aqueous dispersions of the fully formulated system were prepared for rheological assessment. The coating was evaluated at varied concentrations and process parameters to determine optimum conditions that yielded the best efficiency while maintaining tablet coating quality. Round, 450 mg, placebo tablets were used as the coating substrate (3 kg batch size). The coating trials (26) were conducted in the ConsiGma coater fitted with a 160 mm wheel (**Figure 1**).

*Note:* This work was presented at the Annual Meeting of the American Association of Pharmaceutical Scientists, November 4-7, 2018, Washington, DC

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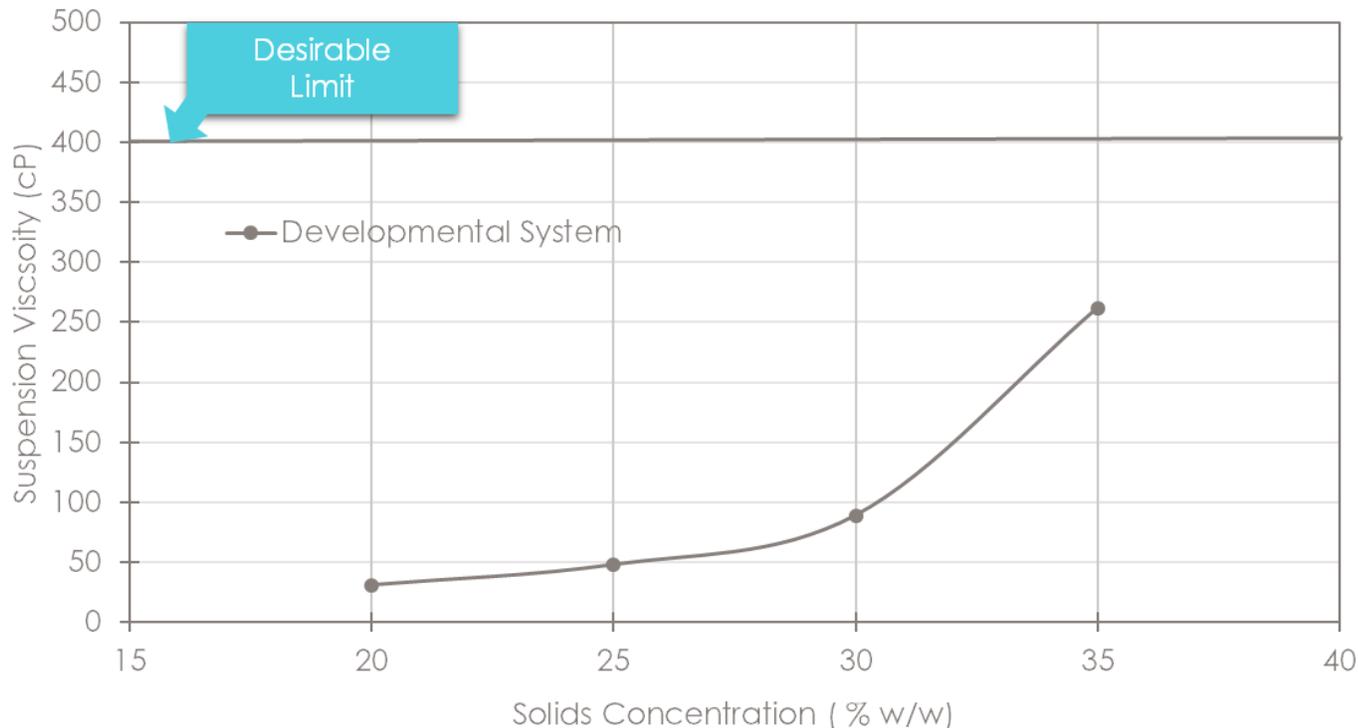


**Figure 1:** GEA ConsiGma\* coater setup

Design of experiments (DoE) methodology was used to evaluate the effect of spray rate (40–80 gm/min), inlet temperature (75–85°C) and solids concentration (25–35%) on surface roughness, gloss and color uniformity of the coated tablets. The tablets were sampled after 3% weight gain and tested for color uniformity using a reflectance spectrophotometer (DataColor\* 650), surface roughness evaluation using an optical profilometer (Nanovea\*) and tablet gloss was measured using a surface analysis system (Tricolor Systems\*).

## results

The new coating system exhibited desirable viscosity even at high solids concentrations (**Figure 2**). Depending on the spray rate and solids concentration levels, a 3% weight gain of coating was achieved in as little as 3 minutes or as long as 9 minutes (**Table 1**). In a twin wheel setup, this would equate to flexibility in production rates from 30 kg/hr to more than 70 kg/hr.



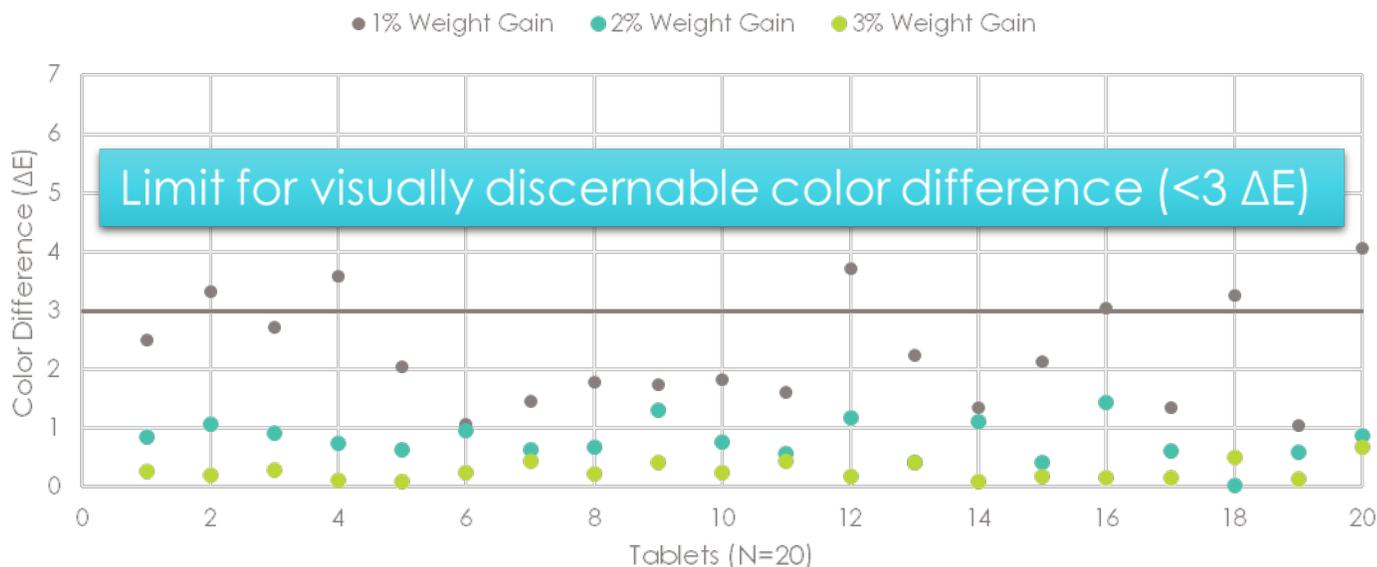
**Figure 2:** Viscosity concentration profile for the new film coating system

**Table 1:** Design of experiment parameters

Solids Conc. (% w/w)	Inlet Temperature (°C)	Spray rate (gm/min)	Run Order	Spray Time (min)
35	85	80	1	3.21
35	75	40	4	6.43
35	75	60	11	4.28
35	80	60	13	4.28
35	85	60	14	4.28
35	80	40	23	6.43
35	80	80	24	3.21
32.5	80	60	16	4.62
32.5	85	80	17	3.46
30	75	40	5	7.50
30	60	60	6	5.00
30	75	60	8	5.00
30	75	60	9	5.00
30	75	60	10	5.00
30	80	60	18	5.00
30	80	40	19	7.50
30	80	80	20	3.75
30	85	60	21	5.00
30	85	80	22	3.75
25	75	60	2	6.00
25	80	60	3	6.00

25	85	80	7	4.50
25	85	60	12	6.00
25	75	40	15	9.00
25	80	40	25	9.00
25	80	80	26	4.50

For all trial runs, color uniformity improved with increasing weight gain of coating with color uniformity reaching  $<1.2 \Delta E$  from 2.0% weight gain (**Figure 3**). These data clearly exemplify the exceptional mixing efficiency of tablets in the wheel using this coating technology.



**Figure 3:** Typical color variability on a high-speed coating run at 35% solids

High solids coatings together with short processing times typically result in coarser tablet coating finishes. The finish of the Aquarius™ Genesis film coating system, however, remains smooth and glossy (**Figure 4**).



**Figure 4:** Tablet appearance at 5X magnification when coated at A) 25% solids, B) 30% solids, C) 32.5% solids, D) 35% solids

Contour plots were developed over the full range of coating temperature conditions, showing the wide range of solids concentration and spray rates. In most cases, the Aquarius™ Genesis film coating system had low surface roughness ( $< 5 \text{ sq } \mu\text{m}$ ) and high gloss ( $> 80$  gloss units) (**Figures 5 and 6**) except under very wet or dry conditions. The Aquarius™ Genesis film coating system performed exceptionally well across a wide range of temperatures and spray rates, resulting in more than acceptable tablet aesthetics (**Figure 7**).

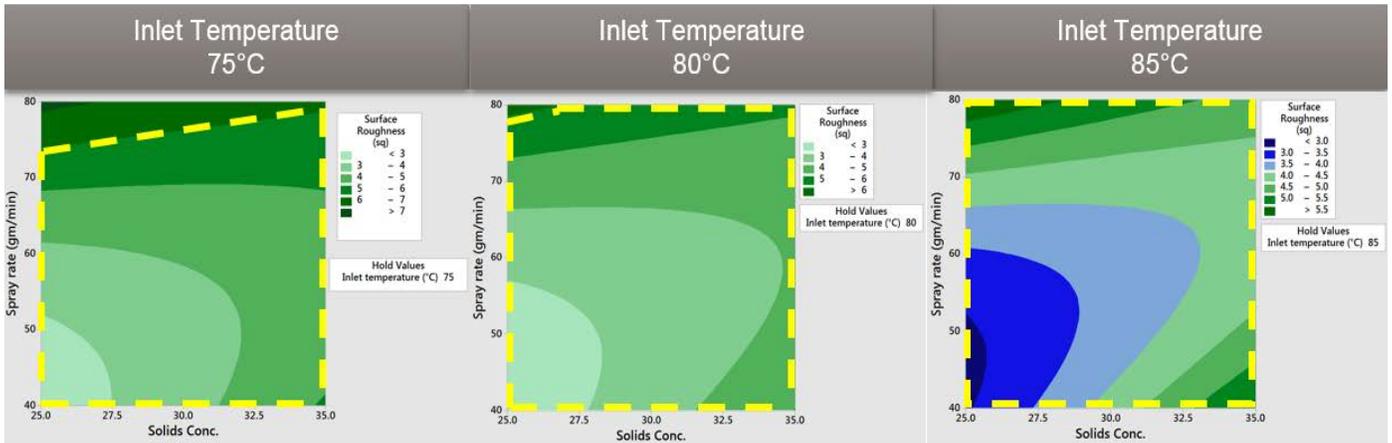


Figure 5: Effect of spray rate and solids concentration on surface roughness

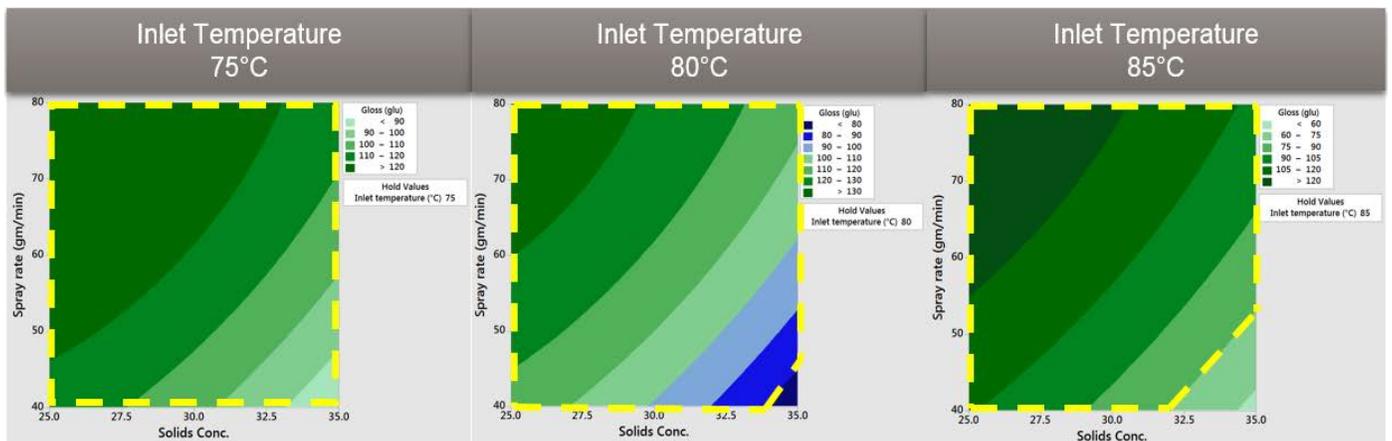


Figure 6: Effect of spray rate and solids concentration on gloss

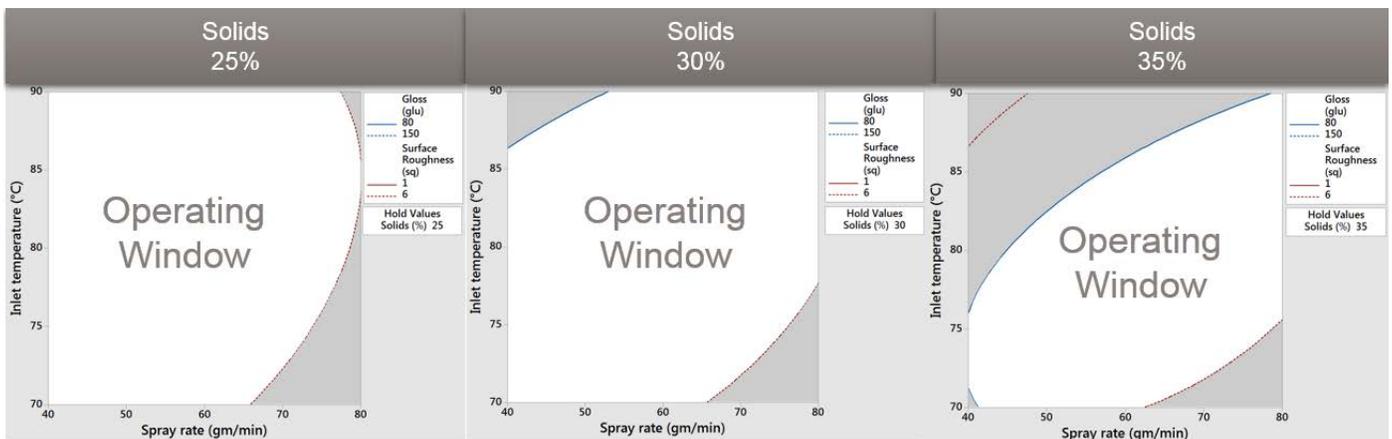


Figure 7: Optimal operating window for gloss and smoothness

## conclusions

- Overall, the appearance of the coated tablets was very impressive even when coated at high solids (35%).
- The high solid concentration of Aquarius™ Genesis film coating system, in combination with the unique design and process of the ConsiGma\* coater, enabled faster application of the material on the tablet cores.
- The entire 26 run DoE was conducted in less than two (2) days while using only 84 kg of the material. The resultant coated tablets exhibited excellent aesthetics and color uniformity.
- The increased solids concentration allowed the ConsiGma\* coater to achieve higher throughputs than with traditional coating material.