Evaluation of Developmental TiO2 Free High Productivity and High Opacity Coating System at Different Scales

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Introduction

In August 2022, titanium dioxide (TiO2) (E 171), was banned as a food additive in the European Union (EU); this means that TiO2 can no longer be used in food supplements sold in the EU. TiO2 is a widely used material in the food and pharmaceutical industry as it provides opacity, brightness, pigmentation and protects active ingredients from light degradation.[1] The EU decision has led formulators to seek alternatives to TiO2 and evaluate materials such as calcium carbonate and plant based opacifiers for use in film coatings.

High solids film coatings are preferred by many companies as they enable faster spray rates and less coating solution, resulting in a more efficient film coating.

The aim of this study was to evaluate a new high productivity, high opacity TiO2 free film coating system at different scales and determine the time savings associated with high solids.

Methods

Nutrafinish® TiO2 Free High Productivity Film Coating System, based on HPMC was applied onto speckled multivitamin cores using fully perforated side-vented coating pans from O'Hara Technologies: 15" (Labcoat I, lab scale) and 24" (Labcoat II, pilot scale), and 48" (Fastcoat, production scale). The process parameters, which are detailed in Table 1, are typical for these scales. The developmental formulas were evaluated at 15%, 20%, and 27.5% solid levels in water. In addition to visual appearance, gloss was measured with a Model 801A Tricor Systems Inc.

Table 1: Developmental Formulation Coating Parameters

Scale	15" Lab	24" Pilot	48" Production
Batch Size (kg)	3	19	130
Number of Guns	1	2	3
Spray Rate (g/min)	20	60	350 or 450
Air Volume (cfm)	160	260	2000
Atomizing Air Pressure (psi)	20	25	25
Pattern Air Pressure (psi)	20	25	25
Pan Speed (rpm)	10	10	8
Weight Gain (%)	4	4	4
Inlet Temp (°C)	60	65	56
Exhaust Temperature (°C)	43.5	43.2	44.3
Product Temp (°C)	45.1	43.0	41.0

Results

Nutrafinish TiO2 Free High Productivity Film Coating System provides high opacity, which is comparable to other high opacity Nutrafinish TiO2 Free Film Coating Systems previously presented, which is described in Figure 1.[2] The system has low viscosity (below 400 cP), even at the highest solids level of 27.5% solids, as shown in Figure 2.

Figure 1. Opacity Comparison of Nutrafinish TiO2 Free High Productivity and Nutrafinish TiO2 Free

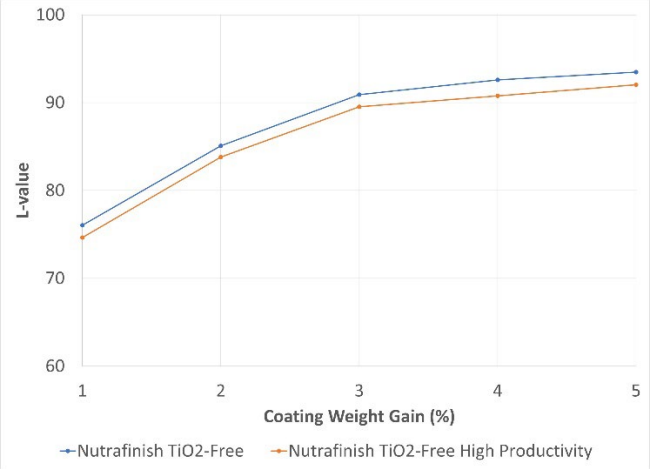
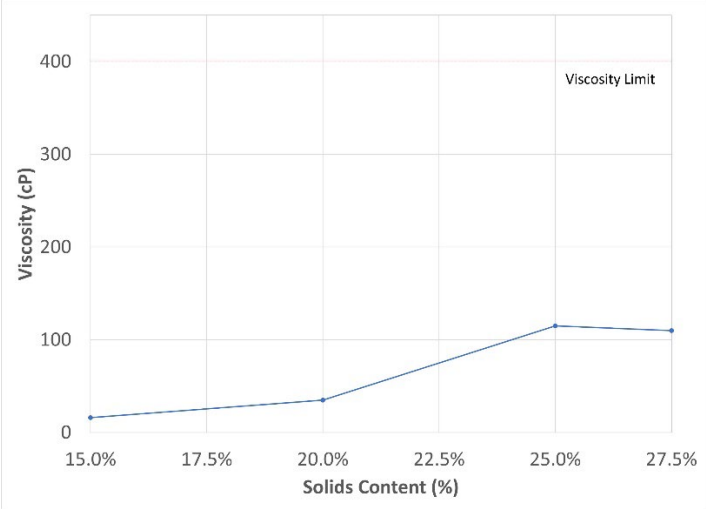


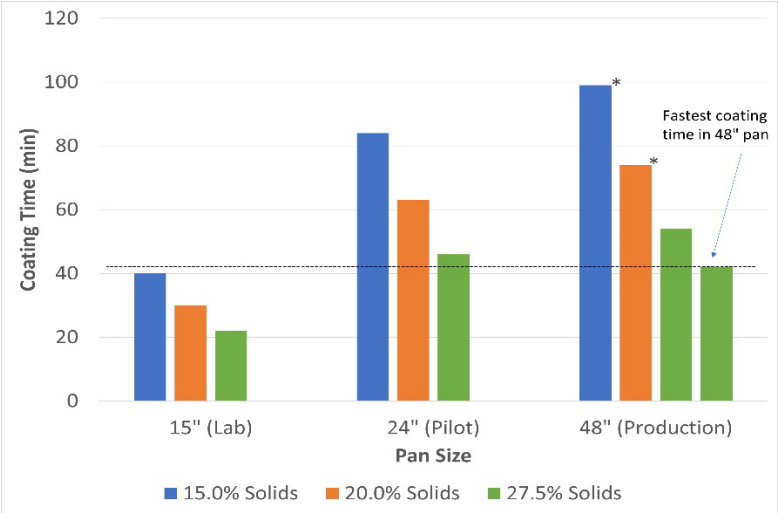
Figure 2. Viscosity of High Productivity Film Coating at 15 to 27.5% Solids



The low viscosity at high solids (27.5%) allows for coating times to be reduced by 45% in compared to 15% solids and a 27% reduction compared to 20% solids, see Figure 3.

At 27.5% solids, the production scale (48") coating trials had a shorter coating time than the pilot scale coating trials at 20% solids. By applying the coating at a higher spray rate of 450 g/min the production scale coating time was further reduced to 42 min.

Figure 3: Coating Times of Nutrafinish TiO2 Free High Productivity at Different Scales



Post coating, tumbling the tablets improved the gloss of the tablets. At 24" scale, the gloss of tablets coated at 27.5% solids increased from 58 GU to 83 GU after tumbling for 10 minutes.

Elegant tablets, with a high-quality finish (although not tumbled to improve gloss), were obtained at 3 and 4% WG for all scales, Figure 4. The speckled appearance of the uncoated cores was completely covered by the high opacity coating.

Figure 4: High Productivity/ High Opacity TiO2 Free Film Coating at 3% and 4% WG using 27.5% Solids

Conclusions

Nutrafinish TiO2 Free High Productivity Film Coating System was successfully coated using 15"(lab), 24" (pilot) and 48" (production) pans. These coatings are formulated to be dispersed at up to 27.5% solids enabling process time to decrease by 45%. To further improve the finished tablet appearance, the multivitamin tablets can be tumbled for 10 min post coating.

References

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2. Mehaffey T, Neeley C, Ghimire M, and Rajabi-Siahboomi, A. Comparison of three phases of Continuous Coater Operation during subsequent application of High Opacity Coating and High Gloss Coating onto Multivitamins. AAPS 360 (2021). M1530-03-17.