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Development and Evaluation of a Label Friendly Film Coating System Containing Naturally Derived Opacifier

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Introduction

Opacifiers are included in film coatings to provide opaqueness, help color matching, and protect active ingredients from light-induced degradation. Titanium dioxide (TiO2), classified as E171 when used as a pigment in foods, has been the preferred opacifier in the industry. However, the use of TiO2 as a food additive has been suspended in Europe, requiring companies to explore alternative materials. Mineral-based opacifiers such as calcium carbonate or magnesium carbonate have lower opacity than TiO2 and are currently being used as an alternative to TiO2. Formulators have achieved high opacity through optimization of the film coating within these mineral-containing systems[1].
Our recent studies have shown that the alkaline nature of minerals can affect the color of naturally derived pigments. In addition, they may interact with some active ingredients. The current study aimed to evaluate the opacity of a novel fully formulated Nutrafinish® Label Friendly System using natural, plant-based opacifiers.

Methods

Nutrafinish® immediate release film coatings are developed specifically for nutritional and dietary supplement products and the formulations shown in Table 1 were used in this study. Nutrafinish high opacity and label friendly formulations were optimized to deliver high levels of opacity using calcium carbonate (CaCO3) and with a natural opacifier, respectively. Their performance will be compared to a formulation containing TiO2.

Table 1. Evaluated Nutrafinish Formulations

Nutrafinish System	Main Polymer	Opacifiers
Nutrafinish TIO2	HPMC	TIO2
Nutrafinish High Opacity	HPMC	CaCO3
Nutrafinish Label Friendly	HPMC	Plant based
Experimental	HPMC	Plant based

The formulations were coated onto 3.0 kg of multivitamin tablets (1000 mg) using a fully perforated 15″ side-vented coating pan (Labcoat II, O'Hara Technologies Inc., Canada) to a 5% weight gain (WG) with samples taken at 3%, 4% and 5% WG to evaluate opacity. In addition to these systems, tablets were coated using anthocyanins in combination with either a calcium carbonate or a plant-based excipient as an opacifier.

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Table 2. Coating Parameters

Parameter	Nutrafinish TIO2/ Experimental	Nutrafinish High Opacity/Label Friendly
Batch Size (g)	3000	3000
Spray Rate (g/min)	18 - 20	18-20
Dispersion Solids Content (%w/w)	20	20
Bed Temperature (°C)	45	45
Inlet Air Temperature (°C)	58	58
Air Flow (cfm/m3/hr)	165	165
Number of Spray Guns	1	1
Pan speed (rpm)	8 - 10	8 - 10
Atomization air (psi)	20	20
Pattern air (psi)	20	20

Results

Figure 1 shows uncoated and coated multivitamin tablets at 3, 4, and 5% coating weight gain.

Nutrafinish with TiO2 showed the best opacity with uniform coverage at 3% WG (Figure 1b).

The best TiO2 free option (Nutrafinish High Opacity) uses CaCO3 as the opacifier, and uniformity can be achieved at 3% WG (Figure 1c).

When TiO2 was directly replaced with a plant-based opacifier, the opacity was significantly decreased, and the coating was unable to hide the spotting of multivitamin tablets even at 5% WG (Figure 1d).

The novel optimized Nutrafinish Label Friendly formulation using a natural opacifier shows good opacity that can be achieved at 3-4% WG, without the use of calcium carbonate (Figure 1e).

Figure 1. (a) Uncoated Multivitamin, (b) Multivitamin Tablets coated with Nutrafinish TiO2, (c) Nutrafinish High Opacity, (d) Experimental, and (e) Nutrafinish Label Friendly

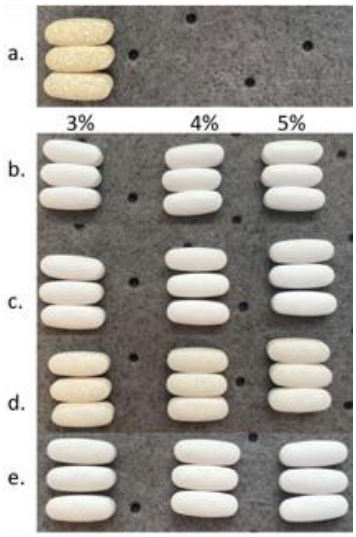

Figure 2. Multivitamins Coated with Nutrafinish Containing Anthocyanin Pigments

Nutrafinish containing calcium carbonate has a high pH of ~ 8.5 causing the film coating color to turn brown. Nutrafinish Label Friendly has a neutral, pH of ~ 7 which allows it to develop a vibrant red color.

This demonstrates the advantage associated with calcium carbonate-free opacifiers for the color development of film coating systems with natural pigments.

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Figure 3. Multivitamins Coated with Nutrafinish Label Friendly Systems Containing a Plant Based Opacifier

Conclusions

A novel Nutrafinish Label Friendly coating was developed using a naturally derived plant-based opacifier that replaced commonly used mineral components such as TiO2 or calcium carbonate.

This system was designed specifically for the nutritional and dietary supplement market to meet consumer demand for a clean-label choice.

The advantage of a naturally derived opacifier within coating systems using non-synthetic pigments such as anthocyanins was shown to result in enhanced and vivid coloring compared to mineral-based formulations.

References

1. Badger S, Ghimire, M and Rajabi-Siahboomi, A. Impact of Opacifier Type in a Film Coating Formulation on Photostability of Tablet Ingredients. AAPS 360 (2021). T1430-07-37.

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