Evaluation of Nutrafinish® Moisture Protection Coating for Dietary Supplements to prevent appearance of Dark Spots

Challenge

Moisture is a major challenge for nutraceuticals and dietary supplements because it can degrade sensitive ingredients, reduce potency, and bring undesirable physical changes. Multivitamin tablets containing iron salts are often formulated with ascorbic acid to improve the absorption of iron. However, formulations containing iron salts with ascorbic acid can form unsightly black spots (considered harmless) in the presence of moisture. As a result, effective moisture control is essential to build brand reputation, loyalty and prevent customer quality concerns. This study evaluates the performance of pigmented Nutrafinish® Moisture Barrier Coating to reduce moisture uptake, enhance physical and chemical stability and therefore, mitigate and conceal black spots appearance.

Method

Multivitamin tablets with niacinamide (table 1) were compressed using direct compression, batch size 3Kg. Half the tablet batch was coated with pigmented Nutrafinish 147A (12% solids) at 3% weight gain (w/g) and half were left uncoated. In order to provide a worst case scenario we chose to apply a 3% w/g rather than the recommended 4% w/g. Coating process thermodynamics were adjusted to achieve a dry coating environment, meaning that tablet bed temperature was ≥45°C, corresponding to an Environmental Equivalence Factor (EEF) of ≥ 4.0 (actual EEF = 5.4), which is recommended for moisture sensitive APIs. Uncoated and coated tablets were decanted into 100 cc HDPE bottles and foil sealed. Bottles were stored at 30ºC/65% RH and 40ºC/75% RH.

Table 1: Core formulation

Ingredients	%w/w	Weight (mg)
Vitamin/mineral pre-mix with niacinamide	67.93	1018.95
Microcrystalline cellulose (90M)	23.27	349.05
Starch 1500®	7.80	117.00
Colloidal silicon dioxide	0.50	7.50
Magnesium Stearate	0.50	7.50
Total	100.00	1500.00

Table 2: Coating parameters

	Parameter
Pan size	15 “
Inlet temperature	65˚C
Product temperature	45˚C
Airflow	165 cfm
Spray rate	20 g/min
Pan speed	18 rpm

Results

Coated tablet appearance and color stability was assessed during storage. Tablets did not significantly change during storage and were considered visually acceptable despite only a 3% w/g.

Color change was measured using Datacolor spectrophotometer. A Δe of > 3 is considered a visual color difference (figure 1). Coated tablets performed significantly better than uncoated tablets (figure 2).

Figure 1. Color change over time: Δe

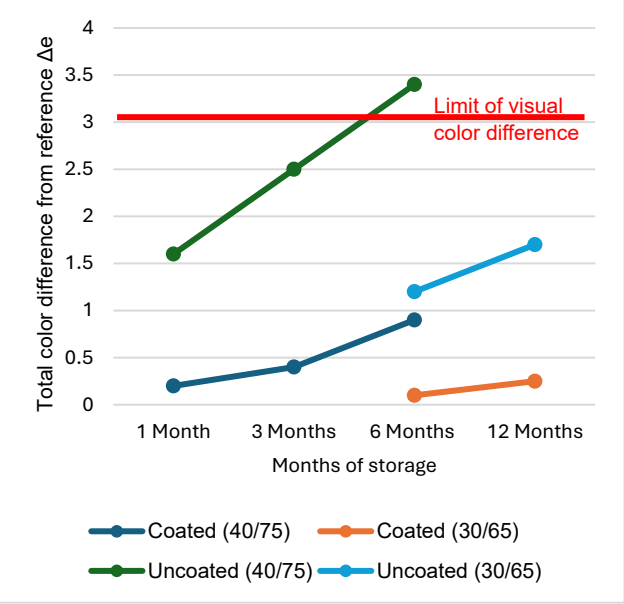
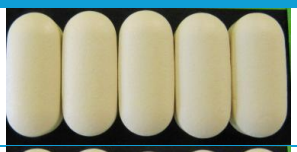


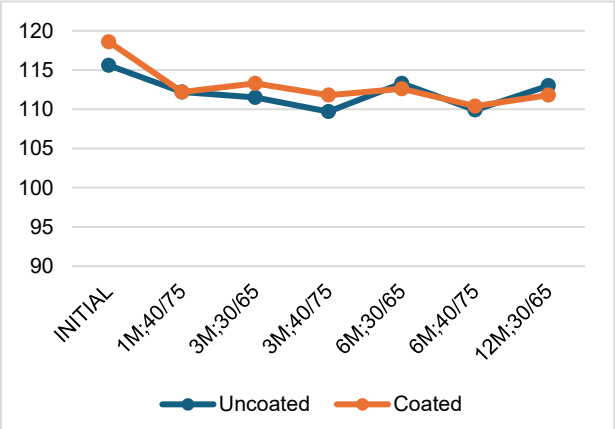
Figure 2. Color change over time: visual.

Uncoated	
Initial	
40°C / 75% RH 6 months	
30°C / 65% RH 12 months	

Coated with Nutrafinish 147A	
Initial	
40°C / 75% RH 6 months	
30°C / 65% RH 12 months	

Niacinamide is often used as a stability marker in multivitamin formulations due to its slow and measurable hydrolysis using HPLC; assay results are shown in figure 3.

Figure 3. Niacinamide assay over time



Tablet properties, including hardness, loss on drying, gloss and assay were assessed during stability and remained stable.

Dissolution testing of the uncoated and coated tablets were performed at 1-, 3- and 6-months following stage at 40ºC/75% RH. Results can be found in figures 4 and 5.

Figure 4. Dissolution - uncoated tablets

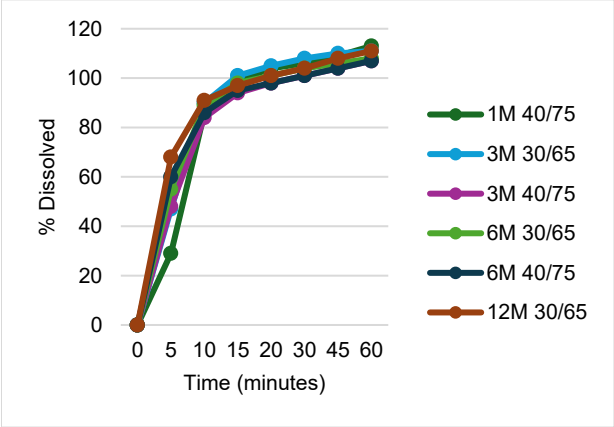


Figure 5. Dissolution - coated tablets

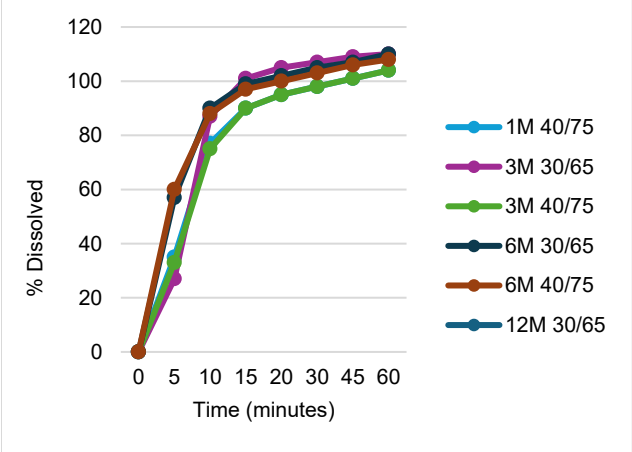


Table 3. Tablet properties after accelerated stability

	Initial	6 months (40/75)
Hardness	34 kP	30 kP
Loss on drying	2.7%	2.9%
Gloss	105 GU	107 GU
Assay	118%	110%

Conclusion

Applying a Nutrafinish Moisture Protection Coating at as low as 3% w/g significantly improved physical stability and aesthetic appearance of dietary supplements tablets by mitigating and/or concealing black spots, when compared to uncoated tablets appearance.

Niacinamide (stability marker that acts as an early warning for degradation) remained chemically stable under accelerated and long-term stability conditions, suggesting that both Nutrafinish formula and coating process parameters prevented hydrolysis, indicating excellent overall stability.

Color, dissolution and assay remained stable during storage at 30ºC/65% RH and 40ºC/75% RH. Film coating increased tablet hardness and gloss considerably and stayed consistent throughout the 6-month stability.

It's worth noting that Starch 1500 Partially Pregelatinized Maize Starch was also included in the core formulation. Starch 1500 is well known for its moisture protection characteristics and may have played a role in improving stability.

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