

Application of Film Coating Systems to Hide Dark Spots on Multivitamin Tablets

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AAPS
Poster Reprint 2022

Introduction

Multivitamin tablets containing iron salts are often formulated with ascorbic acid to improve the absorption of iron.¹ However, formulations containing iron salts with ascorbic acid can form unsightly black spots (considered harmless) in the presence of moisture. A pigmented film coating system can conceal and reduce the visual impact of these unsightly dark spots and improve consumer adherence. In this study multivitamin tablets, with and without a range of different film coatings, were stored at ambient and accelerated ICH conditions for 3- 6 months to understand the impact of the film coating system on the ability to visualize the dark spots.

Methods

1000 mg multivitamin tablets were coated with Opadry®, Opadry II 85 series, Opadry QX, Opadry amb, or Opadry amb II film coating systems to a 4% weight gain (WG) in a Labcoat I (O'Hara Technologies, Inc.). The coating process parameters used are described in Table 1. The coated tablets were stored in induction sealed 75 mL HDPE bottles for 3 months at 40°C/75% RH and up to 6 months at 30°C/65% RH. Uncoated tablets were also exposed to 40°C/75% RH open dish conditions for 24 hours to understand the maximum potential for dark spots. Following storage, tablets were examined for dark spots and color changes, and images were taken for comparative purposes.

Table 1. Opadry Coating Process Parameters

Parameter	Opadry	Opadry II	Opadry QX	Opadry amb	Opadry amb II
Coating Pan Charge (Kg)	1.0	1.0	1.0	1.0	1.0
Dispersion Solids Content (%w/w)	15	20	30	20	20
Spray Rate (g/min)	8	8	8	4	8
Bed Temperature (°C)	45	45	39	45	45
Inlet Air Temperature (°C)	69	69	55	69	64
Air Flow (cfm/m ³ /hr)	125 / 212	125 / 212	125 / 212	125 / 212	125 / 212
Number of Spray Guns	1	1	1	1	1
Spray Gun Type	VAU	VAU	VAU	VAU	VAU
Pan speed (rpm)	18	18	18	18	18
Atomization air (psi / bar)	20 / 1.4	20 / 1.4	20 / 1.4	20 / 1.4	20 / 1.4
Pattern air (psi / bar)	20 / 1.4	20 / 1.4	20 / 1.4	20 / 1.4	20 / 1.4

Tablet color was measured analytically using a DataColor600 (DataColor, Inc.) with Limit of CIE LAB total color difference (DE) defined as 1.5 for white samples.

Results

Uncoated 1000mg multivitamin tablets exposed to 40°C / 75% RH open dish conditions for 24 hours exhibited dark brown spots.

1000 mg multivitamin tablets stored in sealed HDPE bottles in both ambient (30°C / 65% RH) and accelerated (40°C / 75% RH) conditions were examined for appearance of brown spots on the surface of the tablets and color change (Figure 2).

Figure 1. Uncoated Multivitamin Tablets Before and Following Storage for 24 hours at 40°C/75% RH in Open Dish Conditions

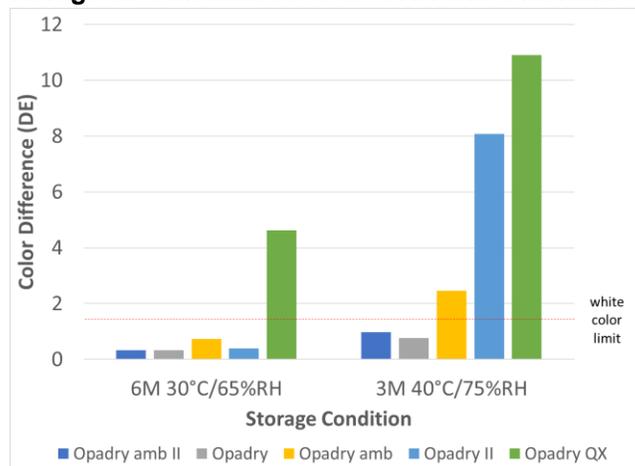


Figure 2. Color Difference (DE) for Tagged and Untagged APAP Tablets Following Storage for 6 Months at 40°C/75% RH

Initial		Opadry	Opadry amb II	Opadry amb	Opadry II 85 series	Opadry QX
	40°C/75% RH Bottles HDPE 3M					
	30°C/65% RH Bottles HDPE 6M					

Tablets coated with Opadry or Opadry amb II did not show any brown spots when stored at either condition, providing a very consistent appearance. When coated on multivitamin tablets, Opadry amb, Opadry II 85 series, and Opadry QX exhibited a change in appearance. Tablets coated with Opadry amb exhibited slight yellowing at 40C / 75% RH, while tablets coated with Opadry II 85 series and Opadry QX exhibited small but noticeable brown spots at 30°C / 65% RH and distinct brown spots at 40°C / 75% RH.

Figure 3. Color Difference (DE) for Coated Multivitamin Tablets Following Storage at 6 Months 30°C/65% RH and 3 Months 40°C/75% RH



The change in color for the stored multivitamin tablets is demonstrated by the color difference (DE). Opadry amb II and Opadry met color difference values (< 1.5 DE) at both 6M 30°C/65% RH and 3M 40°C/75% RH. In comparison, Opadry amb, Opadry II and Opadry QX resulted in a higher color difference.

Conclusions

Multivitamin tablets are prone to form unsightly brown spots when stored under accelerated conditions. A pigmented film coating system with hiding power is an effective way to reduce the visual impact of these unsightly dark spots. However, not all coatings provide the same level of hiding power to cover color changes in the core.

By selecting the right coating solution for a particular active unsightly visual defect can be avoided, and a consistent color and appearance can be ensured. For this application Opadry and the higher productivity Opadry amb II, film coating systems gave the best results and would be the recommended solutions.

References

1. Teucher B, Olivares M, Cori H. Enhancers of Iron Absorption: Ascorbic Acid and other Organic Acids. International Journal Name of Vitamin Nutrition Research. 2004;74(6): 403-419.

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