Evaluation of a Film Coating that Produces Enhanced Tablet-to-Tablet Film Uniformity

OBJECTIVE

To determine if the time to achieve color and weight uniformity of an applied film coating is dependent on the film formulation type. Two different film coating systems, Opadry®, complete film coating system, and Opadry® II, high performance film coating system (85 Series), were evaluated for weight gain uniformity and color uniformity.

INTRODUCTION

For film coating processes, the advantage of reduced processing times must be balanced against the uniformity requirements for the finished product. Reduced processing times can eliminate defects such as edge chipping and erosion by decreasing the overall mechanical stress experienced by the tablets. Ultimately, reduced processing times can improve productivity in manufacturing.

Alternately, a film coating process must produce tablets that are visually uniform. Uniformity can also effect the functional characteristics of a film coating such as protection of the core from environmental moisture or oxygen. In the case of tablets that contain an active pharmaceutical ingredient in the film coating, a very high degree of uniformity must be achieved to ensure accurate patient dosing.

MATERIALS

Tablet Formulation: Uncoated 500 mg acetaminophen caplet cores were purchased from a generic pharmaceutical manufacturer. These tablets were compressed from acetaminophen DC90 granules.

Coating Equipment: Thomas Engineering Compu-Lab™ 24” fully perforated coating pan.

Coating Weight Gain Uniformity

Coating Materials: Opadry clear YS-1-19025-A and Opadry II clear 85F19250.

METHODS

Individually numbered caplets were used to track coating weight gain. The caplets were base coated to a 1.5% weight gain then hand numbered using an indelible ink felt tip pen. Numbered caplets were dried for 24 hours in an electric oven set to 60°C then brought back to room temperature in a vacuum desiccator. The caplets were individually weighed on a Mettler® AG204 analytical balance to a precision of 0.0001 g and the weights were recorded.

Coating trials were performed using caplets with base-coats possessing the same composition as the top-coats. Enough numbered caplets were added to each batch to ensure that a 50-caplet sample could be retrieved for each sampling point. Samples were taken at 1, 2, 3 and 4% coating weight gains. All samples were dried for 24 hours in an electric oven set to 60°C then brought back to room temperature in a vacuum desiccator prior to being weighed to determine individual tablet weight gains. The relative standard deviation of the tablet weight gains was determined for each sampling point. The following coating conditions were used for all of the coating trials. Base-coats were applied under the same conditions as top-coats.

Table 1. Coating Weight Gain Processing Condions

Equipment	24" Compu-Lab
Spray Guns	Spraying Systems, VAU
Pan Loading	16 kg
Coating Pan Rotation Speed	14 rpm
Drying Air Temperature	65ºC
Drying Air Volume	396 cfm
Number of Spray Guns	2 guns
Atomization & Pattern Pressure	30 psi
Fluid Delivery Rate	50g/min
Coating Fluid % Solids	7.5% w/w (water)

COATING COLOR UNIFORMITY

Coating Materials: Opadry blue YS-1-4249 and Opadry II blue 85F90618 color-matched coating systems.
Methods: The solids content of a film coating suspension is limited by its viscosity. A standard hypromellose film coating system, such as Opadry, blue would be sprayed at a maximum of 15% w/w suspension in water. Opadry II blue is a low viscosity, high productivity film coating system and will typically be used at a 20% w/w suspension. For color evaluation, solids concentrations were chosen to be most representative of a production setting. All other processing parameters were identical for the two coating systems. Samples were taken at 1, 2, 3 and 4% coating weight gains. The following coating conditions were used.

Table 2. Color Uniformity Processing Conditions

Equipment	24" Compu-Lab
Spray Guns	Spraying Systems, VAU
Pan Loading	16 kg
Coating Pan Rotation Speed	12 rpm
Drying Air Temperature	80ºC
Drying Air Volume	300 cfm
Number of Spray Guns	2 guns
Atomization & Pattern Pressure	35 psi
Fluid Delivery Rate	60g/min
Coating Fluid % Solids	15% w/w & 20% w/w

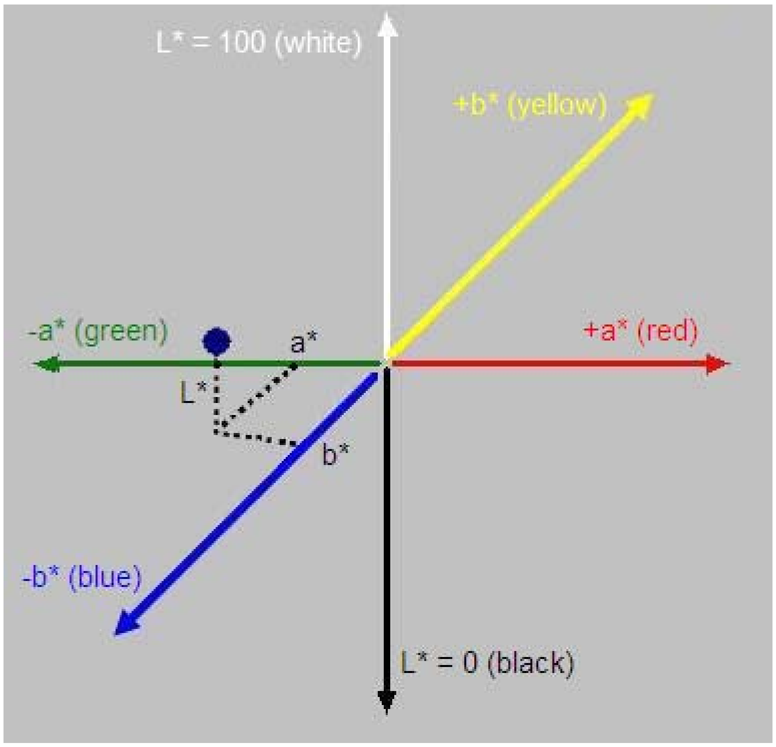
Color Testing: Tablet color was tested using a Diano Color Products Milton Roy Colormate. The data was analyzed using the Commission Internationale de l'Eclairage (CIE) L* a* b* System. In the L* a* b* System, color is represented as a coordinate in a three dimensional space. Lightness and darkness are plotted on the L* axis with L=100 representing pure white and L= 0 representing pure black. The a* and b* axes represent the two complementary color pairs of red / green and blue / yellow respectively. By plotting colors geometrically the difference between two colors (total color difference = ΔE^*) can be determined by calculating the distance between two points using the following equation.

$$\Delta E^* = [(L^*_1 - L^*_2)^2 + (a^*_1 - a^*_2)^2 + (b^*_1 - b^*_2)^2]^{1/2}$$

Using the Colormate, 50 caplets were analyzed for each sample. The Colormate software automatically calculated the standard deviation for each color component (σ_L*, σ_a* & σ_b*). The total color standard deviation (σ_E*) was computed using the following equation:

$$\sigma_{E^*} = (\sigma_{L^*}^{\ 2} + \sigma_{a^*}^{\ 2} + \sigma_{b^*}^{\ 2})^{1/2}$$

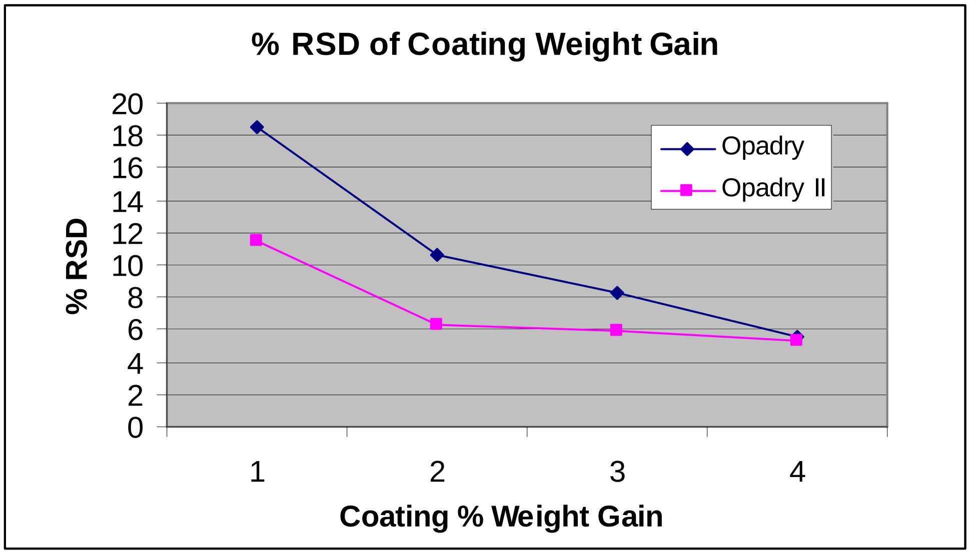
Figure 1. Representation of a Color Using the CIE L* a* b* System



RESULTS

Coating Weight Gain Uniformity

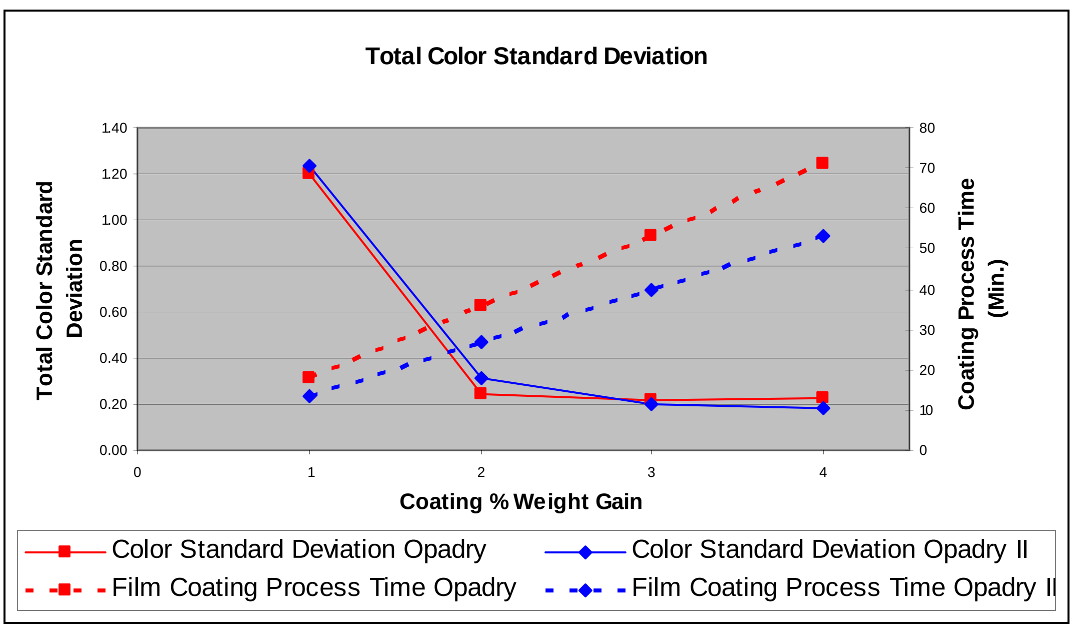
Figure 2. % RSD of Coating Weight Gain



Film Coating Weight % RSD n=50		
% Weight Gain	Opadry	Opadry II
1	18.50	11.40
2	11.33	7.26
3	8.37	5.84
4	5.25	5.12

Coating Color Uniformity

Figure 3. Total Color Standard Deviation



Coating % Weight Gain	Color Standard Deviation		Film Coating Process Time	
	Opadry	Opadry II	Opadry	Opadry II
1	1.20	1.23	18 min.	13 min.
2	0.24	0.31	36 min.	27 min.
3	0.22	0.20	53 min.	40 min.
4	0.23	0.18	71 min.	53 min.

DISCUSSION

Clear film coatings are often applied as a top-coat over a colored or white film coating to aid in packaging efficiency, print clarity and to provide an extra layer of protection to the core. For these types of applications, it is desirable to achieve good tablet-to-tablet uniformity with minimal impact on the overall film coating process time. Under identical processing conditions, Opadry II (85 Series) clear, produced film coating weight gains with a higher degree of tablet-to-tablet uniformity than Opadry clear.

Cosmetic color coatings are typically applied at 3 – 4 % weight gains, depending on core size and color, in order to achieve adequate opacity of the film coating. The solids content of the coating suspension is maximized in order to achieve shorter processing times. Under identical processing conditions but higher solids contents, Opadry II (85 Series) blue showed similar tablet-to-tablet color uniformity to Opadry blue. Samples taken for 1 - 2% weight gains had total color standard deviations slightly higher, whereas 3 - 4% weight gains samples had standard deviations slightly lower for the Opadry II (85 Series) blue samples. Opadry II (85 Series) blue had the additional advantage of decreased processing times. Opadry blue was reconstituted to 15% w/w solids and required 71 minutes for the application of a 4% weight gain. Opadry II (85 Series) blue was reconstituted to 20% w/w solids and only required 53 minutes for the application of a 4% weight gain. By using Opadry II (85 Series) blue, a low viscosity, high productivity film coating, processing times were reduced by 1/3 over a standard hypromellose film coating. Moreover, this time savings were achieved without a reduction in tablet-to-tablet color uniformity.

CONCLUSIONS

Opadry II (85 Series) clear was shown to have lower coating weight gain standard deviations than a standard clear hypromellose-based film coating under identical processing conditions. Opadry II (85 Series) blue was shown to achieve similar or better coating color uniformity than a standard hypromellose film coating with a 1/3 savings in processing time.

Reprint of poster presented at AAPS – Nov 2005. Author: Adam Kevra.

REFERENCES

1. Chrisment, Alain, Color & Colorimetry, Datacolor International

For more information, contact your Colorcon representative or call:

North America	Europe/Middle East/Africa	Asia Pacific	Latin America
+1-215-699-7733	**+44-(0)-1322-293000**	**+65-6438-0318**	**+54-11-4552-1565**

You can also visit our website at **www.colorcon.com**

ads_opadry_II_eval_tablet_to_tablet_v3_05_2009