# Influence of tablet shape on the color of film-coated tablets using two different polyethylene glycol-polyvinyl alcohol graft copolymer based coating system color combinations

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### Objective

Film coating solid-dose pharmaceutical products with instant-release color coatings can make it easier for patients to identify specific medications and therefore improve compliance. Ensuring that the color of a film-coated tablet is consistent from tablet-to-tablet is important in this regard. Developing your own film-coating color is one way to eliminate color variation. Kollicoat® IR Coating Systems, formulated with polyethylene glycol-polyvinyl alcohol graft copolymer (Kollicoat IR, BASE SE, Germany) were developed as an innovative alternative to formulating custom colors. Using seven base global pharmaceutical color formulations alone or in combination, an almost limitless color palette can be developed. Figure 1 below provides an overview of just a few of the color options available. The purpose of this study is to determine the impact tablet shape has on the final color of film-coated tablets when using color combinations of a polyethylene glycol-polyvinyl alcohol graft copolymer based coating system.



Figure 1. Color Combination Examples

## Methodology

#### **Materials**

Oval, round and caplet-shaped placebo tablets were used in this study. The placebo tablets were formulated using LudiPress® LCE (BASF SE, Germany) 79.25%, Kollidon® VA64 (BASF SE, Germany) 20% and magnesium stearate (JT Baker, US) 0.75%. Kollicoat IR Red, Kollicoat IR Carmine and Kollicoat IR White II (BASF SE, Germany), based on polyethylene glycol-polyvinyl alcohol graft copolymer, were used in combination for coating¹.

#### **Coating and Color Measurement**

Coating trials were performed using an Accela-Cota® Compu-Lab (Thomas Engineering, USA) with a 19" pan insert and a 3 kg tablet charge. Tablets were all coated using the conditions as listed in Figure 2 below. Each tablet shape was coated to a 3% actual weight gain for a total of six separate coating trials. Twenty percent solids content was used for each coating suspension combination evaluated. The first coating suspension was a combination of 20% Kollicoat IR Red and 80% Kollicoat IR White II. The second color combination evaluated was prepared with 20% Kollicoat IR Carmine and 80% Kollicoat IR White II.

Parameters	
Fluid Delivery Rate (g/min)	20
Pan Speed (rpm)	15
Inlet Air Volume (cfm)	200-210
Inlet Temp (°C)	60-65
Exhaust Temp (°C)	43-46
Bed Temp (°C)	40-43
Atom. Air Pressure (psi)	45
Actual Weight Gain (%)	3%

#### Figure 2. 19" Accela-Cota Parameters

Using the CIE L\*a\*b\* Color Scale², L\*a\*b\* color values for each set of coated tablets were generated using the Hunter Lab UltraScan XE Colorimeter (HunterLab, USA). Twenty randomly chosen tablets of each coated tablet shape were measured and an average color value determined for each shape. The round coated tablet for each color was used as the standard for measuring color difference (dE\* values) between shapes.

#### Results

Based on the average color difference values generated within and between shapes, no significant color difference was detected between tablets of different shapes (oval, round and caplet-shaped) when coated using the same combination of Kollicoat IR Coating Systems colors and using the same coating parameters. Standard deviation values for measurements within each tablet shape are all low. It is important that the colorimeter aperture opening be appropriately sized to accurately measure comparable surfaces of differently shaped tablets.

# Coating Combination One: 20% Kollicoat IR Red + 80% IR White White II

All coated tablet shapes exhibited dE\* values from standard below 2.5. No visual color differences could be determined between the different tablet shapes coated with the combination of 20% Kollicoat IR Red and 80% Kollicoat IR White II. Table 1 below shows the average data of the L\*a\*b\* and dE\* values between the different tablet shapes. From this, it is evident that tablet shape does not have an impact on the color of the final coated tablet. Twenty round tablets were measured to determine a standard value. This standard value was then used for comparison between shapes. Twenty tablets were measured to obtain average values for each shape. HunterLab's Average Function was used to determine average values.

Between Shapes	L* D65/10	a* D65/10	b* D65/10	dE* D65/10
Standard	63.86	27.80	16.85	_
Ave. Round	63.86	27.80	16.85	0.51
Ave. Caplet	63.61	26.57	16.12	1.55
Ave. Oval	62.81	27.46	17.23	1.37

Table 1. Color Difference Measurements between Tablet Shapes: IR Red (20%) = IR White II (80%)

Table 2 below reviews the Color Difference Measurements within each tablet shape. Standard deviation values for L\*, a\* and b\* average measurements show that color differences between tablet measurements within each shape are not significant.

Within Shape	L* (Ave.)	L* (Std.)	a* (Ave.)	a*(Std.)	b* (Ave.)	b* (Std.)
Ave. Round	63.860	0.21	27.80	0.46	16.85	0.28
Ave. Caplet	63.612	0.49	26.57	0.50	16.12	0.41
Ave. Oval	62.805	0.54	27.46	0.42	17.23	0.45

Table 2. Color Difference Measurements within Tablet Shapes: IR Red (20%) + IR White II (80%)

The tablets displayed in Figure 3 below show that no visible color difference can be detected between the three tablet shapes coated with 20% Kollicoat IR Red + 80% Kollicoat IR White II using the same general coating parameters and to the same actual weight gain of 3%.



Figure 3. Kollicoat IR Red 20% + Kollicoat IR White II 80%

# Coating Combination Two: 20% Kollicoat IR Carmine + 80% Kollicoat IR White II

The same method used to measure color values in Color Combination One above was used for Color Combination Two. All coated tablet shapes exhibited dE\* values from standard below 2.5. Care was taken to ensure that the entire tablet covered the aperture opening to avoid false values by inclusion of stray light. No visible color differences were noted within and between tablet shapes.

Table 3 and Table 4 were generated using the same method as Table 1 and 2 above. The data exhibits no significant difference in color between tablet shapes coated with the combination of Kollicoat IR Carmine 20% + Kollicoat IR White II (80%) to the same 3% weight gain. Also, color difference measurements for tablets within each tablet shape reveal no significant color differences as evidenced by low standard deviation results.

Between Shapes	L* D65/10	a* D65/10	b* D65/10	dE* D65/10
Standard	65.74	36.17	-2.99	_
Ave. Round	65.74	36.17	-2.99	0.58
Ave. Caplet	65.47	34.93	-3.57	1.39
Ave. Oval	65.59	35.61	-3.39	0.70

Table 3. Color Difference Measurements between Tablet Shapes: IR Carmine (20%) + IR White II (80%)

Within Shape	L* (Ave.)	L* (Std.)	a* (Ave.)	a*(Std.)	b* (Ave.)	b* (Std.)
Ave. Round	65.74	0.36	36.17	0.48	-2.99	0.30
Ave. Caplet	65.47	0.46	34.93	0.28	-3.57	0.28
Ave. Oval	65.59	0.90	35.61	0.62	-3.39	0.42

Table 4. Color Difference Measurements within Tablet Shapes: IR Carmine (20%) + IR White II (80%)

The picture in Figure 4 below shows that no visible color difference can be detected between the three tablet shapes coated with 20% Kollicoat IR Carmine + 80% Kollicoat IR White II using the same general coating parameters and to the same actual weight gain of 3%.

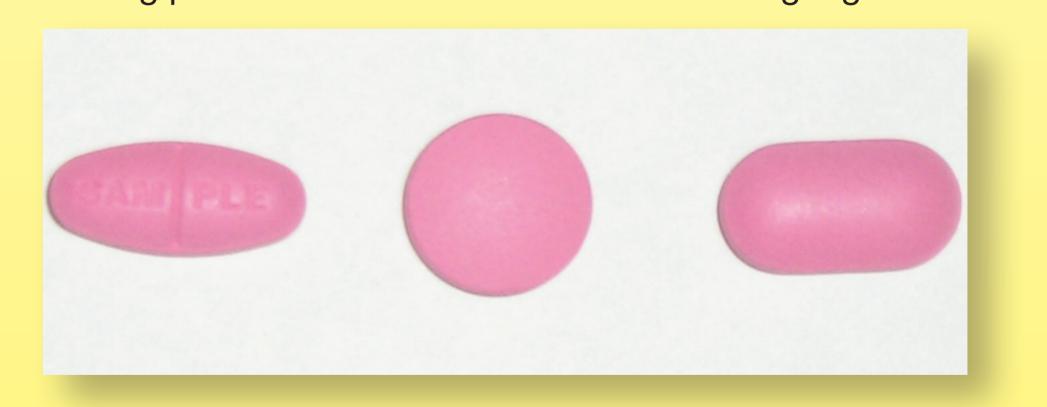


Figure 4. Kollicoat IR Carmine 20% + Kollicoat IR White II 80%

## Conclusion

Kollicoat IR Coating Systems combinations can be used successfully to coat different tablet shapes without measureable color differences. No visible color differences will be seen when coating different tablet shapes with the same Kollicoat IR Coating Systems combinations.

#### References

- 1. A.Maschke, T. Schmeller and K. Kolter, Influence of Coating Parameters on Instant Release Coated Colored Tablets, 2009
- 2. HunterLab, Identification of Measurement Parameters for Effective Color, 2010