Influence of Film Coating Process Parameters on the Gloss of Tablets Coated with Pigmented Aqueous Film Coating Formulations

PURPOSE

A common practice for enhancing the gloss of coated tablets is the application of a clear top-coat after applying a pigmented coating layer. In a recent study, substantial increases in tablet gloss were achieved using this multiple step approach.[1] It was also found that decreasing the solids concentration of the clear top-coat resulted in further improvements in gloss. In some cases it may be impractical or undesirable to utilize a two-step coating process. The purpose of this study was to examine the effects of coating process parameters and dispersion solids concentration on the gloss of tablets coated with single-step, pigmented, aqueous film coating formulations. The coating formulations and processes were evaluated on two different tablet dosage forms.

METHODS

The two substrates used in the study were multivitamin tablets (1000 mg) and placebo tablets (300 mg). The coating systems were Opadry® II, high performance film coating systems, (PVA-based - orange and yellow, Colorcon, Inc.). The trials (47 in total) were conducted in a 24" fully perforated pan (Labcoat II, O'Hara Technologies) equipped with two spray guns (VAU, Spraying Systems Inc.) to a target coating weight gain of 3.0%. A Design of Experiments (DOE) approach was used to evaluate the process variables of inlet temperature, airflow, spray rate, pan speed, and dispersion solids concentration (Table 1).

Table 1. Coating Process Variables, Ranges and Constants, Used in the Design of Experiments

Process Variables	**Multivitamin Tablets**	**Placebo Tablets**
	Ranges studied	
Inlet Temperature (°C)	60 - 90	not included
Airflow (cfm) / (m^3/hr)	150 - 350 / 255 - 595	not included
Spray rate (g/min.)	35 - 75	30.0 - 70.0
Solids concentration (%)	15 - 25	15.0 - 30.0
Pan speed (rpm)	not included	8.0 - 14.0
Process Constants	**Multivitamin Tablets**	**Placebo Tablets**
Airflow (cfm) / (m^3/hr)	Variable	265 / 450
Pan speed (rpm)	14.0	Variable
Pan load (kg)	20.0	14.0
Target weight gain (%)	3.0	3.0
Tablet bed temperature (°C)	Variable based on inlet temperature	44.0 (Via inlet temp. control)

Tablet samples were tested for gloss using a Model 805ASurface Analysis System (Tricor Inc.). For this measurement,a field of coated tablets was arranged on a level surface in an enclosed instrument cabinet. The sample was illuminated with diffuse light. The quantity of light reflected from the surface of tablets was measured by a photo detector and reported in gloss units (GU). Most of the light reflected from a surface is diffuse and scattered. Gloss is the specular (direct) light reflected at a specific angle (60°).

The samples were also tested for surface roughness via optical scanning profilometry (ST400 3D profilometer,Nanovea).For all trials, the tablets were sampled immediately upon completion of the coating runs for gloss and surface roughness testing.

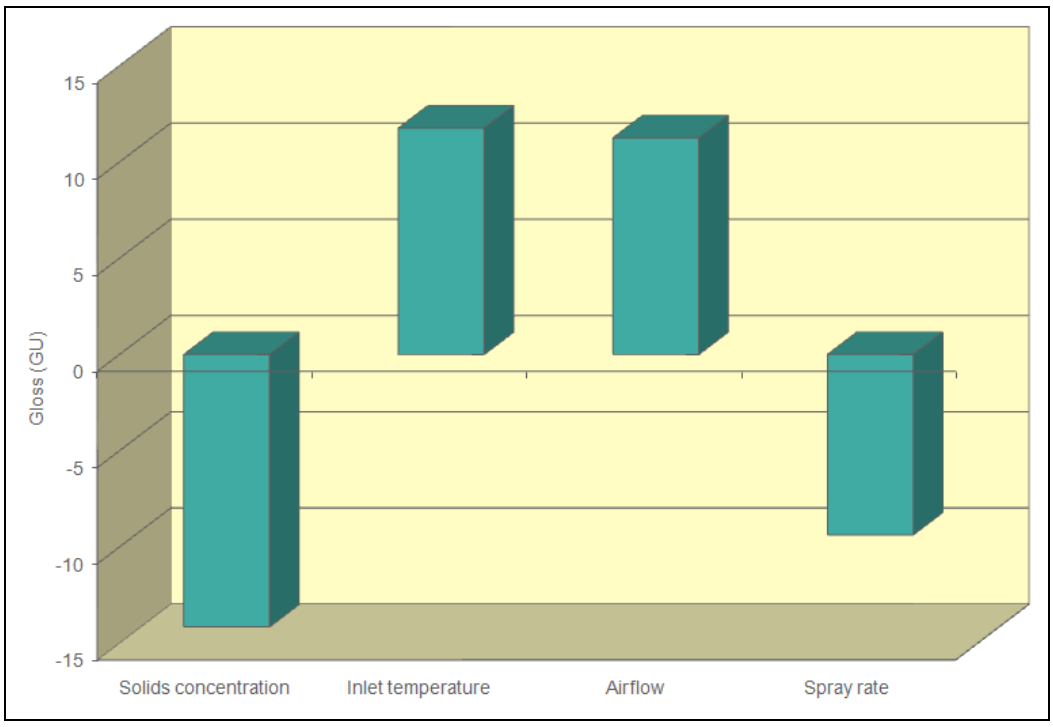
A separate trial was conducted to investigate a polishing step at the completion of the coating runs. For this trial, the tablets were sampled immediately after coating, but then allowed to tumble continuously for an additional 15 minutes at a reduced pan speed (5 rpm) as the tablets cooled in the pan. Samples were taken for gloss measurements after 5,10 and 15 minutes of post-process tumbling.

RESULTS

Multivitamin Tablets - Gloss

For the multivitamin tablets, over the range of trials, gloss values from 57 to 116 GU were achieved. Data analysis indicated that the variable with the most significant effect on gloss was the solids concentration of the coating dispersion. Tablet gloss increased with decreasing dispersion solids concentration, and increasing inlet temperature, airflow and pan speed. Increasing spray rates also decreased gloss (Figure 1).

Figure 1. Variable Effect Ranking for Gloss – Multivitamin Tablets



The increase of inlet air temperature and resultant higher bed temperatures, together with increasing process airflow, had very positive effects on gloss levels. The data suggest that gloss values will decrease in conditions where there is insufficient energy to promptly dry the tablets. The trials conducted at low airflow and inlet temperatures resulted in over-wet conditions and tablets with very rough surfaces. Although increasing the dispersion solids concentration decreased gloss, high gloss could still be obtained at higher inlet temperatures and airflow. (Figures 2 and 3).

Figure 2. Effect of Inlet Temperature and Airflow on Gloss at 15% Solids Concentration

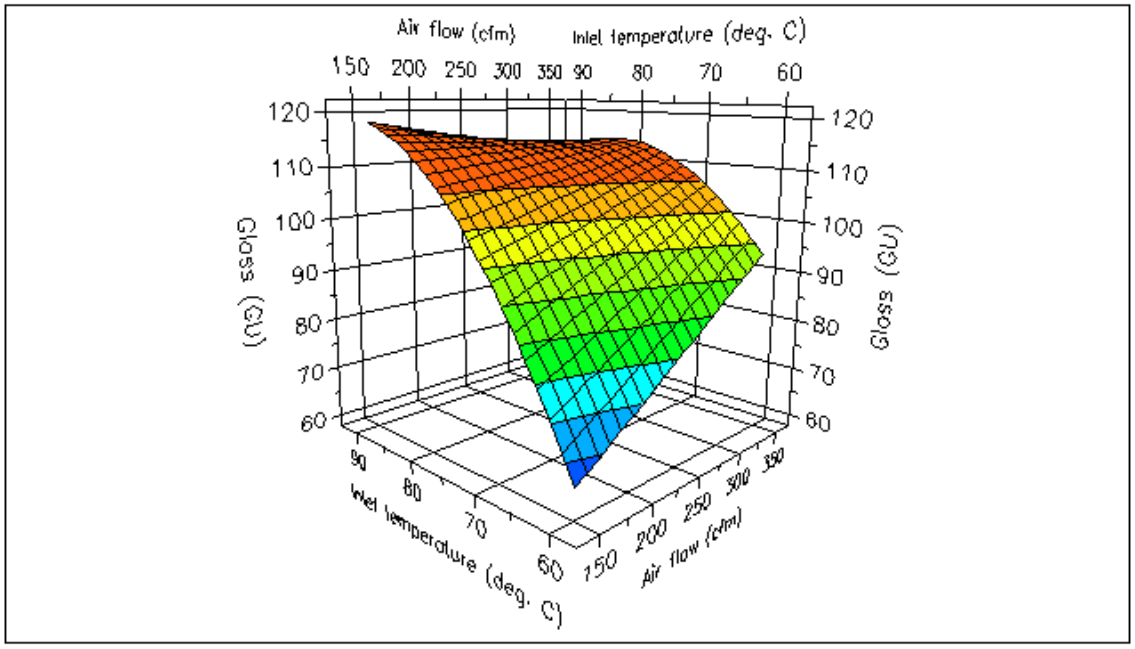
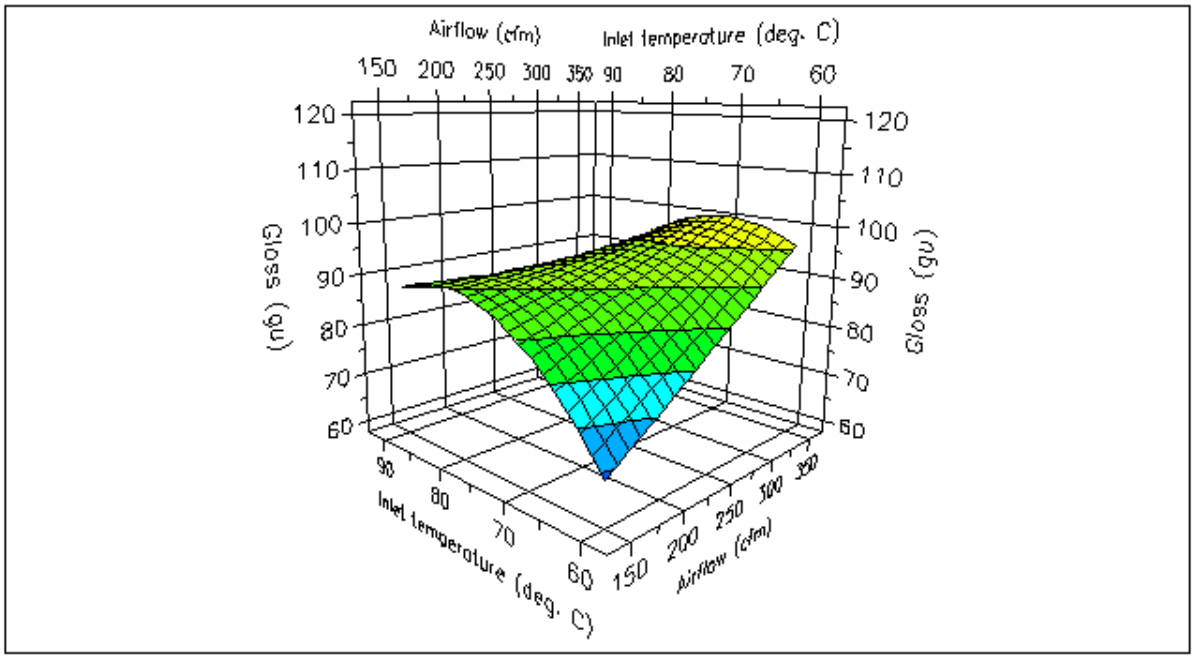
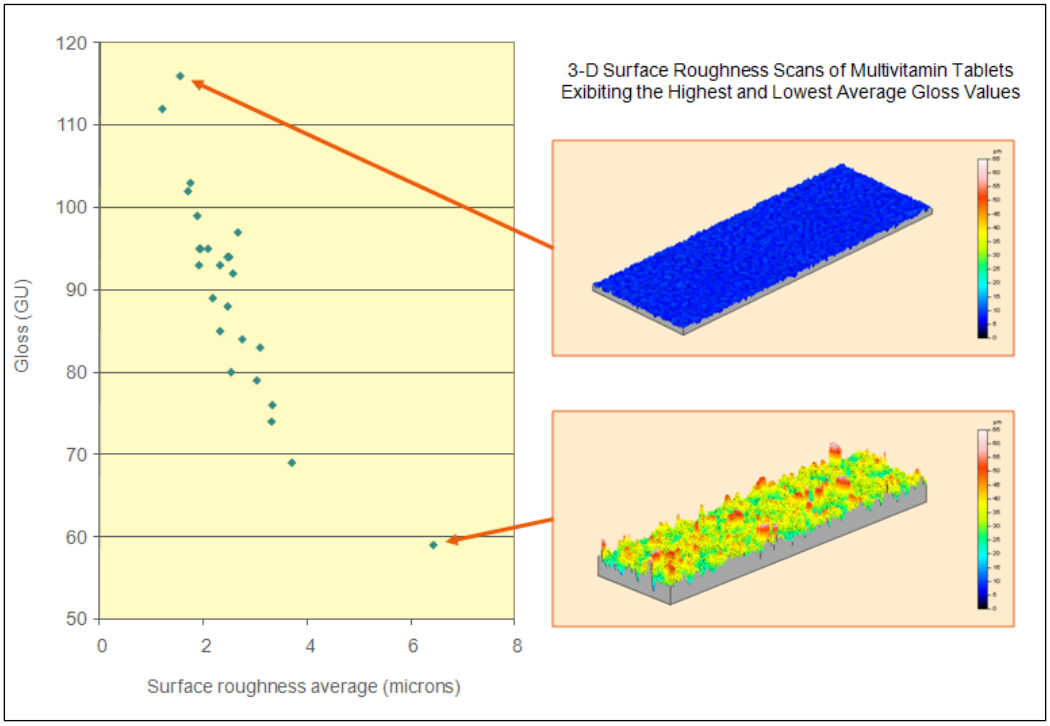


Figure 3. Effect of Inlet Temperature and Airflow on Gloss at 25% Solids Concentration



There was a strong inverse correlation between gloss and surface roughness, where the highest roughness average (RA) of 6.8 was obtained on the sample with the lowest gloss of 57 GU. Surface roughness of 1.2 RA was obtained for the tablets with a high gloss of 116 GU (Figure 4).

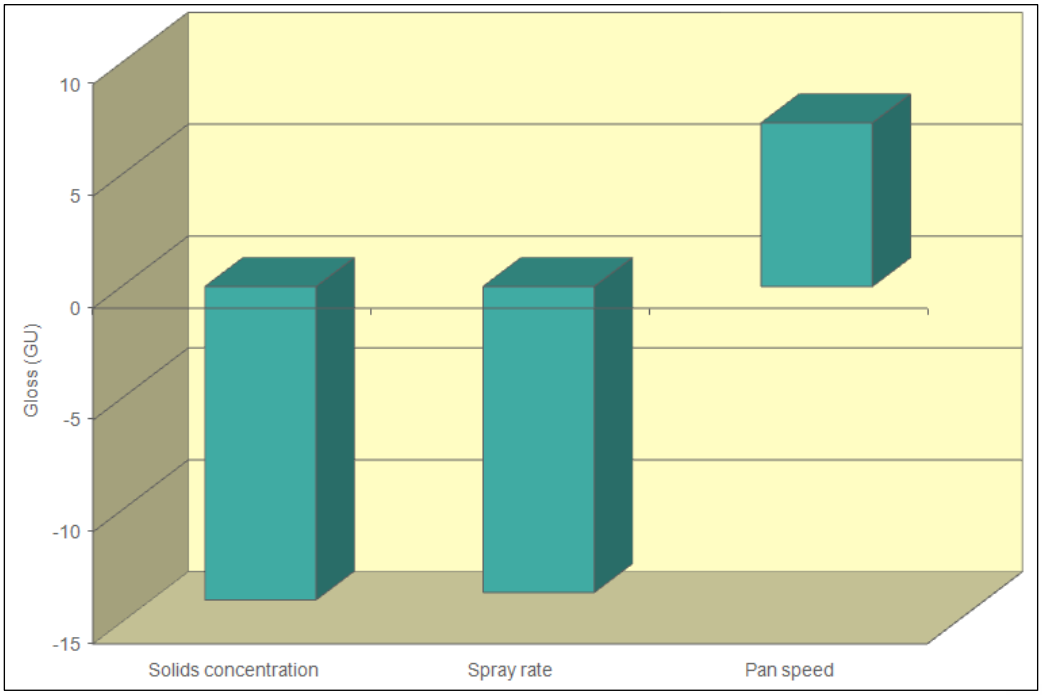
Figure 4. Relationship between Coated Tablet Gloss and Surface Roughness



Placebo Tablets - Gloss

Gloss values for the placebo tablets ranged from 63 to 100 GU. As with the multivitamin trials, the solids concentration of the dispersion had the greatest impact on gloss. As the solids concentration increased, gloss values decreased. Increasing the spray rate also decreased gloss. Increasing pan speed, which was not evaluated in the multivitamin DOE, had a positive effect on gloss values (Figure 5).

Figure 5. Variable Effect Ranking for Gloss – Placebo Tablets



Increasing the pan speed increased the number of passes a tablet made through the spray zone throughout the duration of the coating process. Increased pan speed also reduced the dwell time of the tablets under the spray zone reducing potential over-wetting that leads to surface roughness and reduced gloss. The combination of high pan speeds and low spray rates with low dispersion solids concentration resulted in the highest gloss levels in the placebo tablet trials (Figures 6 and 7).

Figure 6. Effect of Pan Speed and Spray Rate on Gloss at 15% Solids Concentration

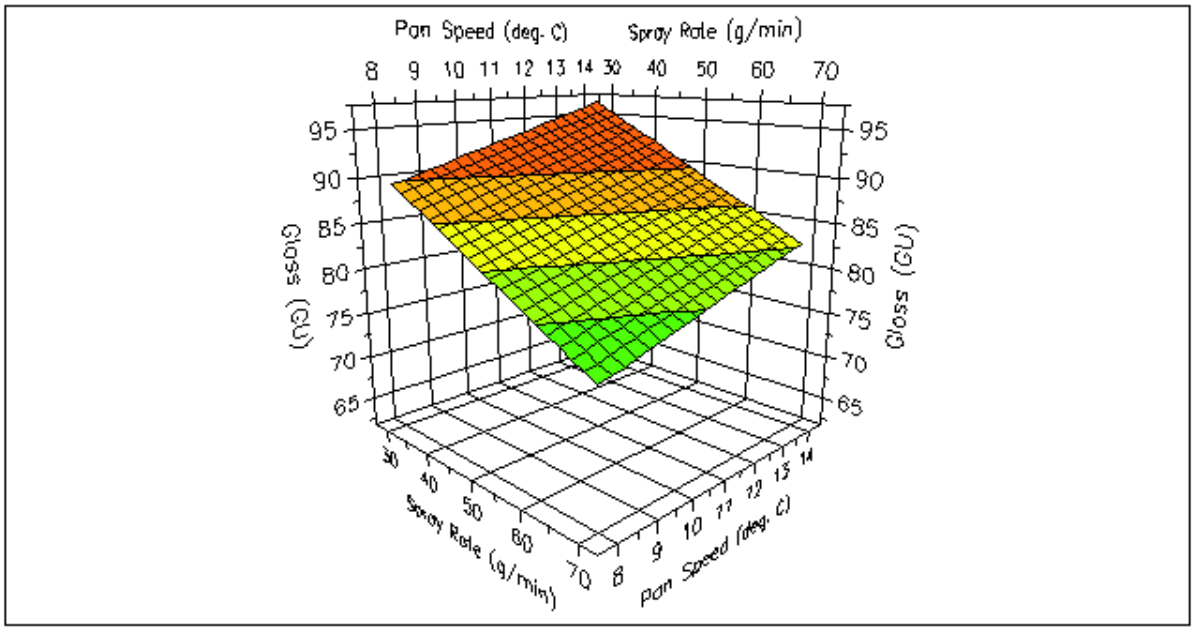
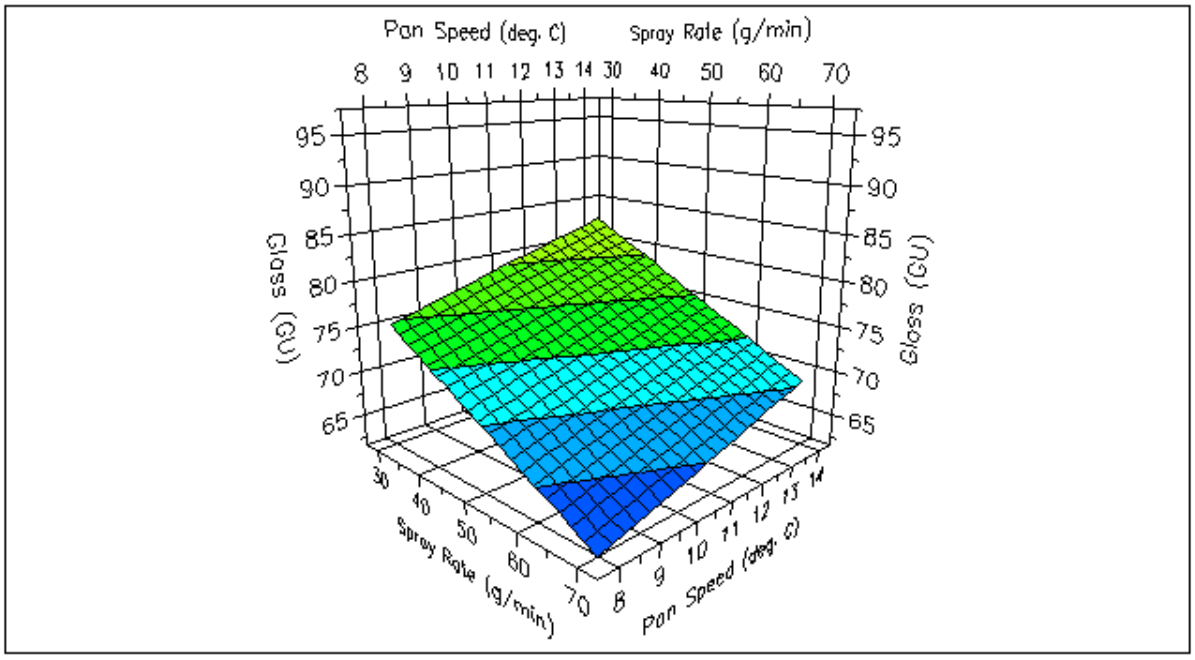


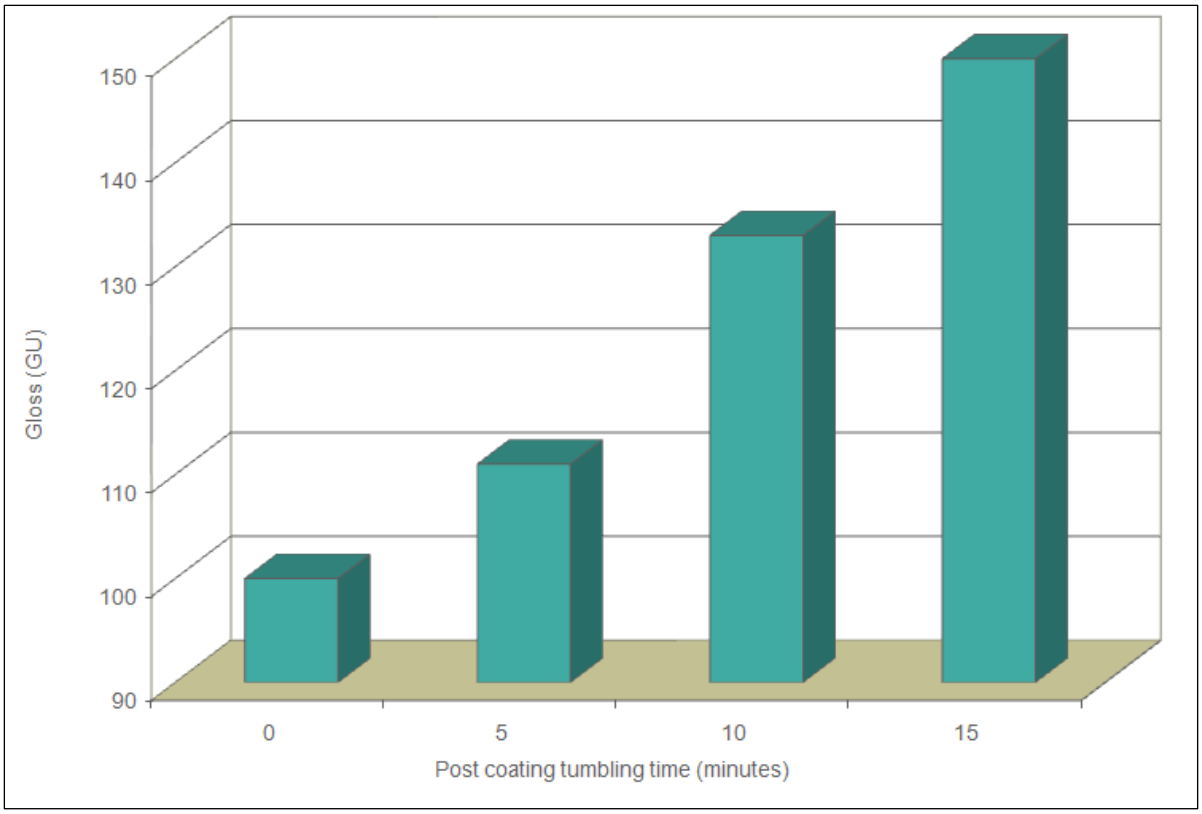
Figure 7. Effect of Pan Speed and Spray Rate on Gloss at 30% Solids Concentration



Post–process Tumbling

Tablets that were tumbled at reduced pan speed for up to 15 minutes post coating showed up to a 50% increase in gloss levels (Figure 8).

Figure 8. Effect of Post-process Tumbling Time on the Gloss of Tablets Coated with Opadry II (PVA-based)



Further increases in gloss were not observed at tumbling times > 15 minutes. The increase in gloss with post-process tumbling may be attributed to the physical properties of the film coating composition used in this study, which has been previously shown to have a higher degree of “slip” than other coating systems. This higher slippage during tumble in the pan allows further smoothing of the coating surface after the spray has been stopped.

CONCLUSIONS

The tablets coated with the pigmented Opadry II formulae in this study showed enhanced gloss through the adjustment of a variety of coating process parameters. A unique aspect of these coating formulations is their self polishing nature. Simple tumbling of the tablets after coating resulted in substantial increases in gloss. High gloss tablet appearance was achieved with a single coating formulation without the need for additional clear top-coats, waxing or polishing steps. Process capability, manufacturing complexity and process time should be considered when selecting the best approach

Reprint of poster presented at American Association of Pharmaceutical Scientists Meeting, 2009.
Authors, Charles R. Cunningham, Adam Kevra, Chris R. Neely

REFERENCES

1. Kevra, A, (2008) Maximizing the Gloss of PVA Based Film Coating Systems, American Association of Pharmaceutical Scientists Annual Meeting, Poster Presentation, (November).
2. Hughes, K, Wan, P, (2005) Investigation into the Flow Properties of Coated and Uncoated Tablets and its Relevance to Blister Packaging Efficiency, American Association of Pharmaceutical Scientists Annual Meeting, Poster Presentation, (November).

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**	**+54-1-5556-7700**

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