Investigation of the Influence of High Solids Content of a Film Coating Formulation on Color Uniformity and Surface Smoothness of Coated Tablets

Daniel To, Brad Prusak, Jason Teckoe, and Ali Rajabi-Siahboomi
www.colorcon.com

The developmental film coating from this study was commercially launched in April 2016 as:

Opadry® QX
Quick and FleXible Film Coating System

AAPS
Poster Reprint 2015

Purpose

To study the influence of aqueous coating solids content on color uniformity, appearance, and tablet surface smoothness using a developmental high productivity, immediate release film coating system based on Kollicoat® IR†. The performance of the developmental film coating system was evaluated and compared to a PVA-based Opadry® II, high performance film coating system.

Methods

Dispersion Viscosity

Aqueous dispersions of the fully formulated developmental system based on Kollicoat IR were prepared at 20 to 35% w/w solids level and viscosity determined with a DV-II+Pro viscometer (Brookfield Engineering Laboratories Inc., USA) using RV1 spindle at 50 rpm and 25±1°C.

Coating Performance

The developmental film coating system was applied to a 4% weight gain (WG) from 20 to 35% w/w solids dispersions onto a 15 kg pan charge of biconvex placebo tablets (10 mm, round) at 60 g/min in a coating pan fitted with a 24" fully perforated drum insert (Labcoat IIX, O'Hara Technologies Inc., CA) and two Schlick spray guns. The inlet temperature was adjusted to maintain a bed temperature of 38°C. Other coating parameters are described in Table 1. Opadry II was applied at 20 to 30% w/w solids to a 4% WG using equivalent processing conditions, with the exception that the bed temperature was maintained at 45°C.

Table 1. Coating Process Parameters

	Developmental Film Coating System	Opadry II
% Solids	20-35%	20-30%
Tablet Bed Temperature	38°C	45°C
Pan charge (kg)	15	15
Airflow (m^3/hr)	450	450
Pan speed (rpm)	14	14
Gun to bed distance (cm)	11.4	11.4
Atomizing air pressure (bar)	1.7	1.7
Pattern air pressure (bar)	1.7	1.7

Color Uniformity Evaluation

Color uniformity for the developmental film coating system was determined by measuring the color difference of 20 individual coated tablets from 1 to 4% WG, at 0.5% increments, with a reflectance spectrophotometer (DataColor 600, DataColor Inc., USA). The data was analyzed using the Commission Internationale de l'Eclairage (CIE) L* a* b* System, where color is represented by a three dimensional space composed of lightness (L*), and the red/green, and blue/yellow complementary color pairs (a*, and b* respectively). The total color difference (DE) between any sample and a reference standard can be expressed by Equation 1.[1] The 4% WG samples were used as the reference standard and color uniformity was achieved when all tablets had color differences below 2.5 DE.

Equation 1.

$$DE = [(L^*_1 - L^*_{standard})^2 + (a^*_1 - a^*_{standard})^2 + (b^*_1 - b^*_{standard})^2]^{1/2}$$

Appearance Evaluation

Tablet gloss was measured using a Surface Analysis System (Model 805A, Tricor Systems Inc., USA).

Surface roughness (Sa) of a 1x1 mm^2 area on the crown of nine tablets, sampled from each coating run, was measured using a PS50 optical profilometer (Nanovea, USA). A *t* Test was used to confirm statistically significant differences between the roughness values for coatings prepared with dispersions at different % solids.

Disintegration Time of Film Coated Tablets

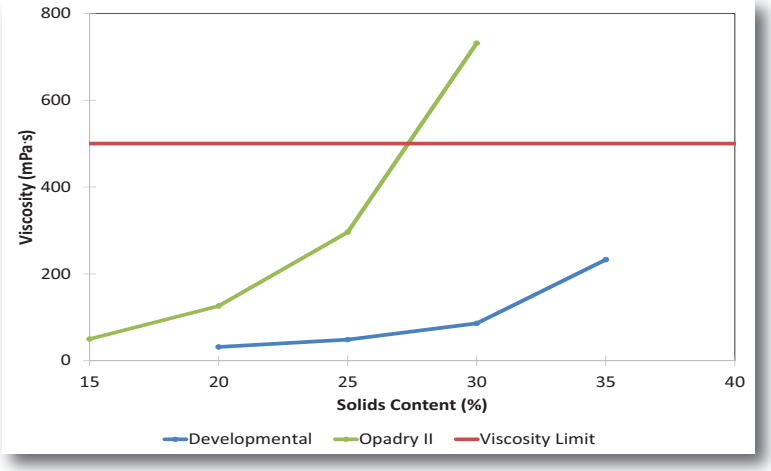
The disintegration times of uncoated and film coated tablets were measured in 0.1N HCl, pH 4.5 acetate buffer, and deionized water following USP guidelines (ZT44, Erweka GmbH, Germany).[2]

Results

Dispersion Viscosity

The dispersion viscosity for the developmental film coating system and Opadry II are shown in Figure 1. A viscosity limit of 450-500 mPa·s is commonly recommended to avoid pumping issues of the dispersion, as shown by the red line in Figure 1.

Figure 1. Viscosity of Fully Formulated Film Coating Systems



Coating Performance and Color Uniformity

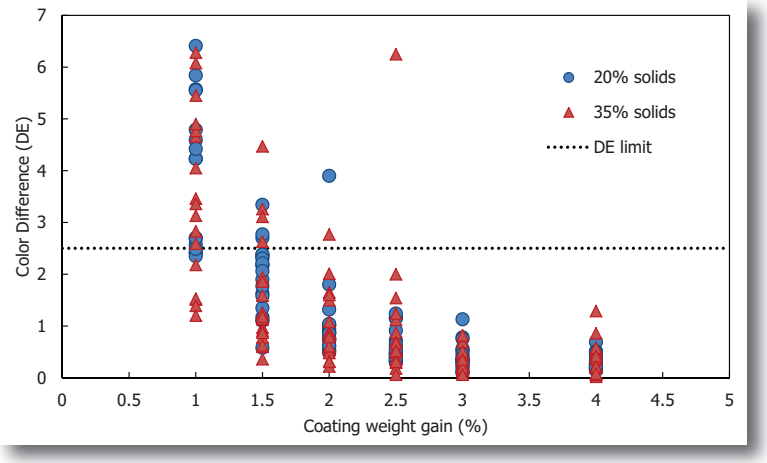
The developmental film coating system was applied without any sticking issues at both 20 and 35% solids. Increasing the dispersion solids content dramatically reduced the amount of coating dispersion required to achieve a 4% WG from 3000 to 1714 g, which led to a 42% reduction in the coating time, as indicated in Table 2. The coating time to achieve a 4% WG of Opadry II could also be reduced by going to a higher solids content, however coatings at higher than 30% solids could not be performed due to high dispersion viscosities.

Table 2. Coating Productivity at 20% and 35% w/w Solids

Formulation	Solids (w/w%)	Time to Color Uniformity (min)	Time to 4.0% WG (min)
Developmental Film Coating System	20	30	48
	35	21	28
Opadry II	20	Not measured	48
	30	Not measured	32

Tablets coated with the developmental film coating system were collected from 1 to 4% WG for color uniformity analysis, as shown in Figure 2. At 20% solids, color uniformity was achieved after 2.5% WG, as determined by an absence of any tablets with a color difference above 2.5 DE. At 35% dispersion solids level, the color uniformity was achieved after 3.0% WG. The increase in coating productivity at 35 % w/w solids resulted in a 30% reduction in the time to achieve color uniformity.

Figure 2. Color Uniformity Measurements at 20 and 35% w/w Solids Content for the Developmental Film Coating System



Appearance Evaluation

The developmental coating system offered both exceptional tablet appearance and logo definition at 20 and 35% w/w solids (Figure 3). Tablets with high gloss and low surface roughness at both solids contents were produced. As expected the smoother and glossier tablets were obtained at lower dispersion solids content. Unexpectedly, the appearance (gloss) of the tablets coated with the developmental system coated at 35% solids were found to be comparable to values obtained for Opadry II at 20% w/w solids, and significantly better than tablets coated with Opadry II at 30% w/w solids (Table 3).

Figure 3. Images of Logo Section of Coated Tablets at (a) 20% and (b) 35% w/w Solids

(a) 20% solids **(b) 35% solids**

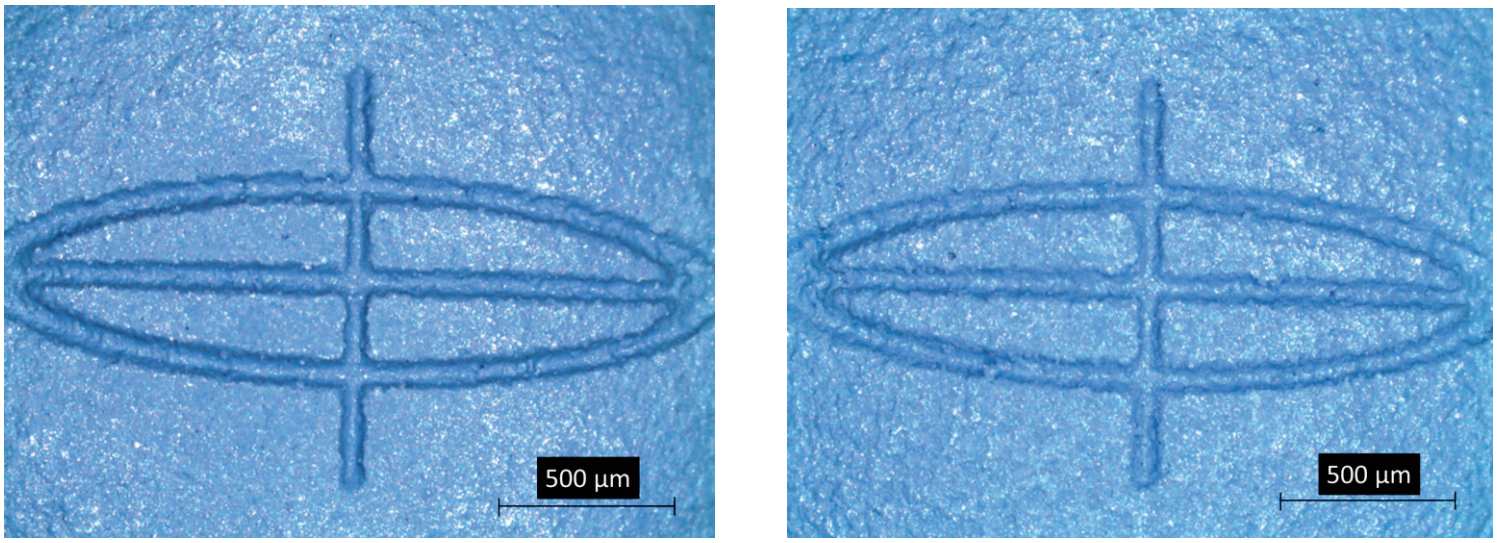


Table 3. Coating Productivity, Gloss and Surface Roughness at 20% and 35% w/w Solids

Formulation	Solids (w/w%)	Tablet Surface Roughness (µm)	Gloss (GU)
Developmental Film Coating System	20	3.1 ± 0.6	114
	35	4.6 ± 0.5	89
Opadry II	20	3.5 ± 0.3	89
	30	6.8 ± 0.6	65

Viscosity and surface tension are considered key dispersion properties that can affect surface roughness and gloss. Lower viscosity dispersions are easier to atomize, which can improve coating coverage and enhance film coalescence through droplet spreading,[3] while reduced surface tension can improve droplet spreading on the surface and film coalescence through improved surface wetting.[4] Kollicoat IR has low viscosity and significantly lowers the surface tension of water,[5] which enabled the elegant tablet appearance of the developmental film coating system at elevated dispersion solids.

Disintegration Time of Film Coated Tablets

The disintegration time of uncoated placebo tablets were measured to be 4.3, 4.6, and 4.8 min in 0.1 N HCl, pH 4.5 acetate buffer, and deionized water, respectively. The application of the developmental film coating system (4% WG) increased the disintegration time by approximately 1-2 min for tablets coated at 20 and 35% w/w solids in all media, which is typical for an immediate release coated tablet.

Conclusions

The developmental film coating system based on Kollicoat IR has a low viscosity, which offers an opportunity for higher dispersion solids content and exceptional coating productivity. At dispersion solids greater than 20% w/w, the developmental coating system provides color uniformity at 3% WG and tablets with elegant appearance and excellent surface smoothness. Increasing the dispersion solids from 20 to 35% w/w offers a 42% reduction in the coating time, while still providing excellent tablet appearance and color uniformity.

References

1. Chrisment A. Color and Colorimetry. Paris, FR: Editions 3C Conseil; 1998.
2. US Pharmacopeia. USP/NF General Chapter 701, Disintegration. Website: http://www.uspnf.com/uspnf/pub/index?usp=38&nf33&s=1&officialOn=August 1, 2015. Accessed Aug 26, 2015.
3. Werner SRL, Jones JR, Paterson AHJ, Archer RH, Pearce DL. Air-suspension coating in the food industry: Part II – micro-level process approach. *Powder Technology.* 2007: 171(1):34-45.
4. Teunou E, Poncelet D. Batch and continuous fluid bed coating review and state of the art. *Journal of Food Engineering* 2002:53(4):325-340.
5. Kolter K, Gotsche M, Schneider T. Physicochemical Characterization of Kollicoat® IR. ExAct: *Excipients and Actives for Pharma*. 2002:8: 2-3.

The information contained herein, to the best of Colorcon, Inc.'s knowledge is true and accurate. Any recommendations or suggestions of Colorcon, Inc. with regard to the products provided by Colorcon, Inc. are made without warranty, either implied or expressed, because of the variations in methods, conditions and equipment which may be used in commercially processing the products, and no such warranties are made for the suitability of the products for any applications that you may have disclosed. Colorcon, Inc. shall not be liable for loss of profit or for incidental, special or consequential loss or damages.

Colorcon, Inc. makes no warranty, either expressed or implied, that the use of the products provided by Colorcon, Inc., will not infringe any trademark, trade name, copyright, patent or other rights held by any third person or entity when used in the customer's application.

For more information, contact your Colorcon representative or call:

North America **+1-215-699-7733**

Europe/Middle East/Africa **+44-(0)-1322-293000**

Asia Pacific **+65-6438-0318**

Latin America **+54-1-5556-7700**

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

©BPSI Holdings, LLC 2015

All trademarks, except where noted, are property of BPSI Holdings LLC. The information contained in this document is proprietary to Colorcon, Inc. and may not be used or disseminated inappropriately

†Kollicoat IR is a registered trademark of BASF SE

pr_aaps_cc_weight_transit_03_15.pdf