Investigation of Optimum Coating Conditions for an Easy Swallow Coating System

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Purpose

Opadry® EZ, Easy Swallow Film Coating System is a fully formulated, aqueous film coating designed to improve tablet mobility and reduce adhesion whilst in the oral cavity, as well as during esophageal transit. The coating provides a smooth, high gloss finish to enhance the visual perception for ease of swallowing. The aim of this study was to identify a design space for coating parameters that enhance the wet slip and appearance (gloss) properties of the coated tablets.

Methods

Using design of experiments (DoE), eleven coating trials were performed to investigate the impact of dispersion solids concentration, spray rate and bed temperature on the slip and gloss performance for tablets coated with pigmented versions of Opadry EZ. Each trial used 15 kg of acetaminophen caplets (500 mg), coated with Opadry EZ using a Labcoat II (O'Hara Technologies, Inc.) fitted with a fully perforated 24″ coating pan. The range of coating process parameters used are described in Table 1.

Table 1: Range of Coating Process Parameters Used in the DoE Study at Pilot Scale

Parameter	Value
Charge (kg)	15.0
Solids Content (% w/w)	6 – 20
Spray Rate (g/min)	40 – 76
Bed Temp (°C)	35 - 55
Inlet Air Temperature (°C)	53 - 93
Air Flow (cfm/m^3/hr)	265 / 450
No. of Spray Guns	2
Spray Gun Type	VAU 1/8 VAU-SS930 7-1 S37
Pan Speed (rpm)	14
Atomization Air (psi/bar)	20 / 1.4
Pattern Air (psi/bar)	20 / 1.4
Coating Time (min)	25 – 125

In addition, 130 kg of placebo caplets (950 mg) were coated in an O'Hara Fastcoat 48″ pan (production scale) with pigmented Opadry EZ at 18% solids (w/w), using coating conditions scaled up from the 24″ pan. Opadry EZ clear was also coated over the pigmented system to a 2% WG at 8% solids (w/w). The processing conditions for the 48" pan are described in Table 2.

Table 2: Range of Coating Process Parameters Used at Production Scale

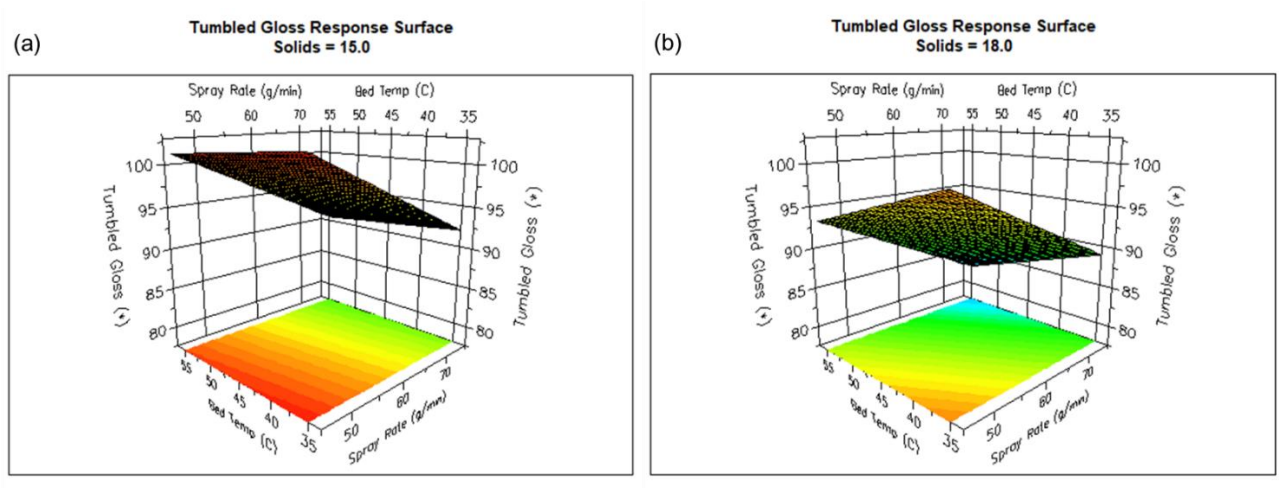
Parameter	Pigmented Opadry EZ	Clear Opadry EZ
Charge (kg)	130	130
Solids Content (%w/w)	18	8
Spray Rate (g/min)	400	350
Bed Temp (°C)	45	45
Inlet Air Temperature (°C)	64	64
Air Flow (cfm/m^3/hr)	1800 / 3060	1800 / 3060
No. of Spray Guns	3	3
Spray Gun Type	Schlick 930 7-1 S37	Schlick 930 7-1 S37
Pan Speed (rpm)	9	9
Atomization Air (psi/bar)	25 / 1.7	25 / 1.7
Pattern Air (psi/bar)	25 / 1.7	25 / 1.7

The wet slip behavior of the coated tablets was characterized by determining the static and dynamic friction coefficients, using an in-house Colorcon method with an Instron tensile tester. Three tablets weighted with a 0.5 N normal force were dragged across a water saturated substrate at 500 mm/min. Tablet appearance was assessed by measuring gloss using a Tricor Surface Analysis System and surface roughness using a Nanovea Optical Profilometer.

Results

Opadry EZ exhibited low static and dynamic friction coefficients of less than 1.54 and 1.00 for all processing conditions evaluated. This indicates excellent wet slip behavior regardless of the processing conditions used. The impact of bed temperature, spray rate and solids content on gloss and surface roughness are shown in Figures 1 and 2.

Figure 1: Effect of Bed Temperature and Spray Rate on Gloss at (a) 15% Solids, (b) 18% Solids and (c) 20% Solids



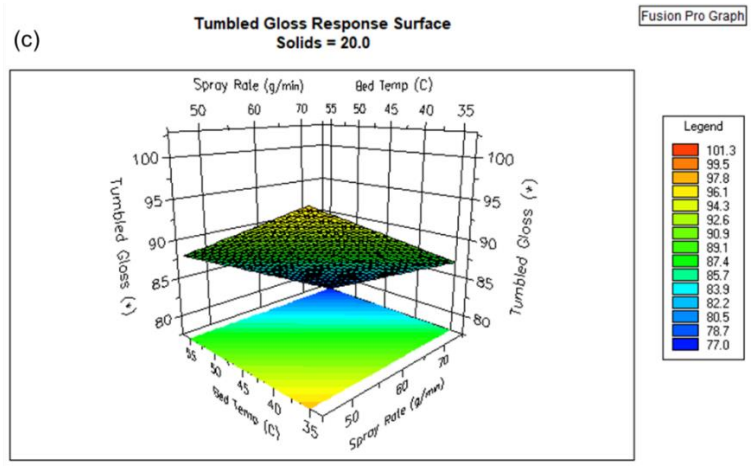
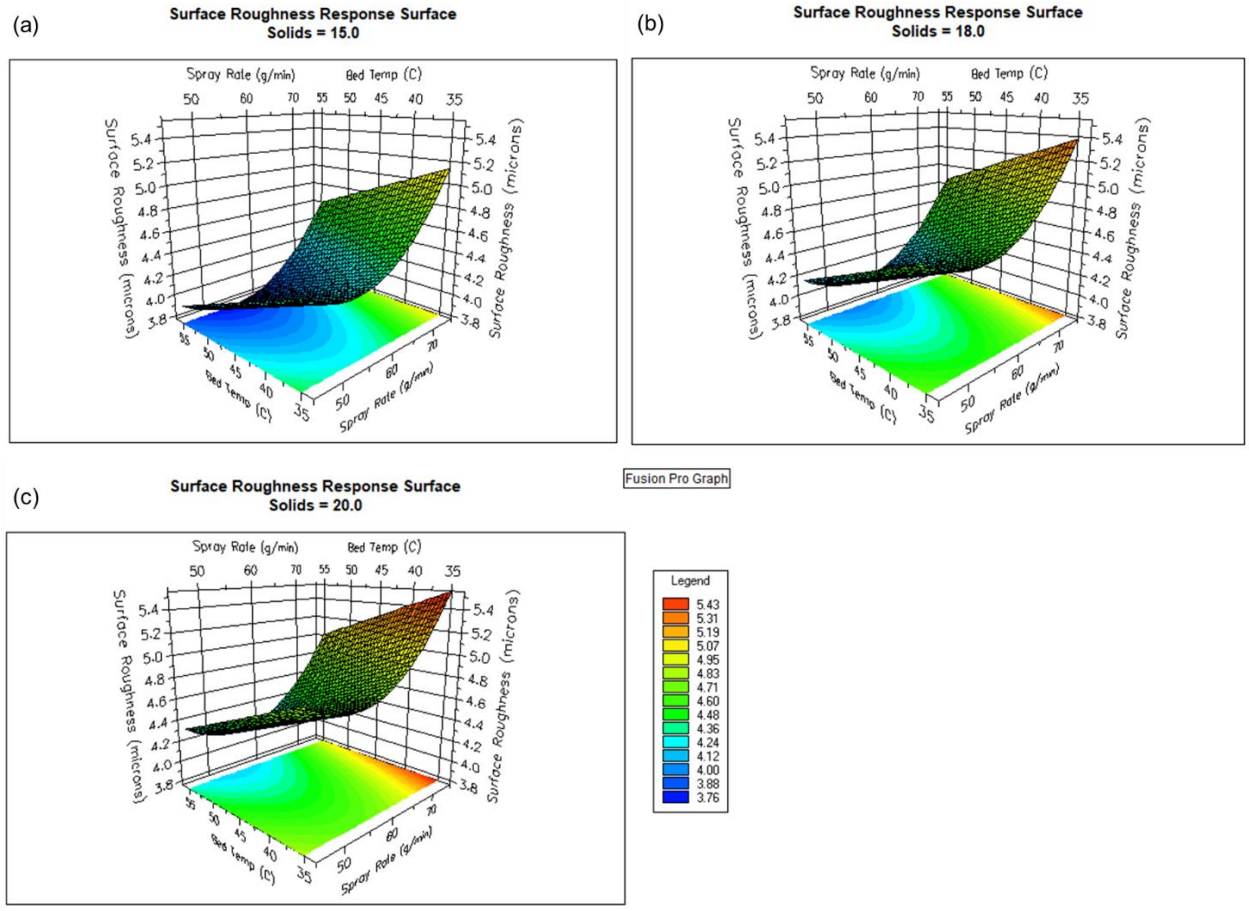


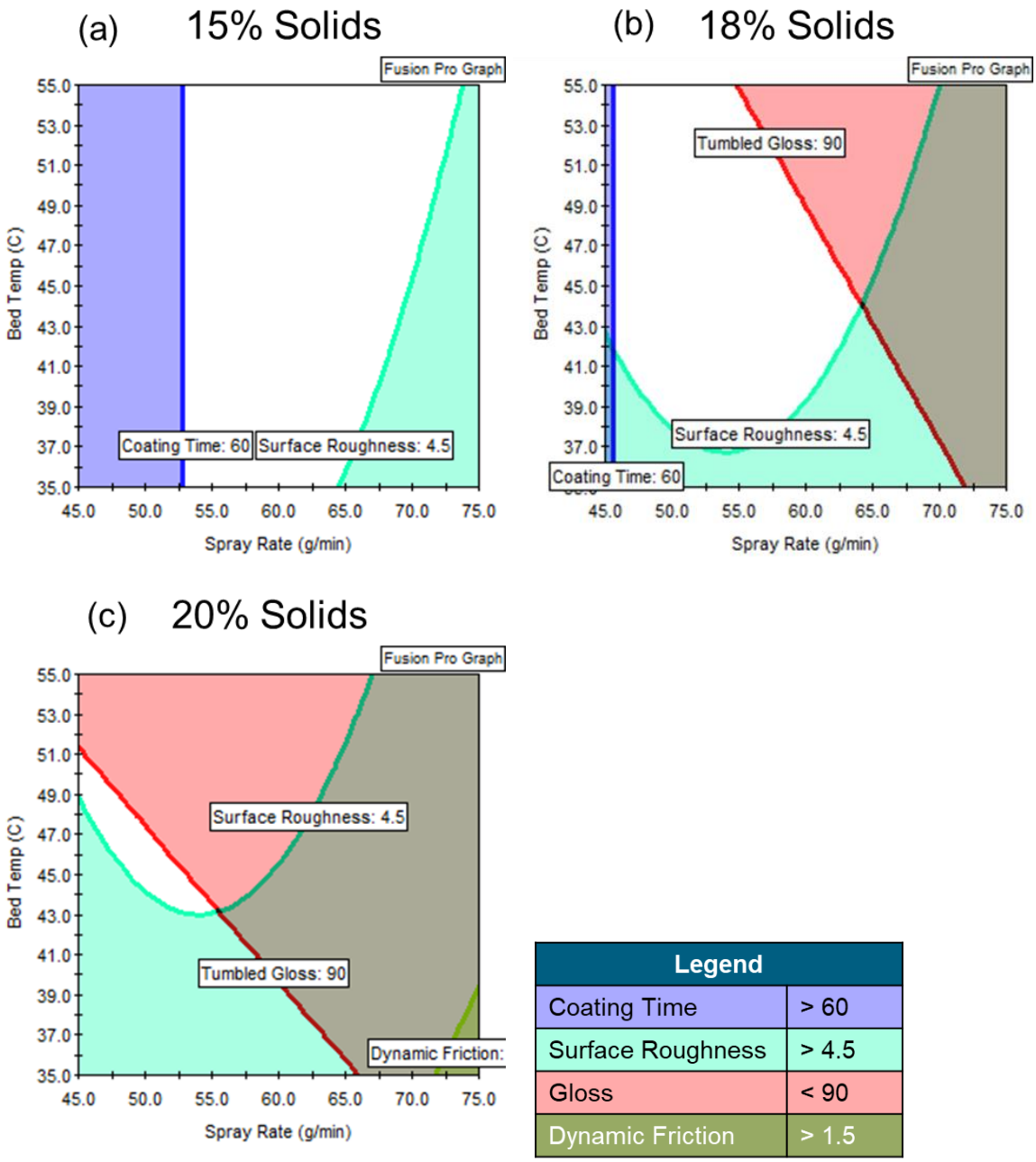
Figure 2: Effect of Bed Temperature and Spray Rate on Surface Roughness at (a) 15% Solids, (b) 18% Solids and (c) 20% Solids



In Figure 3 the white area reflects the design space that provided optimum performance based on wet slip behavior, surface roughness, gloss, and coating time. Dispersion solids concentration had a strong impact on surface roughness, gloss, and coating time. At 15% solids, a wide range of spray rates and product temperatures provided excellent performance. With 18% solids the coating time was significantly reduced; however, the gloss was negatively affected at high product temperatures, while both surface roughness and gloss were negatively affected by high spray rates.

At 20% solids, the acceptable range was limited to lower spray rates to achieve the maximum gloss and minimum surface roughness goals.

Figure 3: Design Space for Processing Conditions for a Pigmented Version of Opadry EZ.



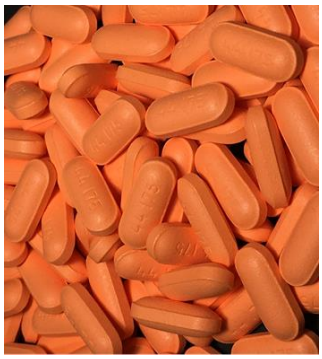
Legend	
Coating Time	> 60
Surface Roughness	> 4.5
Gloss	< 90
Dynamic Friction	> 1.5

Confirmation runs were performed on APAP caplets in the 24” scale to confirm the DoE model. The spray rate and bed temperatures were chosen to provide ideal coating performance at 15, 18 and 20% solids as shown in Table 3.

Table 3: Processing Parameters of Confirmation Runs Performed on 24″ Scale

Parameter	Pigmented # 1	Pigmented # 2	Pigmented # 3
Solids Content (%w/w)	15	18	20
Spray Rate (g/min)	60	60	50
Bed Temp (°C)	45	45	45
Inlet Air Temperature (°C)	73	68	64
Coating Time (min)	50	42	45
Gloss (GU)	97	92	84
Surface Roughness (µm)	4.5	4.5	4.4

Figure 4: APAP Caplets Coated in the 24″ Pan with Pigmented Opadry EZ at 18% Solids



Placebo caplets were coated in the O'Hara Fastcoat 48″ pan using the processing conditions described in Table 2. The production scale coating trial produced tablets with excellent appearance as shown in Figure 5. A comparison of the tablet gloss and surface roughness, shown in Figures 6 and 7, indicates that comparable performance can be achieved on both the 24″ and 48″ scale.

Figure 5: Image of Placebo Caplets Coated on the 48″ Pan with (a) Pigmented Opadry EZ followed by (b) Clear Opadry EZ

Figure 6: Gloss Coated of Placebo Caplets Coated with Pigmented Opadry EZ and Opadry EZ Clear on the 24″ and 48″ Scale

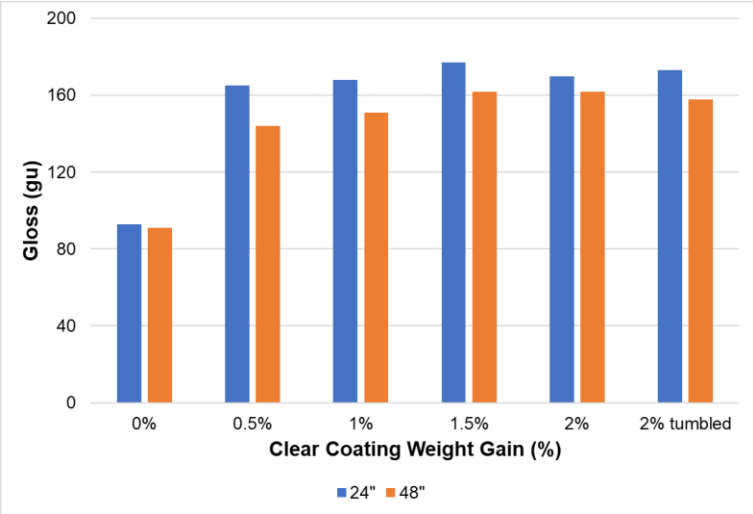
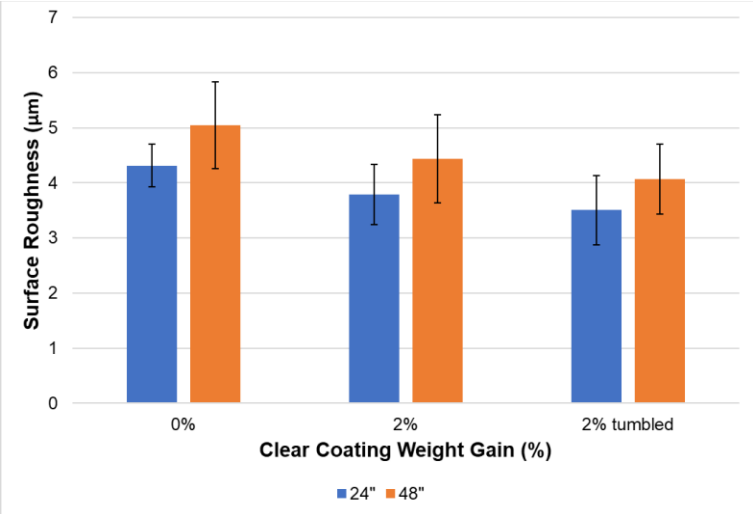


Figure 7: Surface Roughness of Placebo Caplets Coated with Pigmented Opadry EZ and Opadry EZ Clear on the 24″ and 48″ Scale



Conclusions

Opadry EZ is a novel film coating system that provides exceptional wet slip behavior and can improve tablet mobility in the oral cavity. Desirable tablet appearance was obtained with tablets coated with pigmented formulations from 15 – 20% solids. Application of Opadry EZ clear significantly improved tablet gloss, providing elegance and appeal for easy swallowing.

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