

# Novel Immediate Release Coating Composition Based on PVA and an Acrylic Polymer Offering Excellent Coating Productivity, Moisture Barrier and Drug Release

Jason Teckoe and Thomas P. Farrell

Colorcon Inc., Global Headquarters, 275 Ruth Road, Harleysville, PA 19438 USA; [www.colorcon.com/about/contact](http://www.colorcon.com/about/contact)



## Purpose

High productivity immediate release film coatings with enhanced moisture barrier functionality, and no impact on drug release compared to uncoated tablets are increasingly preferred. The aim of this study was to characterize a novel fully formulated film coating comprised of polyvinyl alcohol and an acrylic polymer that offers a desirable combination of all these attributes.

## Methods

Aqueous dispersion viscosity, pH and coating assessments to determine maximum fluid delivery rate (MFDR) with dispersions up to 25% solids were performed. The MFDR is defined as the maximum grams/minute of coating dispersion that can be sprayed onto the tablet bed during the coating process (under typical process conditions), without causing the tablets to stick to the coating pan or each other (agglomeration).

The MFDR was determined using a 1.5 kg charge of standard convex placebo tablets (10 mm diameter), which were coated in a fully-perforated, 15" side-vented pan containing one spray gun. The coating process parameters used to prepare the coated tablets are shown in **Table 1**.

**Table 1.** Coating Process Parameters

Coating Process Parameter	Value
Inlet Air Temperature (°C)	65
Tablet Bed Temperature (°C)	45
Airflow (m <sup>3</sup> /hr)	250
Atomizing Air Pressure (bar)	1.5
Pan Speed (rpm)	22
Spray Gun to Bed Distance (cm)	10
Fan Air (bar)	1.5

Disintegration testing of placebo tablets, coated with 3% weight gain of the novel film coating system in purified water and 0.1N HCl, was conducted to confirm the immediate release character of the coating.

Water vapor transmission rate (WVTR) was determined on cast films (thickness ~100 microns) using a VTI WPA-100 unit fitted with a 6.39 cm<sup>2</sup> test cell. The test film was first dried to an equilibrium dry state at 25°C with a dry N<sub>2</sub> purge gas flowing at a rate of 200 cm<sup>3</sup>/min for 30 minutes. Moisture vapor was then introduced into the purge gas to develop relative humidity of 80% on one side of the test film. The moisture content on the opposite side of the test film was monitored, and the equilibrium rate of moisture transmission through the film was determined over a period of time. The test period was completed either when the measured transmission rate deviated by less than 0.001 g/water/day/100 inches<sup>2</sup> for a period of 5 minutes or the total time allowed for the test was elapsed (typically up to 4 hours), whichever occurred first.

Dissolution testing of acetaminophen (APAP, 500 mg caplets, LNK International Inc.) and ibuprofen (IB, 200mg, 9.53 mm round tablets, LNK International Inc.) was conducted according to USP recommended guidelines (**Table 2**). Both uncoated and coated tablets with a 3% weight gain of the novel film coating system were tested following 6 months storage at 40°C/75% RH, and 12 months storage at 30°C/65% RH.

**Table 2.** FDA Recommended Dissolution Methods<sup>1</sup>

Active	USP Apparatus	Speed (RPM)	Medium	Volume (mL)
Acetaminophen	II (paddle)	50	Phosphate buffer, pH 5.8	900
Ibuprofen	II (paddle)	50	Phosphate buffer, pH 7.2	900

## Results

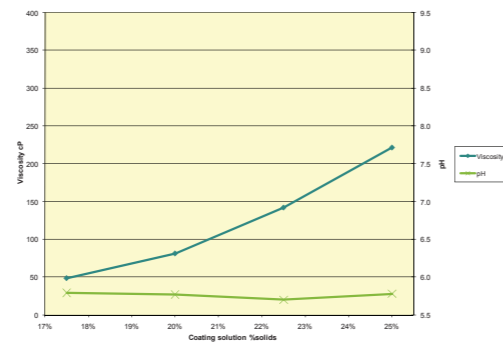
The qualitative formula for the novel IR film coating is shown in **Table 3**.

**Table 3.** Qualitative Formula for Novel Immediate Release Film Coating

Ingredient
Polyvinyl alcohol
Methacrylic acid copolymer- Type C
Polyethylene glycol
Talc
Neutralizing agent
Pigment

The dispersion viscosity of the novel coating composition was determined at solids levels up to 25%, as shown in **Figure 1**. The dispersion viscosity is well below the commonly accepted viscosity threshold of about 400 cP, indicating that this coating system is capable of application at solids in excess of 25%.

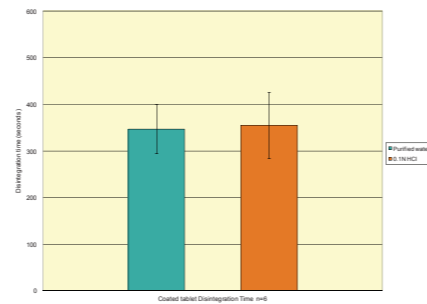
**Figure 1.** Dispersion Viscosity and pH vs % Solids for the Novel IR Film Coating



During coating trials with dispersions at 20% solids, the maximum fluid delivery rate for the system was determined to be between 26-28 g/min, which is comparable to existing commercial high performance film coating systems.

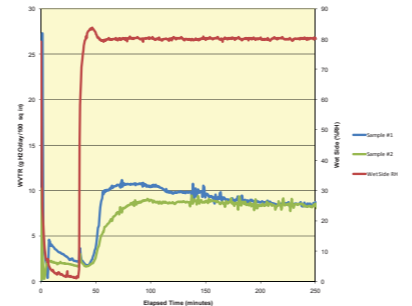
The average disintegration times for 3% weight gain coated placebo tablets were 347 (±52) seconds and 355 (±70) seconds in purified water and 0.1 N HCl, respectively (**Figure 2**). This demonstrated that the coating provided consistent pH independent immediate release performance.

**Figure 2.** Average Disintegration Time for Placebo Tablets Coated with the Novel IR Coating Formulation in Purified Water and 0.1N HCl



The WVTR of cast films was determined to be 8-9g water/day/100 inches square as can be seen in **Figure 3**. This result compares favorably with existing commercial film coating formulations as shown in **Table 4**.

**Figure 3.** Water Vapor Transmission Rate Traces for the Novel IR Film Coating

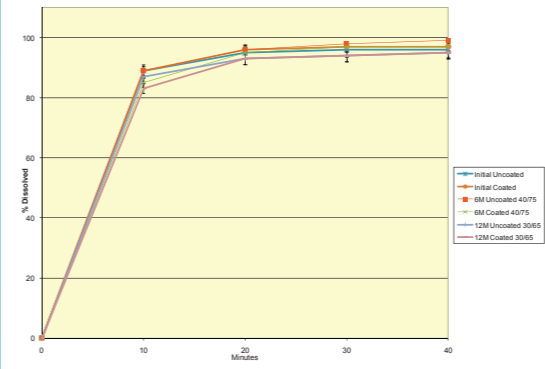


**Table 4.** WVTR Comparison of the Novel IR Film Coating Formulation to Existing Commercial Products (n=2)

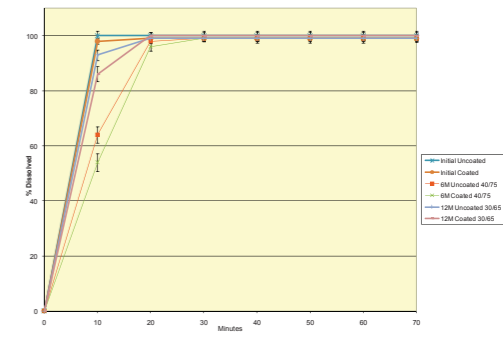
Formulation	Water Vapor Transmission Rate g/water/day/100 inches <sup>2</sup>
Opadry® amb	7 ± 1
Novel IR coating	9 ± 1
Opadry® II (PVA-based)	16 ± 2
Opadry® (HPMC)	32 ± 2

Dissolution performance of APAP and IB tablets coated with the novel IR film coating met the USP release guidelines and were similar to the corresponding uncoated tablets at every time point following accelerated storage stability (**Figures 4 & 5**).

**Figure 4.** Dissolution Results Following Accelerated Storage Stability for Coated and Uncoated Acetaminophen Tablets (30°C / 65% RH and 40°C / 75% RH)



**Figure 5.** Dissolution Results Following Accelerated Storage Stability for Coated and Uncoated Ibuprofen Tablets (30°C / 65% RH and 40°C / 75% RH)



A variation in the dissolution was observed for the 30°C / 65% RH and 40°C / 75% RH samples at the 10-minute time point. This variation was consistent for both the coated and uncoated tablets, indicating that the tablet core, rather than the coating, was responsible for the observed delay.

## Conclusions

The novel immediate release film coating evaluated in this study provides a desirable combination of high dispersion solids, high coating productivity, excellent moisture barrier performance and equivalent drug release vs. uncoated tablets following accelerated storage.

## References

1. US Department of Health and Human Services. FDA US Food and Drug Administration. Dissolution Methods Web site. <http://www.accessdata.fda.gov/scripts/cder/dissolution/index.cfm>. Accessed January 6, 2010.

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