

Enhanced Moisture Protection and Film Properties of an Opadry fx Pearlescent Film Coating System Based on PVA

OBJECTIVE

Characterize the moisture vapor transmission rate (MVTR) and other film properties of Opadry[®] fx[™], special effects film coating systems, containing polyvinyl alcohol (PVA).

BACKGROUND

Opadry fx, is an immediate release, special effects film coating system designed to impart gloss and pearlescence to tablets. Additionally, Opadry fx based on sodium carboxymethylcellulose, (NaCMC), provides protection to oxygen-sensitive cores by acting as a barrier to atmospheric oxygen.¹ However, films comprised of cellulosic polymers have relatively high moisture vapour transmission rates (MVTR).² For this reason, Opadry fx containing polyvinyl alcohol (PVA) was developed, which was anticipated to have better MVTR properties than those of Opadry fx containing NaCMC. PVA-based Opadry fx also imparts gloss and pearlescence to tablets sub-coated with film coatings comprised of either PVA or cellulosic polymers.

METHODOLOGY

Properties investigated include tensile strength (σ), Young's Modulus (E), moisture and oxygen permeability of free films, and adhesion of the film coating to its core.

Free film preparation was made by casting films from a dispersion using a BYK-Gardner casting knife to apply a uniform layer of solution of known initial thickness. Free films were cast on a Teflon coated surface from which the dried film could be easily removed for analysis. Cast films were allowed to equilibrate for 24 hours in a controlled environment at 25°C and 50% relative humidity, prior to testing.

The tensile strength and modulus of elasticity of cast films was determined using an Instron Mini 44 material analyzer.

The measure of the elastic modulus (E) was taken as the slope of the initial linear portion of the stress (σ) versus strain (ϵ) curve where deformation in this region obeys Hooke's law.

Adhesion of the polymer film coatings to waxy flat-face tablet surfaces was also determined using an Instron Mini 44 material analyzer. Adhesion is the force needed to pull the coating from the face of the tablet core.

Moisture vapor transmission rates (MVTR) were determined using a Water Permeability Analyzer, WPA-100 (VTI Corporation), which detects moisture passing through a free film.

Oxygen transmission rates were obtained using an OX-TRAN 2/20 (Mocon Inc.) system utilizing a coulometric sensor to detect oxygen transmission through the free films.

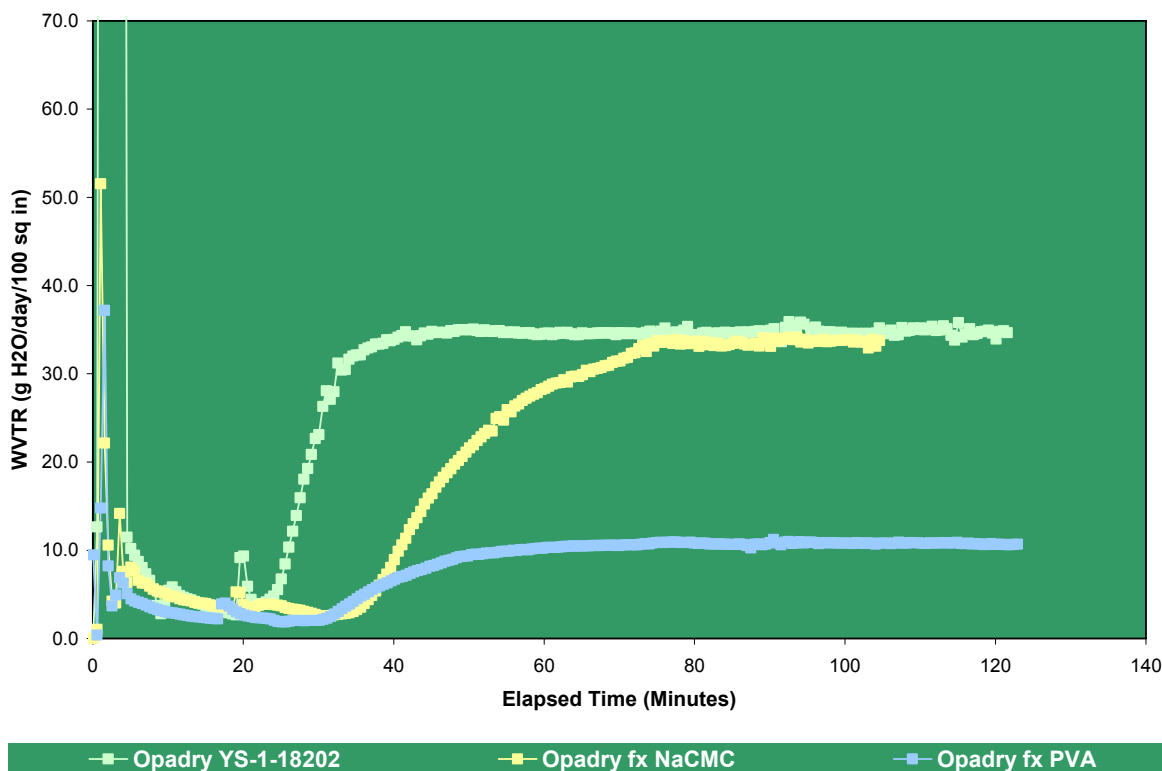
The optical property of luster was characterized for Opadry fx PVA-based formulations. The formulas were cast onto black and white draw-down cards and measured with an X-Rite MA68II multi-angle spectrophotometer using 45° illumination. The X-Rite instrument generates L* values at 15°, 25°, 45°, 75°, and 110° viewing angles (relative to specular) using D65/10° conditions. Luster is the change in lightness (L*) with change in angle, and is calculated using the following equation:

$$L = 3X \frac{(L^*_{15^\circ} - L^*_{110^\circ})}{L^*_{45^\circ}}$$

Additionally, gloss measurements were performed on 60 tablets from coating trials of both PVA and NaCMC Opadry fx systems using Tricor Systems Incorporated, Gloss Analysis System Model 801A.

RESULTS

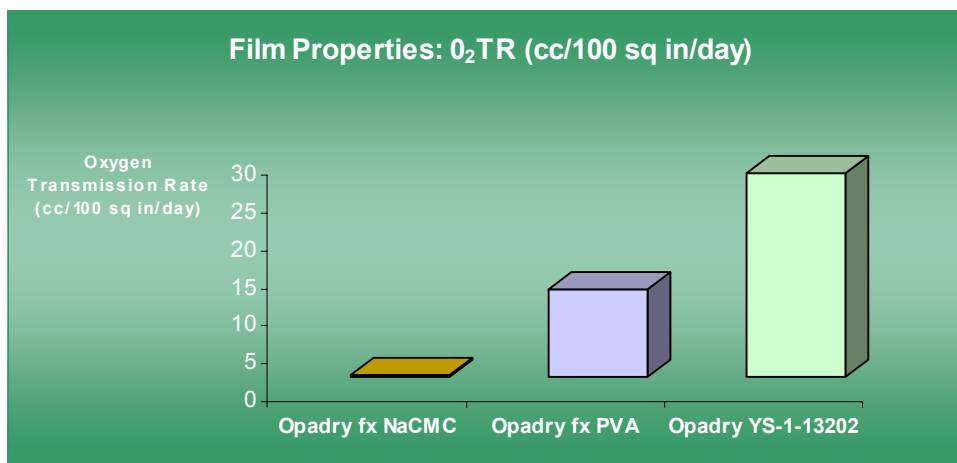
Figure 1. Water Permeability Testing (gH₂O/day/100 sq in)



The moisture vapour transmission rate (MVTR) of Opadry fx based on PVA (10.7 gH₂O/day/100 in²) is three times lower than that of films containing cellulosic polymers (31-35 gH₂O/day/100 in²).

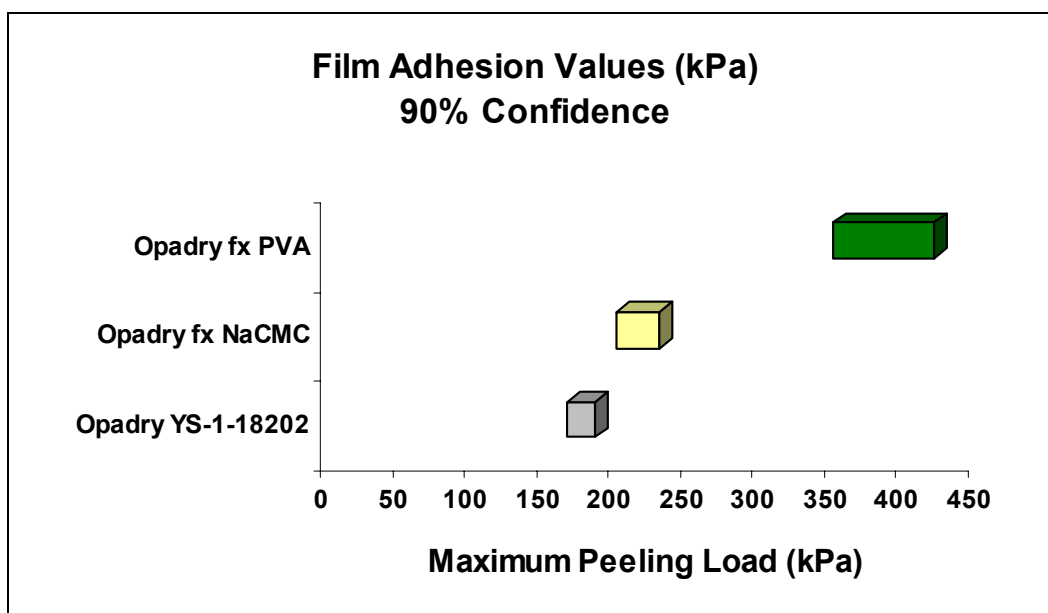
When the film coating application requires protection against ingress of moisture, Opadry fx containing PVA is the optimum choice.

Figure 2. Oxygen Permeability Testing (cc/100 in²/day)



Opadry fx PVA-based films exhibit better oxygen barrier properties (11.66 cc/100 in²/day) when compared to HPMC-based films, but it is not as good a barrier as Opadry fx based on NaCMC. Opadry fx containing NaCMC is the preferred choice when oxygen transmission and resultant API oxidation are primary concerns.

Figure 3. Film Properties: Adhesion



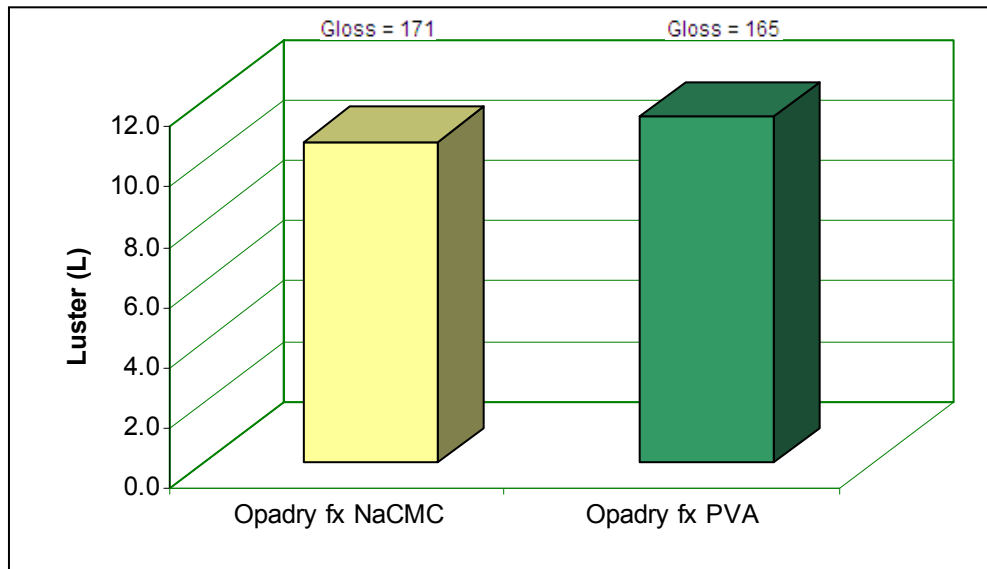
Even over a waxy substrate, tablet adhesion (379.7 kPa) for Opadry fx containing PVA far exceeds that of cellulosic film coatings. This characteristic enables Opadry fx with PVA to adhere to a wide variety of subcoats to provide a pearlescent finish to the coated tablets.

Figure 4. Film Properties of Opadry fx: Tensile Strength (σ) and Young's Modulus (E)

Film Coating Formulation	Tensile Strength		Modulus of Elasticity	
	σ (MPa)	SD (MPa)	E (MPa)	SD (MPa)
Opadry fx PVA	13.35	1.33	1349.3	123.3
Opadry fx NaCMC	45.35	2.63	2316.0	91.0

Both Opadry fx systems have more than adequate film strength and elasticity for typical film coating processes. Although the tensile strength of Opadry fx containing PVA is lower than Opadry fx with NaCMC, it is nearly two times more elastic. These values confirm the excellent film forming properties observed in actual coating trials.

Figure 5. Film Properties: Luster (L)



Opadry fx containing PVA (L=11.7) and Opadry fx based on NaCMC (L=11.0) have similar luster and gloss values. Both provide an elegant pearlescent appearance to the coated dosage form, as shown in the photo below.



CONCLUSIONS

Opadry fx special effects film coating systems:

- possess excellent mechanical film properties
- impart an elegant pearlescent and glossy appearance to solid dosage forms.

Opadry fx containing NaCMC is the preferred film coating for oxygen-labile dosage forms.

Opadry fx containing PVA is the preferred film coating for moisture-sensitive dosage forms.

REFERENCES

1. Oxidative Protection of Ibuprofen Using Opadry® fx™ Special Effects Film Coating System. F. Gulian, R. Steffenino, D. Ferrizzi, T. Farrell; AAPS; 2004
2. Correlation of Free Salicylic Acid Content to the Water Vapor Transmission Properties of Aqueous Film Coating Systems. K. Fegely & B. Prusak; AAPS; 2003

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