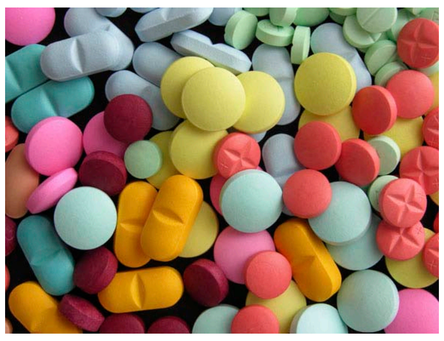

Film Properties and Performance of a Two Polymer Immediate Release Coating Formulation

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Introduction

HPMC based coatings have been widely used for nutritional supplement cores. HPMC based coatings often have limitations with nutritional supplements, such as a

- a typical upper limit of 15% solids in suspension leads to relatively inefficient processing time
- adhesion issues with pigmented coatings often necessitates a clear subcoat , adding material cost and processing time
- Logo definition of HPMC based coatings can be poor, unless a carbohydrate diluent is added. These diluents lead to decreased film strength and labeling issues (lactose, starch)

With the approval of PVA for use in nutritional supplements in the EU (E#1203), these issues can be overcome with PVA based coatings. PVA does have one significant potential limitation – the coatings must often be sprayed at lower spray rates or with a higher bed temperature (46-48C) in order to avoid overwetting issues. These elevated temperatures often preclude the use of PVA-only systems on temperature sensitive cores. By utilizing PVA as a secondary polymer in an HPMC based system, a coating formulation with increased processing efficiency potential at the lower processing temperatures of HPMC. This formulation also shows ideal film characteristics properties.

Materials and Methods

Free Film Casting: Suspensions of 20% solids in water were cast on aluminum pans and dried in a 55 C oven, followed by equilibration for 24 hours at 25 C/60% RH .

Measurement of free film strength and elasticity: 1” samples of the film were measured for thickness and tested with a Texture Technologies TA.XT2i texture analyzer. A 0.25” stainless steel ball probe was moved down to contact and then break the film. Measurements of force encountered by the probe and distance travelled were taken. Film strength is calculated as force per film thickness (kg/mm). Film elasticity was calculated as the distance in which force was applied with the ball probe to the film prior to breaking and is expressed as distance per film thickness (mm/mm).

Adhesion testing method: Flat faced placebo tablets (49.5% lactose/49.5% MCC/1% magnesium stearate) were compressed and coated with the sample coating formulations. The TA.XT2i texture analyzer was used to measure the pressure require to pull the coating from the face of the tablet core.

Tablets were coated in a Vector LDCS (300g or 1500g batches). Color measurements were taken with a Konica Minolta Spectrophotometer with OnColor QC software.

SheffCoat™ MP composition

Ingredient	E#	CI number	CAS number
Hydroxypropylmethyl cellulose / hypromellose (USP, EP, JP)	E464		9004-65-3
Polyvinyl Alcohol (USP, EP, JPE)	E1203		9002-89-5
Titanium dioxide (USP, JP, EP)	E171	77891	13463-67-7
Polyethylene glycol 3350 (USP, EP, JP)	E1521		25322-68-3
Talc (USP,EP, JP)	E553b		14807-96-6

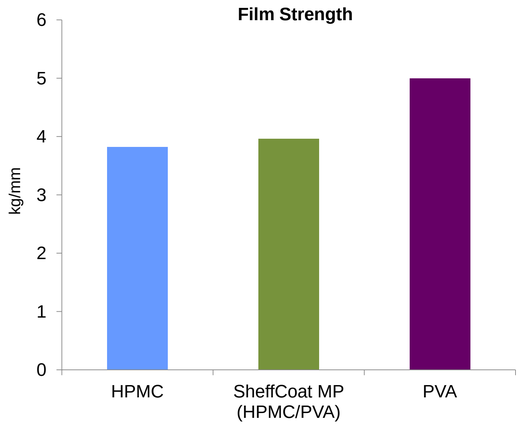


Figure 1: Film strength analysis
SheffCoat™ MP shows film strength identical to that of HPMC films; unlike other diluents such as carbohydrates, the addition of a secondary film former does not decrease film strength.

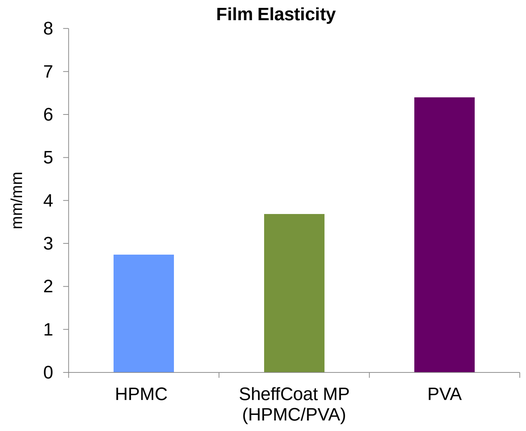


Figure 2: Free film elasticity
The use of PVA in conjunction with HPMC increases film elasticity over HPMC only films.

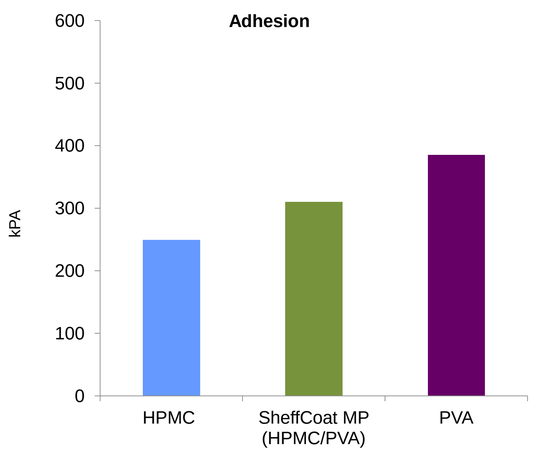


Figure 3: Adhesion testing
SheffCoat™ MP shows increased adhesion to tablet cores when compared to HPMC based coating films.

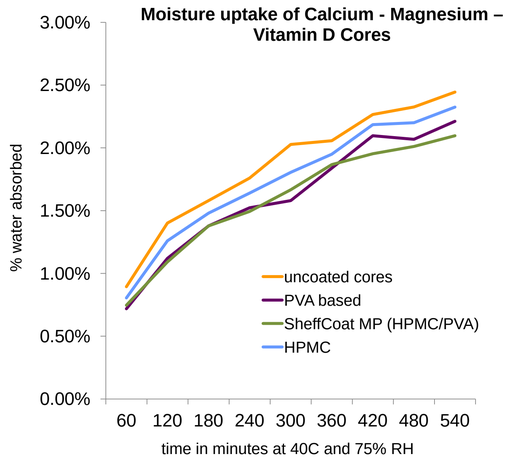


Figure 4: Moisture protection provided by SheffCoat™ MP on coated tablets
SheffCoat™ MP shows moisture protection equivalent to a PVA based coating on Calcium Magnesium Vitamin D tablets. Coated tablets were placed in an open dish in a stability chamber and monitored for weight change.

Color stability with SheffCoat MP

Placebo tablet cores were coated with colored versions of HPMC, PVA, and SheffCoat™ MP bases. A coated tablet color standard was made at day 0 and tablets were checked for color over time. In all cases, SheffCoat™ MP demonstrated better long term stability than the corresponding HPMC based coating, and was better than or equivalent to PVA alone in all but the chlorophyll color.
Note – values are delta Eab; a value of <3.0 is generally considered acceptable.

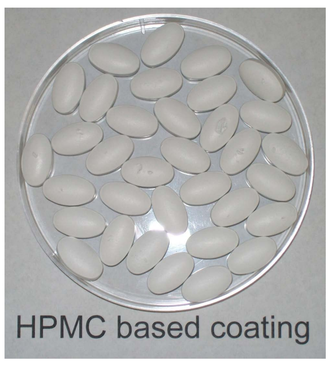
Color Stability Testing – Coated Placebos (180 days, ambient, amber poly bottles)			
	HPMC based coating	HPMC/PVA based coating	PVA based coating
Caramel	0.98	0.55	0.54
Chlorophyll	2.43	1.18	0.96
Riboflavin	0.92	0.55	1.44
Red beet	16.02	13.45	19.02
Black carrot	4.59	1.61	2.98

Logo definition of SheffCoat™ MP
The increased elasticity and adhesion of SheffCoat™ MP leads to excellent logo definition.

Decreased coating defects with SheffCoat™ MP

Calcium -magnesium-vitamin D cores were coated in a Vector LDSC (1.5kg pan) at 23 rpm (higher than normal pan rotation utilized to increase the frequency of tablet defects – the rapid tumbling increases frequency of collisions between tablet and stainless steel pan) . Tablets were examined for defects after coating. SheffCoat™ MP showed a decrease in tablet defects over HPMC and over the more expensive HPMC/HPC blend (added adhesion coating)

Coating Formulation	Defects per 100 tablets
HPMC based coating	21
HPMC with HPC (added adhesion formula)	4
SheffCoat™ MP (HPMC with PVA)	2



Summary

A dual polymer system composed of HPMC and PVA provides the benefits of

- low temperature application of HPMC based system
- moisture protection benefits of PVA
- smooth tablet surface – providing improved finished tablet appearance, particularly on poor tablet core formulations
- increased processing efficiency due to low viscosity of PVA
- excellent elasticity and adhesion, yielding excellent logo definition and reduced surface defects