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The Hygroscopicity of Moisture Barrier Film Coatings

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ABSTRACT The hygroscopicity of three commercial moisture-barrier film coatings, namely, Eudragit L30 D-55 (methacrylic acid–ethyl acrylate copolymer), Opadry AMB (polyvinyl alcohol based system), and Sepifilm LP 014 (hypromellose, microcrystalline cellulose, and stearic acid based formulation), was investigated using a dynamic vapor sorption apparatus. Moisture uptake by cast films and uncoated and coated tablet cores, which were designed to be hygroscopic, low hygroscopic, and waxy, was measured following exposure to repeat relative humidity (RH) cycles of 0-50-0-50-0%, 0-75-0-75-0%, and 0-90-0-90-0% RH at 25°C. Eudragit cast film exhibited the fastest equilibration but was also the least hygroscopic. Sepifilm had the fastest sorption and took up the greatest mass of water. The rate of uptake for Opadry film was similar to Sepifilm. However, this film continued to sorb moisture for a longer period. When returned to 0% RH it retained moisture in the film showing that it had a high affinity for moisture within the film. The data for the different cores indicated that there was very little benefit in using a moisture barrier film on cores with low hygroscopicity, the mass gain being a sum of that which would be expected to sorb to the film and that which sorbs to the uncoated core. There was, however, some advantage for hygroscopic cores where, even though the barrier coatings allowed substantial water sorption into the core, the extent of this was less and the rate of uptake lower than for the uncoated sample.

KEYWORDS Moisture sorption, Film coating, Moisture barrier, Eudragit, Opadry, Sepifilm

INTRODUCTION

Moisture is an important factor in the deterioration of medicinal products. Sorption of moisture must therefore be prevented or at least minimized for products that are susceptible to hydrolysis. This can be achieved by careful formulation, e.g., the selection of the appropriate excipients for tablets (Carstensen, 1993; Zografi & Hancock, 1994), and/or through the use of more efficient packaging (Allinson et al., 2001). For certain formulations of solid dosage forms, it is preferable to apply a polymer coating with moisture-barrier properties (Prinderre et al., 1997). This approach is appealing because polymers

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afford coatings that are mechanically strong and their permeability can be tailored to meet specific formulation needs.

The functional qualities of polymer films can be profoundly affected by the presence of moisture (Alvarez-Lorenzo et al., 2000; Cervera et al., 2004; Morillon et al., 2000). Sorbed moisture interacts with hydrophilic polymers disrupting inter- and intramolecular hydrogen bonds. This reduces chain cohesion and mechanical integrity, increases the free volume of the polymer, and may enhance permeation through the polymer (Cervera et al., 2004; Morillon et al., 2000). This is of particular significance to the functionality of moisture barrier coatings. Thus, the role of environmental conditions, particularly humidity, on moisture uptake by moisture barrier coatings and how such conditions affect barrier performance must be examined.

Moisture uptake and permeation through polymers is commonly analyzed in terms of the solution-diffusion mechanism. The basic assumption of this mechanism is that the permeants partition ("dissolve") in the polymer membrane at the upstream side and then travel down a concentration gradient to the downstream side where they subsequently desorb ("desolve"). The quantitative measure of the amount of permeant transported through the membrane is the permeability coefficient, P, which is a product of the sorption coefficient S, and the diffusion coefficient D (Debeaufort et al., 1994; Vieth & Sladek, 1965):

$$P = [S][D] \quad (1)$$

The solubility coefficient S is a measure of the amount of penetrant sorbed by the polymer while the diffusion coefficient D characterizes the ability of the permeant to move within the polymer. Experimentally, the diffusion coefficient is obtained from sorption kinetics plots while S is obtained from the linear portion of the sorption isotherm where it is assumed Henry's law applies (Debeaufort et al., 1994; Rodríguez et al., 2003; Ruthven, 2004; Vieth & Sladek, 1965).

Data on the utility of moisture barrier coatings is very limited. Although the general consensus for formulation of moisture sensitive drug substances is to use excipients of low hygroscopicity and/or low water activity (Ahlneck & Zografi, 1990; Zografi & Hancock, 1994), it is not clear whether the nature of the tablet formulation influences the performance of barrier coatings. To the authors' knowledge, no work has previously evaluated the sorption properties of barrier coatings, especially after application to tablet cores of different hygroscopicities. This study, therefore, aimed to evaluate the sorption and desorption properties of three moisture barrier coatings, i.e., Eudragit L30 D-55 (a methacrylic acid–ethyl acrylate copolymer), Opadry AMB (polyvinyl alcohol based system), and Sepifilm LP 014 (hypromellose, microcrystalline cellulose, and stearic acid based formulation) after application onto tablet cores designed to be highly hygroscopic, low hygroscopic, and waxy. Dynamic vapor sorption technique was adopted as the method of choice as it has been been demonstrated a suitable technique for studying sorption phenomenon in pharmaceutical materials (Begren, 1994; Lane & Buckton, 2000).

MATERIALS AND METHODS

Materials

Eudragit L30 D-55, Opadry AMB, and Sepifilm LP 014 were free samples from Rohm GmbH (Darmstadt, Germany), Colorcon Limited (Dartford, UK), and Seppic UK Ltd. (Hounslow, London, UK), respectively. Tablet excipients were lactose monohydrate NF (Fastflow, Foremost, Wisconsin, USA), dibasic calcium phosphate dihydrate, BP (Emcompress, Penwest, Patterson, New York, USA), pregelatinized starch (Starch 1500, Colorcon Limited, Dartford, UK), and microcrystalline cellulose (Avicel PH101, FMC Corporation). All other materials were from Sigma-Aldrich and were of analytical grade.

METHODS

Preparation of Coating Dispersions

Opadry AMB and Sepifilm LP are proprietary ready-to-use systems that are supplied in powder form for reconstitution in water. The Opadry AMB system consists of partly hydrolyzed polyvinyl alcohol, titanium dioxide, talc, lecithin soya, and xanthan gum. It is recommended for use as a 25% w/v aqueous dispersion. Sepifilm LP is comprised of hypromellose, microcrystalline cellulose, stearic acid, and titanium

TABLE 1 Formula for Preparing Eudragit L30 D-55 Coating Dispersion

Ingredient	Quantity (*g*)
Polymer solution	
Eudragit L 30 D-55	333
Triethyl citrate	10
Water	267
Pigment suspension	
Talc	168
Titanium dioxide	100
Polyethylene glycol 6000	17
Sodium carboxymethylcellulose	5
Water	700

dioxide for use as a 12% w/v aqueous dispersion. Eudragit L30 D-55 is an anionic polymer supplied as a 30% w/v aqueous dispersion. Although it is mainly used for enteric coatings, it is also recommended for moisture barrier coatings where it is used as a 15% w/w aqueous dispersion. The manufacturer's recommended formula for such coatings is shown in Table 1 (Rohm GmbH). The coating dispersion was prepared by mixing a specified amount of Eudragit L30 D-55 and triethyl citrate with part of the water. In a separate container, polyethylene glycol was dissolved in the remaining amount of water, to which talc and sodium carboxymethylcellulose were added. The mixture was then homogenized with a high speed stirrer for 10 min. The polymer suspension and the pigment suspension were then combined with gentle stirring which was continued during coating.

Cast Film Preparation

Cast films were prepared by dispensing respective coating dispersions onto shallow teflon molds. Dispersions were then evenly spread with the aid of a draw down bar. Molds were subsequently transferred into a hot air oven and dried at 40°C for eight hours. After cooling, films were removed from molds and stored at room temperature over silica gel. Film thickness was measured to the nearest 0.001 mm by a digital micrometer (Mitutoyo Corporation, Japan).

Tablet Manufacture and Coating

Tablet cores were manufactured by direct compression using a Manesty Type F3 single stage tablet press (Manesty Machines Ltd., Liverpool, UK) equipped with 8.0 mm standard concave tooling. Details of the three tablet formulations used were: lactose monohydrate (69.4%), microcrystalline cellulose (15.0%), pre-gelatinized starch (15.0%), magnesium stearate (0.5%), and colloidal silica (0.1%) for hygroscopic cores; dibasic calcium phosphate dihydrate (99.5%) and magnesium stearate (0.5%) for low hygroscopic cores; and lactose monohydrate (78.0%), carnauba wax (14.0%), talc (3%), magnesium stearate (4.0%), and colloidal silica (1.0%) for waxy cores. The target tablet fill weight and mean crushing strength were 200 mg and 125 N, respectively.

Coating was undertaken in an Aeromatic Strea 1 (Aeromatic-Fielder AG, Bubendorf, Switzerland) fluidized bed coater. Coating conditions were: charge 100 g, inlet temperature 40±2°C, drying temperature 38±2°C, spray rate 5 mL/min, and atomizing air pressure of 0.2 bar. Coating levels were in keeping with dry weight gains recommended by the respective manufacturers, i.e., Eudragit L 30 D-55 1.8% (or a polymer loading of 1.0 mg/cm^2), Opadry AMB 4%, and Sepifilm LP 3%.

Vapor Sorption Studies

Moisture sorption/desorption of cast films and uncoated and coated tablet cores was studied in a Dynamic Vapour Sorption apparatus (DVS 1, Surface Measurement Systems, London, UK) equipped with a Cahn D-200 digital recording balance, a moisture sorption analyzer, and an IBM compatible PC with DVSWIN software that allowed pre-programming of sorption/desorption regimes. A description and applicability of the dynamic vapor sorption technique has been made by (Begren, 1994). In this study, the following relative humidity (RH) cycles were employed, i.e., 0-50-0-50-0% RH, 0-75-0-75-0% RH, and 0-90-0-90-0% RH. The temperature was maintained at 25°C with the help of an incubator. All reported experiments were performed in triplicate unless otherwise stated.

RESULTS AND DISCUSSION

Moisture Sorption Profiles of Cast Films

The sorption and desorption profiles of the films following exposure at the 0-90-0-90-0% RH cycle are

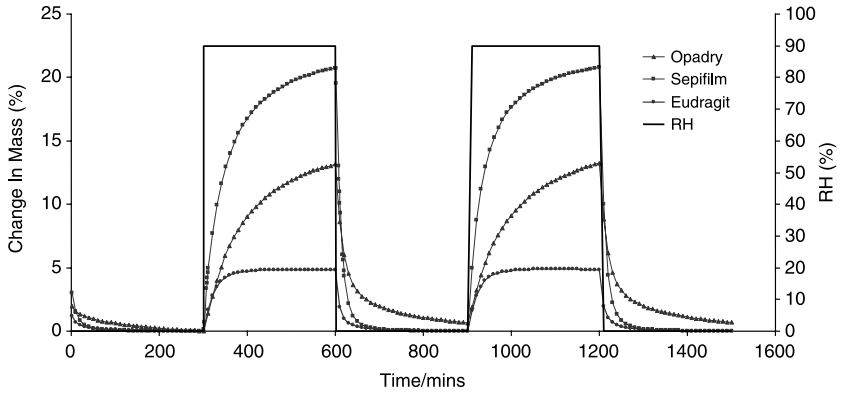

FIGURE 1 **Moisture Sorption Profiles After Exposure to 0-90-0-90-0% RH Holding at Each Stage for 300 min at 25°C for Cast Films.**

shown in Fig. 1. Data for the mean moisture uptake or loss, $M_{(t)}$ at 0-90-0-90-0% RH, 0-75-0-75-0% RH, and 0-50-0-50-0% RH is summarized in Table 2. These values were calculated from the weight, $W_{(t)}$, recorded at time $t=600$ min or 1200 min and the weight, $W_{(d)}$, of the dried sample at time $t=300$ min, 900 min, or 1500 min (refer to Eq. 2):

$$M_{(t)} = W_{(t)} - W_{(d)}/W_{(d)} \times 100 \qquad (2)$$

The results show that Eudragit has the fastest equilibration and sorbs only a limited amount of moisture. Sepifilm has the fastest sorption and takes up the greatest amount of moisture but does not reach equilibrium within the experimental time. The rate of sorption for Opadry is similar to that of Eudragit, but Opadry continues to sorb moisture for a longer period and is not at equilibrium when the sorption process is stopped.

Desorption from the Eudragit film appears to be equal and opposite to the sorption response, with very rapid equilibration to the dry state. Sepifilm shows very rapid desorption, equilibrating to the dry state much more rapidly than during sorption. The behavior of Opadry films is quite different with desorption seeming to be a two-step kinetic processes, a rapid event followed by a very slow desorption resulting in incomplete moisture loss. Although Sepifilm is the most hygroscopic film (presumably due to the hydrophilic nature of the hypromellose and microcrystalline cellulose), it loses moisture much more easily than it gains.

Sorption and Desorption Kinetics

The kinetics of sorption or desorption in polymer coatings are commonly interpreted in terms of the diffusion coefficient which characterizes the rate of diffusion of penetrant molecules in the polymer (Debeaufort et al., 1994; Ruthven, 2004; Vieth & Sladek, 1965). Crank (1968) proposed a model for calculating diffusion coefficients in polymer films. This model is basically a differential solution to Fick's second law applied to a homogenous film with a

TABLE 2 **Amount of Moisture [$M_{(t)}$] Sorbed or Desorbed by Eudragit L30, Opadry AMB and Sepifilm LP Cast Films Following Exposure to 0-50-0-50-0% RH, 0-75-0-75-0% RH, and 0-90-0-90-0% RH Cycles**

	$M_{(t)}$ (std. dev)		
RH cycle/coating	Eudragit L 30	Opadry AMB	Sepifilm LP
0-50	1.26 (0.0035)	1.96 (0.058)	4.59 (0.011)
50-0	1.26 (0.001)	1.79 (0.020)	4.59 (0.020)
0-75	2.74 (0.004)	5.46 (0.010)	9.17 (0.015)
75-0	2.74 (0.031)	4.55 (0.020)	9.17 (0.007)
0-90	4.90 (0.015)	12.26 (0.012)	21.84 (0.014)
90-0	4.87 (0.010)	10.43 (0.020)	21.85 (0.233)

Values (% dry basis) computed from means of both cycles for $n=3$ runs.

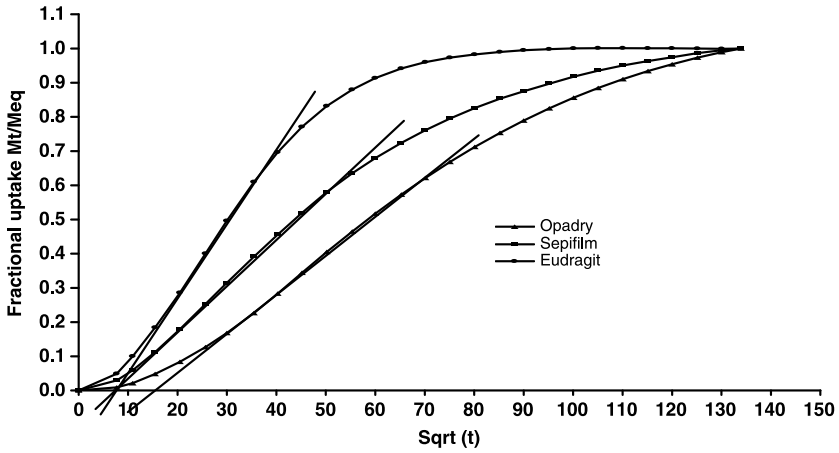

FIGURE 2 **Fractional Uptake, $M_{(t)}/M_{(eq)}$ Versus Square Root of Time Plot Showing the Kinetics of Moisture Sorption for Cast Films at 0-90% RH Gradient.**

constant diffusion coefficient. The simplified form of this model is as follows:

$$M_{(t)}/M_{(eq)} = 4(Dt/\pi L^2)^{1/2} \qquad (3)$$

where $M_{(t)}$ is the moisture uptake at time, t (s), and $M_{(eq)}$ is the uptake at saturation for a film of thickness L, with diffusion coefficient D (cm^2/s) subjected to a step change in surface concentration of permeant (e.g., a change in RH). A plot of the fractional uptake, $M_{(t)}/M_{(eq)}$ versus $(t)^{1/2}$ is initially linear but levels off as $M_{(t)}/M_{(eq)}$ approaches 1. Kinetics such as these are known as Fickian. The coefficient D is calculated from the gradient of the linear portion of the curve, i.e., $D=\pi S^2 L^2/4$.

Figures 2 and 3 show the fractional uptake versus the square root of time plots for sorption and desorption at the 0-90% RH and 90-0% RH gradients (for 0-90-0-90-0% RH cycle). The plots show sigmoidal curvature and are consistent with published reports for other polymer systems displaying the so-called non-Fickian kinetics (Debeaufort et al., 1994; Vieth & Sladek, 1965). In Fig. 2, sorption curves are displaced towards the time coordinate and are consistently below the corresponding desorption curves (Fig. 3) indicating significantly higher desorption rates in the films. Although the sorption profile (in Fig. 1) shows that Sepifilm has the fastest sorption rates and the highest moisture uptake, the kinetics plot indicates that overall, Eudragit has the fastest kinetics. The kinetics for Opadry suggest significantly slower sorption and desorption processes pointing to a possible slowing up of the diffusion process by this film.

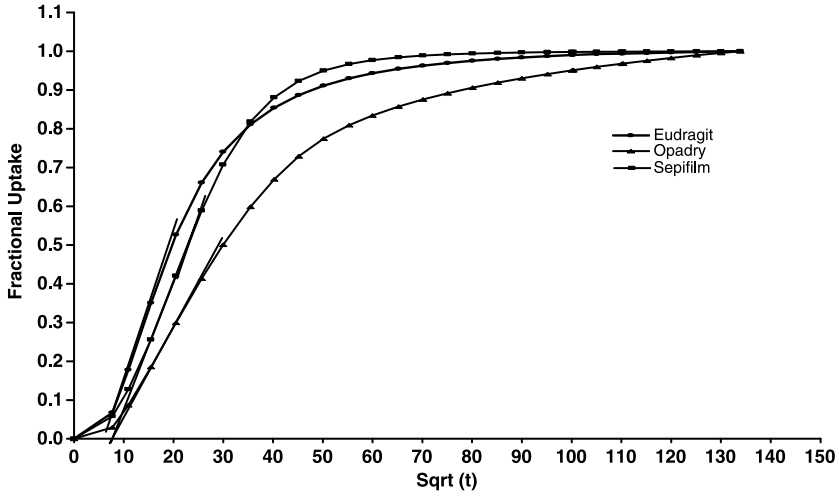

FIGURE 3 **Fractional Uptake, $M_{(t)}/M_{(eq)}$ Versus Square Root of Time Plot Showing the Kinetics of Moisture Desorption for Cast Films at 90-0% RH Gradient.**

TABLE 3 **Diffusion Coefficients, *D* (cm/s) of Cast Films for Sorption and Desorption Cycles Following Exposure to 0-50-0-50-0% RH, 0-75-0-75-0% RH, and 0-90-0-90-0% RH**

Polymer	Thickness *L* (μm)	% RH gradient	D ($\times 10^{-8}$) cm/s (std. dev)	R^2
Sorption				
Eudragit L	50	0-90	9.07 (0.981)	0.995
		0-75	9.33 (2.022)	0.991
		0-50	24.05 (3.505)	0.987
Opadry	80	0-90	5.84 (2.003)	0.986
		0-75	11.88 (1.332)	0.985
		0-50	5.64 (0.616)	0.989
Sepifilm	60	0-90	6.411 (1.462)	0.994
		0-75	30.66 (2.177)	0.993
		0-50	83.95 (0.526)	0.988
Desorption				
Eudragit L	50	90-0	21.512 (0.535)	0.975
		75-0	15.394 (1.148)	0.986
		50-0	23.371 (1.760)	0.997
Opadry	80	90-0	24.606 (1.712)	0.978
		75-0	15.284 (0.524)	0.999
		50-0	66.380 (0.589)	0.996
Sepifilm	60	90-0	50.990 (0.534)	0.999
		75-0	76.454 (0.603)	0.988
		50-0	108.950 (0.585)	0.977

Film thickness approximated to the nearest decimal. R^2 shown for fitted and experimental values between $0.1 \geq M_t/M_\infty \leq 0.6$.

Values of *D* obtained from a least squares line of best fit for $0.1 \geq M_{(t)}/M_{(eq)} \leq 0.5$ are tabulated in Table 3. The data corroborate well with the interpretation above. It is apparent that *D* increases with RH but not by a big magnitude suggesting that *D* is not strongly dependent on the amount of moisture in the films. When the kinetics are Fickian, diffusion is the rate limiting step as the rate of diffusion is slower than the rate of polymer chain relaxation (Rodríguez et al., 2003; Ruthven, 2004). The corresponding diffusion coefficient is proportional to the concentration of moisture. However, when the kinetics of sorption are also influenced by rate of relaxation of polymer chains in response to the presence of moisture, the amount sorbed or desorbed increases gradually with time, resulting in apparent slow kinetics. The latter scenario might be the reason for the observed trends in the diffusion coefficients, but given the limited information at our disposal, it is impossible to make firm conclusions

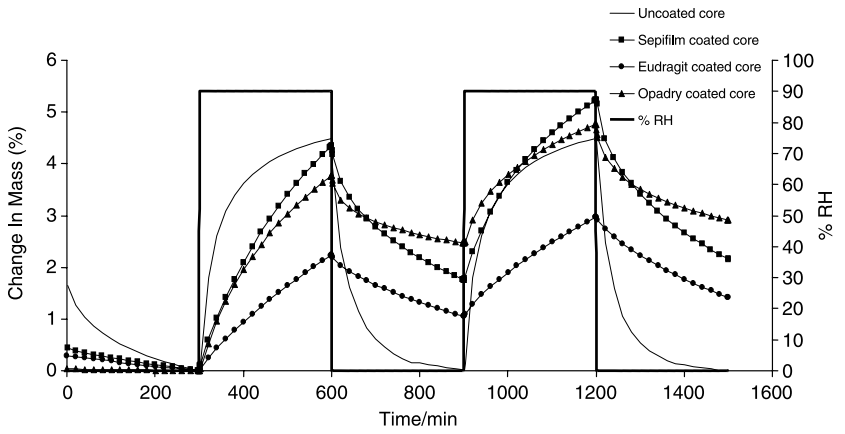

FIGURE 4 **Moisture Sorption Profiles After Exposure to 0-90-0-90-0% RH Holding at Each Stage for 300 Min at 25°C for Hygroscopic Cores Without Coating and With Different Barrier Coats.**

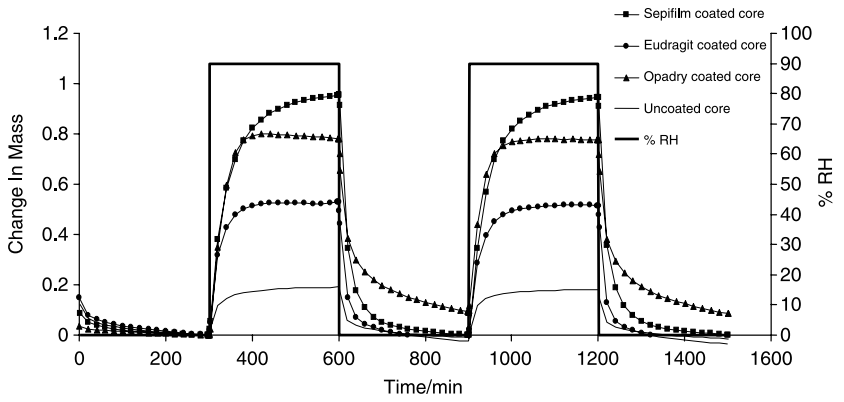

FIGURE 5 **Moisture Sorption Profiles After Exposure to 0-90-0-90-0% RH Holding at Each Stage for 300 Min at 25°C for Low Hygroscopic Cores Without Coating and With Different Barrier Coats.**

on the behavior of the films at this juncture without further investigations.

Moisture Sorption by Coated and Uncoated Tablet Cores

The data for moisture sorption to the different tablet cores at 0-90-0-90-0% RH cycle are shown in Figs. 4, 5, and 6. Data at other RH cycles is summarized in Tables 4, 5, and 6. It is clear that the nature of the tablet core has a substantial influence on the extent of moisture sorption. Uncoated and coated hygroscopic cores sorb more moisture than the uncoated and coated waxy cores which in turn have some differences over the sorption to the uncoated and coated low hygroscopic cores. Uncoated hygroscopic cores clearly show an exponential rise in mass uptake and are far from reaching equilibrium in the 300 min exposure time.

The desorption cycle of uncoated hygroscopic cores shows a return to the original dry mass. For coated hygroscopic cores, the second exposure to RH results in more uptake than the first. It is not clear whether this is a function of the core or the barrier coating. In any case, it may be that following contact with moisture during the first sorption cycle barrier integrity is somewhat compromised. This might result in more moisture reaching the cores. Alternatively, the hygroscopicity of the films might be increasing as a result of moisture destroying polymer crystallinity.

Coating of the hygroscopic cores with Eudragit results in a reduction of total moisture sorbed, clearly due to a change in sorption kinetics. The Eudragit free film itself rapidly established an equilibrium mass gain and then rapidly desorbed moisture on drying. The coating on the tablet however, results in a system that does not allow the tablet to equilibrate as rapidly as when it is uncoated. Also, despite the fact that both the Eudragit film and the tablet core are able to lose

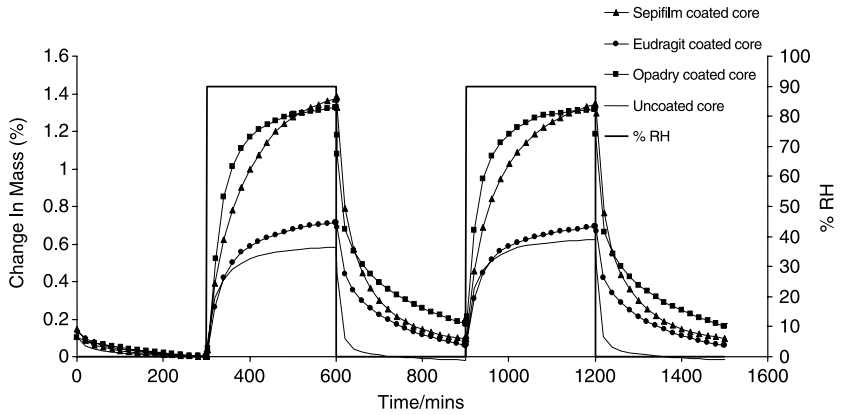

FIGURE 6 **Moisture Sorption Profiles After Exposure to 0-90-0-90-0% RH Holding at Each Stage for 300 Min at 25°C for Waxy Cores Without Coating and With Different Barrier Coats.**

TABLE 4 Amount of Moisture [$M_{(t)}$] Sorbed or Desorbed by Uncoated and Coated Hygroscopic Tablet Cores Following Exposure to 0-50-0-50-0% RH, 0-75-0-75-0% RH, and 0-90-0-90-0% RH Cycles

	$M_{(t)}$ (std. dev)			
RH cycle/core	Uncoated	Eudragit L 30	Opadry AMB	Sepifilm LP
0-50%	1.57 (0.010)	0.91 (0.005)	1.09 (0.001)	1.21 (0.006)
50-0%	1.57 (0.011)	0.57 (0.006)	0.85 (0.003)	0.98 (0.006)
0-75%	2.40 (0.021)	1.00 (0.066)	1.40 (0.015)	2.17 (0.000)
75-0%	2.40 (0.023)	0.69 (0.010)	0.60 (0.006)	1.47 (0.001)
0-90%	0.25 (0.006)	2.35 (0.025)	3.78 (0.010)	3.56 (0.012)
90-0%	4.25 (0.003)	1.32 (0.006)	2.36 (0.021)	2.56 (0.005)

Values (% dry basis) computed from means of both cycles for $n=3$ runs.

moisture completely during desorption cycles, the Eudragit coated tablet does not. Both the sorption and desorption are pseudo zero order kinetic processes, but with much faster rate of sorption than desorption. Presumably the slower desorption relates to the geometry of the diffusion path which is a typical cause of hysteresis.

For Sepifilm coated hygroscopic cores, the process again failed to reach equilibrium and showed substantial hysteresis, such that desorption did not complete in the 300 min window. The total mass of moisture sorbed was slightly less than that sorbed by the uncoated cores, but much more than could possibly be accommodated in the film (total uptake for the cast film was ≈21%, which for a 3% coating on the tablet cores would accommodate 21*3/100=0.63%). Consequently (assuming the retention of moisture in the film to be similar to that seen with cast films), the mass of moisture transferring to the tablet core is greater for this coat.

The Opadry film, which has already shown a tendency to retain moisture during desorption, shows a somewhat similar pattern for coated cores but with the desorption rate being very much different to the sorption rate. This behavior is much more extreme for the coated hygroscopic tablets. In the first sorption process, 3.7% moisture was sorbed (the mass expected to be accommodated in the film if it behaved as a free film would be 13*4/100=0.52%). Interestingly, this is approximately the mass that was desorbed rapidly at the start of the first desorption cycle. It is possible, therefore, that the mass of moisture that is transferred remains in the tablet core, whereas that in the film desorbs again. The second sorption process results in much less moisture uptake than the first, as if the process were moving toward a pseudo-equilibrium state. The quantity of moisture desorbed after the second sorption process is greater than that for the first, indicating a greater mass of moisture that is situated near the surface in an environment from which desorption is easy.

The extent of sorption to the cores with low hygroscopicity (Fig. 5) is much less than for the hygroscopic cores (Fig. 4). The data for the low hygroscopicity are close to being a sum of the mass of moisture that is sorbed by the uncoated core and the mass that is

TABLE 5 Amount of Moisture [$M_{(t)}$] Sorbed or Desorbed by Uncoated and Coated Low Hygroscopic Tablet Cores Following Exposure to 0-50-0-50-0% RH, 0-75-0-75-0% RH, and 0-90-0-90-0% RH Cycles

	$M_{(t)}$ (std. dev)			
RH cycle/core	Uncoated	Eudragit L 30	Opadry AMB	Sepifilm LP
0-50%	0.08 (0.001)	0.13 (0.001)	0.19 (0.001)	0.27 (0.003)
50-0%	0.08 (0.006)	0.13 (0.000)	0.16 (0.000)	0.26 (0.002)
0-75%	0.11 (0.006)	0.19 (0.001)	0.35 (0.000)	0.26 (0.009)
75-0%	0.12 (0.000)	0.18 (0.001)	0.14 (0.000)	0.27 (0.003)
0-90%	0.19 (0.006)	0.53 (0.001)	0.79 (0.000)	0.95 (0.009)
90-0%	0.19 (0.000)	0.53 (0.001)	0.69 (0.000)	0.27 (0.003)

Values (% dry basis) computed from means of both cycles for $n=3$ runs.

TABLE 6 Amount of Moisture [$M_{(t)}$] Sorbed or Desorbed by Uncoated and Coated Waxy Tablet Cores Following Exposure to 0-50-0-50-0% RH, 0-75-0-75-0% RH, and 0-90-0-90-0% RH Cycles

	$M_{(t)}$ (std. dev)			
RH cycle/core	Uncoated	Eudragit L 30	Opadry AMB	Sepifilm LP
0-50%	0.23 (0.003)	0.25 (0.001)	0.33 (0.001)	0.38 (0.006)
50-0%	0.19 (0.001)	0.25 (0.000)	0.30 (0.005)	0.36 (0.002)
0-75%	0.37 (0.018)	0.40 (0.01)	0.52 (0.023)	0.75 (0.005)
75-0%	0.35 (0.002)	0.40 (0.012)	0.14 (0.011)	0.75 (0.006)
0-90%	0.63 (0.017)	0.71 (0.010)	1.32 (0.018)	1.36 (0.011)
90-0%	0.58 (0.030)	0.65 (0.013)	1.10 (0.027)	0.65 (0.020)

Values (% dry basis) computed from means of both cycles for $n=3$ runs.

taken up by the free film (refer to the previous example above for this mass corrected to tablet weight gain of coat). For example, the Sepifilm coat is expected to take up ca 0.63%, the core 0.2%, and the Sepifilm coated core takes up 0.9% (which is close to expected given the inevitable differences between the coat on the tablet and the cast film; Fig. 1). Equally, the Opadry coated low hygroscopic cores have a mass gain that is only slightly above that which would be expected from the sum of uptakes on the uncoated core and the cast film. The coated low hygroscopic cores all lose their mass in a similar way to that seen for the cast films, with only the Opadry coated sample retaining moisture in a similar way to Opadry free film (Fig. 1). It is reasonable to assume that the coatings on low hygroscopic cores perform in a similar way to free films, with little sign of excess moisture transfer to the cores, but equally with little sign of protection to the core over that seen for the uncoated tablets.

The data for the waxy cores (Fig. 6) are interesting in comparison to Figs. 4 and 5. For instance, the difference between the uncoated sample and the Eudragit coated core is smaller than that seen for the low hygroscopic cores (Fig. 5). The Sepifilm coated samples show a displacement above the core mass uptake that is in keeping with the data in Fig. 5 and which would indicate that the response here is a sum of the moisture held in the film (ca that expected from the cast film results) and the mass of moisture taken up by the uncoated core. As previously, there is modest accumulation of moisture in the Opadry coat.

The data for the low hygroscopic and waxy cores indicate that there is no real benefit of using a moisture barrier for these formulations, as the final result is essentially a sum of the mass of moisture that would be expected to be taken up by the free film and the uncoated tablets. For the hygroscopic cores, all of the coats did limit the total mass of moisture in the system in comparison with the uncoated cores. Eudragit was the most effective coating for limiting moisture sorption but equally the most effective in limiting desorption from the core, which could be a disadvantage.

CONCLUSIONS

Moisture-barrier film coatings slowed moisture sorption into hygroscopic tablet cores. However, the extent and rate of moisture sorption was influenced by the tablet core formulation and there was no discernible benefit for cores which sorbed limited mass of moisture when uncoated.

On the basis of the amount of moisture sorbed, Sepifilm and Opadry films were more hygroscopic than the Eudragit film. The moisture sorption–desorption behavior of the films was very complex, and films exhibited different rates and extents of sorption and desorption. The Opadry film showed a tendency to retain moisture within the film which was attributed to a high moisture binding capacity.

The benefits of moisture barrier films, in terms of rate and extent of moisture transfer from an environment with abundant water vapor, would seem to be limited to formulations with hygroscopic tablet cores.

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