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DVS Application Note 111

Application of Dynamic Vapor Sorption to Assess Moisture Protection by Tablet Film Coatings

Rebecca Griffin[1], Majid Naderi[1], Andrew Davies[1], Manaswini Acharya[1], Daniel Burnett[1], M. Majumder[2], D. McCarthy[3].
[1]Surface Measurement Systems Ltd.
[2]M2M Pharmaceuticals Ltd.
[3]DM Microscopy Services.

Application of Dynamic Vapor Sorption to Evaluate Moisture Protection Provided by Film Coating on Tablets of Different Film Thicknesses.

Introduction

Coating materials act as moisture barriers to protect pharmaceutical tablets, ensuring product stability, shelf-life and drug release performance. Film uniformity and efficacy are dependent on the precise control of coating parameters, specifically film thickness.

This study investigated the impact of film quality on moisture barrier performance by analysing three tablets with thicknesses varying in the range of 30 - 600 µm. Dynamic Vapor Sorption (DVS) was employed to evaluate the water uptake and sorption kinetics, aiming to quantify the efficiency of film-coated tablets at varying thicknesses. Cross-sectioned tablets were analysed to evaluate moisture uptake within the bulk/core material.

DVS was also employed in this project to determine the water vapor diffusion constant of Tablet 1 (whole) at ambient temperature (25 °C) and at slightly above human core temperature (40 °C) using Fick's Law. The diffusion constants are calculated by analysing the water sorption kinetics at selected RH's. For a single humidity step experiment conducted on a double-sided film of thickness d, the initial kinetics of sorption into the bulk of a material may be described by Fick's Law, as shown in Equation 1.

Equation 1

$$\frac{M_t}{M_\infty} = \frac{4}{d}\sqrt{\frac{Dt}{\pi}}$$

Where M_t is the amount of moisture adsorbed at time t, and M_∞ is the amount adsorbed at thermodynamic equilibrium. The equation is valid for values $M_t/M_\infty < 0.4$, where a plot M_t/M_∞ against $t^{1/2}/d$ is linear. The diffusion constant D can be calculated from the slope of this line. (Application Note 16)

Methods

The objective of this experiment was to analyze the water sorption behavior of 3 off-the-shelf vitamin tablets with varying film thicknesses. Figure 1 presents cross sectioned Scanning Electron Microscopy (SEM) images of the tablets, with measured film thickness calculated using the SEM software.

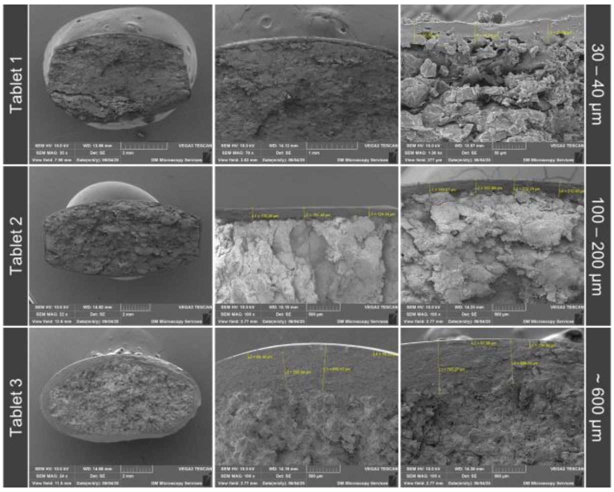

Figure 1: Images of samples showing Tablet 1, Tablet 2 and Tablet 3, in two different experimental forms: whole and cut. SEM images were carried out by M2M Pharmaceuticals and DM Microscopy Services.

Water sorption measurements were performed using the DVS Adventure, DVS Resolution and DVS intrinsic instruments (SMS), with data analysis conducted using the DVS Advanced Analysis Suite (SMS). The water sorption method consisted of two sequential steps outlined in Table 1 and Figure 2. Samples were initially dried step at 0% RH for 10 hours, followed by a single humidity step at 60% RH for 24 hours.

Table 1: DVS method parameters.

Step	RH (%)	Time (min)
Dry	0	600
RH Step	60	1440

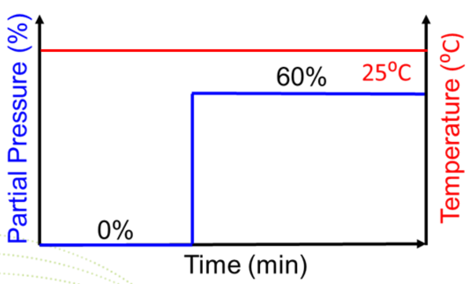

Figure 2: Experimental method

The diffusion coefficients were calculated using the DVS Advanced Analysis Suite (SMS) based on Fick's Law (Equation 1), with a film thickness of 35.9 µm determined from averaging the measured SEM data for Tablet 1.

Results and Discussion

Initial experiments were performed on whole tablets at 25°C. Cross sectioned SEM image data (Figure 1) determined the film thickness of the tablets as follows: Tablet 1, 30-40 µm; Tablet 2, 100-200 µm; and Tablet 3, ~600 µm.

Table 2: Mass and moisture uptake of tablets whole and cut

Tablet Type	Form	Mass (mg)	Moisture Uptake (%)	Film Thickness (µm)
Tablet 1	*whole*	*150.9*	*2.96*	30 - 40
	cut	*80.81*	*3.94*	
Tablet 2	*whole*	*632.36*	*1.61*	100 - 200
	cut	*179.46*	*4.43*	
Tablet 3	*whole*	*575.5*	*no uptake*	~600
	cut	*126.67*	*0.96*	

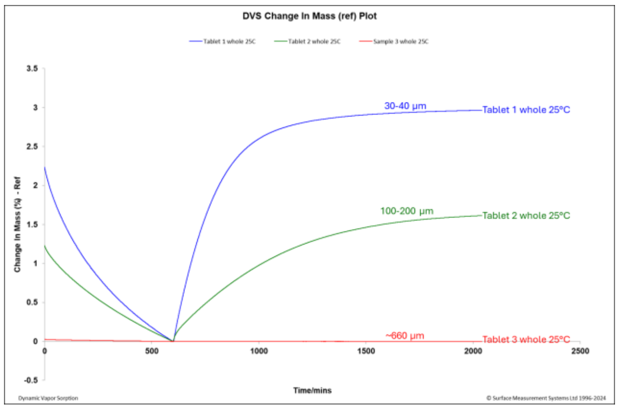

Figure 3: DVS change of mass overlay plots of Tablet 1, 2 and 3 whole at 25°C.

DVS instrument measured the moisture uptake (% mass uptake) of the tablets at 60% RH, shown in Table 2.

Whole tablet measurements showed increased film coating thickness progressively reduced the moisture uptake (Figure 3), indicating improved moisture barrier performance with increased coating thickness.

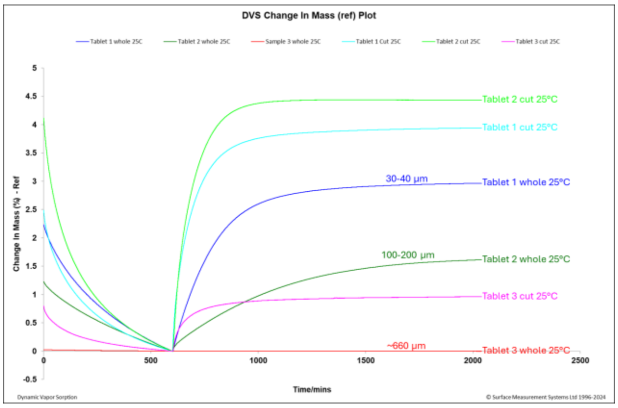

Figure 4: DVS change of mass overlay plots of Tablets 1, 2 and 3 whole at 25°C.

Cross-sectioned (cut) tablets exhibited higher moisture uptake, than the equivalent whole tablet, across all samples (Figure 4). Cutting the tablets compromised the integrity of the coating and exposed the core pharmaceutical material, which increased the uptake of water. Table 2 quantitatively presents the increase in uptake of the cut tablets compared to the whole (coated) equivalent, highlighting the extent to which the coating reduces moisture absorption.

To quantify the protective effect of the film coating, a reduction ratio was calculated using Equation 2:

Equation 2

$$Reduction\ Ratio\ (\%) = 100 - \frac{Uptake_{Whole}}{Uptake_{Cut}} \times 100$$

This ratio represents the proportion of moisture uptake prevented by the coating relative to the exposed core material. The calculated reduction ratios demonstrate that the film coating reduced moisture uptake by approximately 25% for Tablet 1, 64% for Tablet 2, and 100% for Tablet 3, highlighting the strong correlation between coating thickness and moisture barrier performance.

Diffusion coefficient experiments were conducted on Tablet 1 (whole) at 25°C and 40°C.

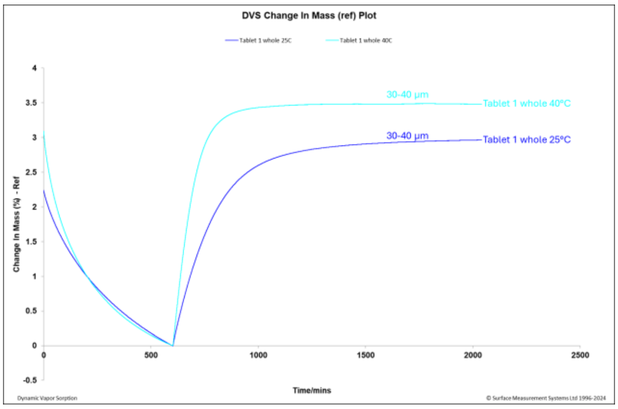

Figure 5: DVS change of mass overlay plots of Tablet 1 (whole) at 25°C and 40°C.

Water sorption data (Figure 5) demonstrated an increased water uptake at the elevated temperature, with values 3.48% at 40°C compared to 2.96% for 25°C (Table 3). The data plot also suggests that the tablet exhibits faster kinetic behavior at 40°C.

Tablet type	Temp (°C)	Mass (mg)	Moisture Uptake (%)	Diffusion Coefficient (cm²/s)	R^2 value (%)	Thickness (µm)
Tablet 1 (whole)	25	150.9	2.96	1.33×10^{-10}	99.47	35.9
	40	147.5	3.48	3.15×10^{-10}	98.92	

Table 3: Mass, moisture uptake and diffusion coefficient at 25°C and 40°C.

The kinetic behavior observed in Figure 5 is supported by the diffusion constant analysis. The increase in temperature resulted in higher moisture diffusion rates, with values of 1.33×10^{-10} cm²/s at 25 °C and 3.15×10^{-10} cm²/s at 40 °C (Table 3). As expected, water diffusion is faster at human core temperatures for drug delivery than at ambient temperatures, therefore film thickness should be tailored for the desired drug release profile in the body.

Conclusion

DVS data showed that moisture uptake decreased with increasing film thickness (~30 µm: 2.96%; 100-150 µm: 1.61%; and ~600 µm: no uptake) for the intact (whole) tablets. Cross-sectioned samples exhibited higher uptake due to compromised film barriers and exposure of the tablet core (~30 µm: 3.94%; 100-150 µm: 4.43%; and ~600 µm: 0.96%). The reduction ratios between the whole intact and cross-sectioned samples illustrates the effectiveness of the film coating: moisture uptake was reduced by approximately 25% for Tablet 1, 64% for Tablet 2, and 100% for Tablet 3.

Diffusion coefficient data demonstrated enhanced moisture diffusion at elevated temperatures, with values increasing from 1.33×10^{-10} cm²/s at 25 °C to 3.15×10^{-10} cm²/s at 40 °C for Tablet 1.

These findings quantitatively demonstrate that both coating thickness and integrity critically influence the moisture barrier properties of film-coated tablets, with significant implications for product stability, shelf-life, and drug release performance.

References

Application Note 16