Study of a Range of Blister Packaging Materials Using the New Technique of Moisture Profiling to Give Early Indications of Moisture Barrier Properties

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INTRODUCTION

A key role of pharmaceutical packaging is to limit the exposure of pharmaceutical products to moisture and the consequential affects on their chemical and physical stability. Moisture-sensitive products require a higher degree of protection facilitated by more efficient barrier properties of the packaging material. Relequa® Moisture Profiling is a new and unique way of exploring how materials interact with atmospheric moisture. Moisture Profiles were generated that showed high sensitivity to moisture movement into 3 different types of blister packaging materials. This movement of moisture, and hence the moisture barrier efficiency of the packaging materials, was demonstrated over only a few days, instead of months normally employed in pharmaceutical stability studies.

METHODS

Epilim 250mg Film-Coated Tablets and Lipitor 10mg Tablets obtained from a local pharmacy were de-blistered and immediately re-packed into blisters using a manual EZ Blister Packing Machine by Pharma-Assist, Clonmel, Ireland. Three different types of blister packaging material were used (Table 1). Blisters were placed in humidity cabinets at 25ºC/60%RH and 40ºC/75%RH for 1, 2, 3 and 7 days at Q1 Scientific, Waterford, Ireland. Moisture profiles were generated using a Relequa Moisture Profiling System. The Relequa test chambers were adjusted to above 70%RH to obtain a moisture uptake profile of the tablets. Moisture profiles were run at ambient temperature and until the tablet - Water Vapour Equilibrium Point (WVEP) was reached.

Table 1

Packaging Type Code	Packaging Material
PVC 1	250 PVC Clear
PVC 2	250PVC/60PvDC Opaque
PVC 3	Aquaba Opaque

RESULTS & DISCUSSION

The labels employed for the Moisture Profile graphs are those shown for the packaging type in Table 1, ICH stability conditions and T0, T1, T2, T3 and T7 for Initial, 1d, 2d, 3d and 7d time points respectively

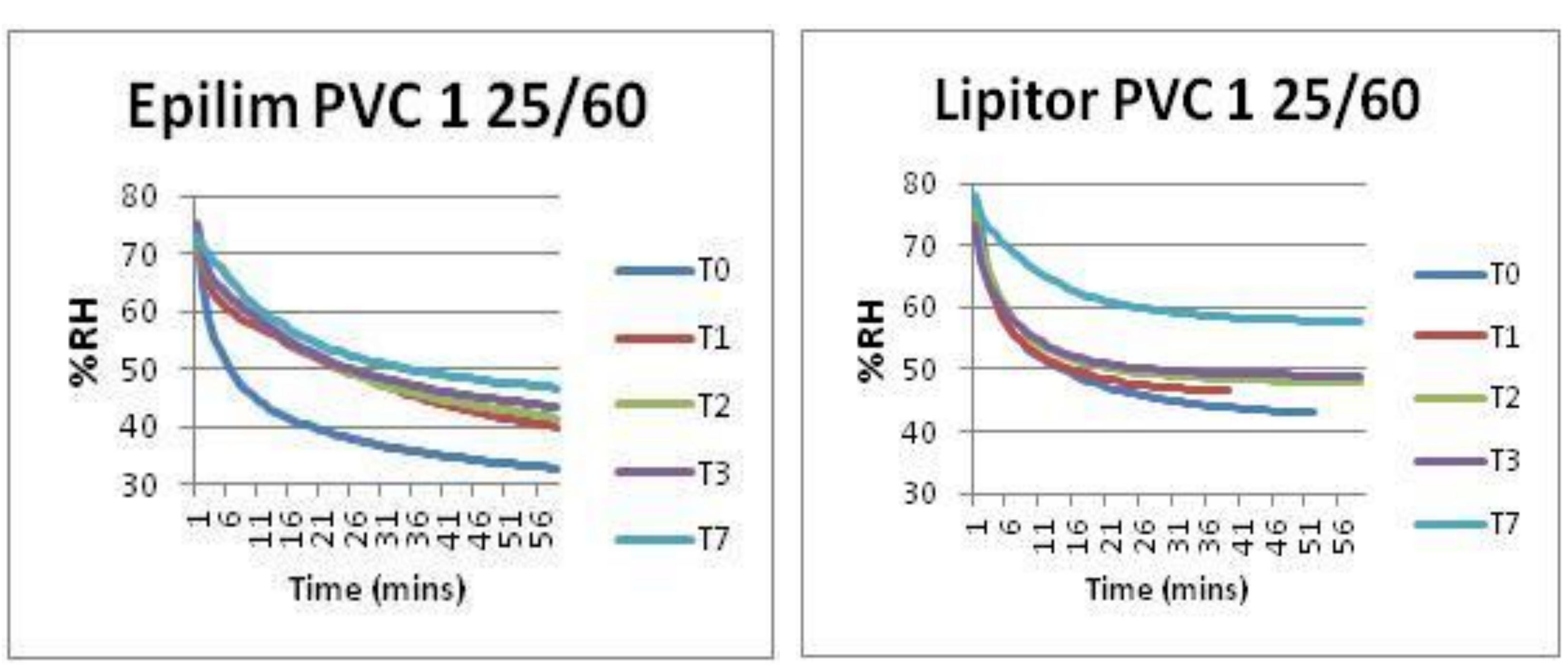

Figure 1. Moisture profiles of Epilim and Lipitor Tablets packed in 250 PVC Clear and stored at 25ºC/60% RH

The products we chose for this trail demonstrate water vapour diffusion according to Fick's second law. This mathematical relationship allows us to limit the amount of data displayed as the initial part of the Moisture Profile without needing to show the complete exponential decay curve to the equilibrium point (WVEP).

Figure 1 shows there is a trend of progressively shallower curves over time for both types of tablets packed in 250µm PVC Clear stored at 25ºC/60%RH. These changes in the Moisture profiles from T0 to T7 are due to an increase in the WVEP as a result of moisture uptake by the tablets.

This trend over time is very much more accelerated at 40ºC/75%RH as shown in Figure 2.

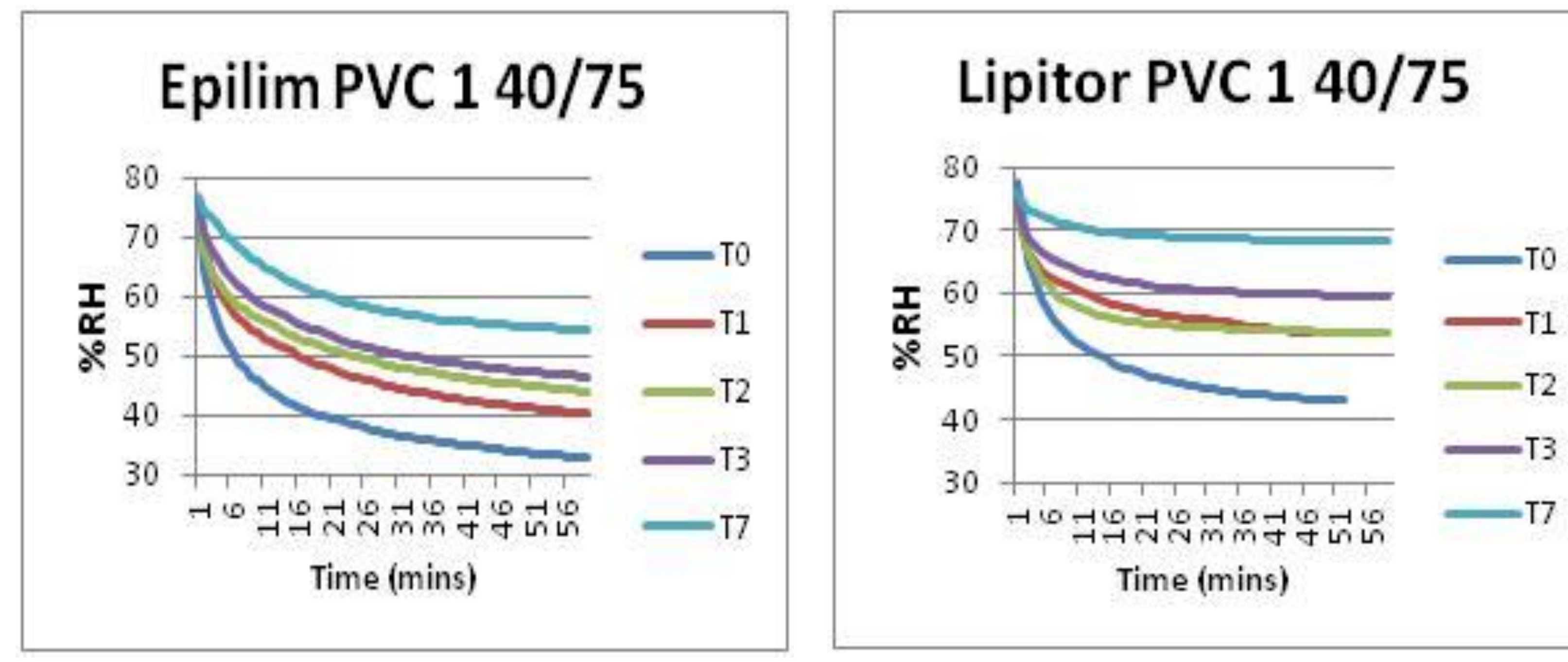

Figure 2. Moisture profiles of Epilim and Lipitor Tablets packed in 250 PVC Clear and stored at 40ºC/75% RH

An interesting observation in these results is that the Lipitor tablets have nearly equilibrated with the 60%RH condition of storage (Figure 1) and would probably also equilibrate to the 75%RH storage condition (Figure 2). All materials tend to equilibrate to the moisture environment to which they are exposed which is the principle of Dynamic Vapour Sorption (DVS) and is also true for static moisture absorption. One of the key functions of packaging is to act as a barrier to moisture exposure and slow down this natural tendency of moisture interaction.

Clearly, from the data in Figures 1 and 2, 250µm PVC Clear is not an efficient barrier for moisture ingress. Compare these data to Moisture Profiles of the same lots of Epilim and Lipitor tablets packed in Aquaba Opaque (PVC 3, Figure 3), a packaging type that the manufacturer claims to be an effective moisture barrier.

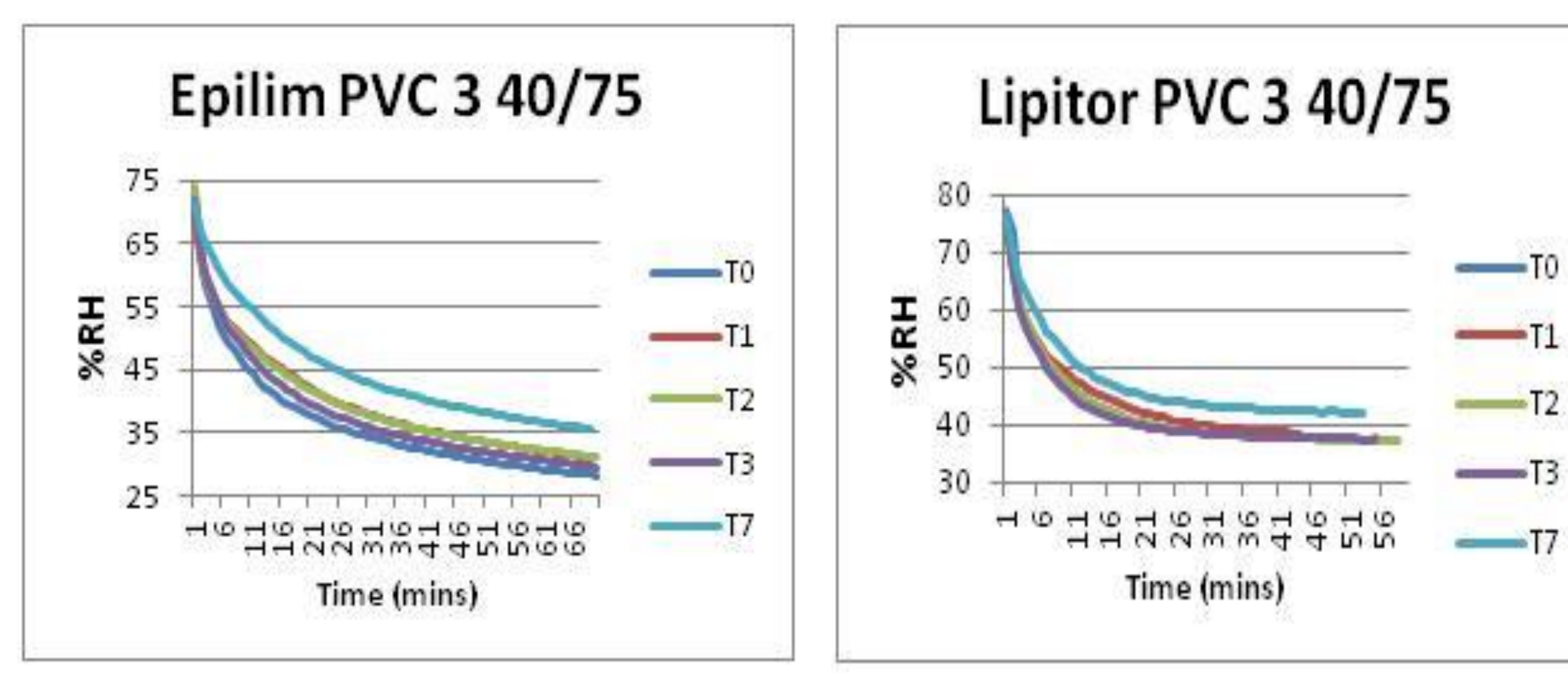

Figure 3. Moisture profiles of Epilim and Lipitor Tablets packed in Aquaba Opaque and stored at 40ºC/75% RH

In Figure 3 we see that over the first 3 days there is no significant change in the moisture status of the tablets when packed in Aquaba Opaque and stored at 40ºC/75%RH. Only at day 7 was an increase in the WVEP observed.

Figure 4 shows that the 250PVC/60PvDC (PVC 2) material barrier efficiency lies between 250µm PVC Clear and Aquaba Opaque.

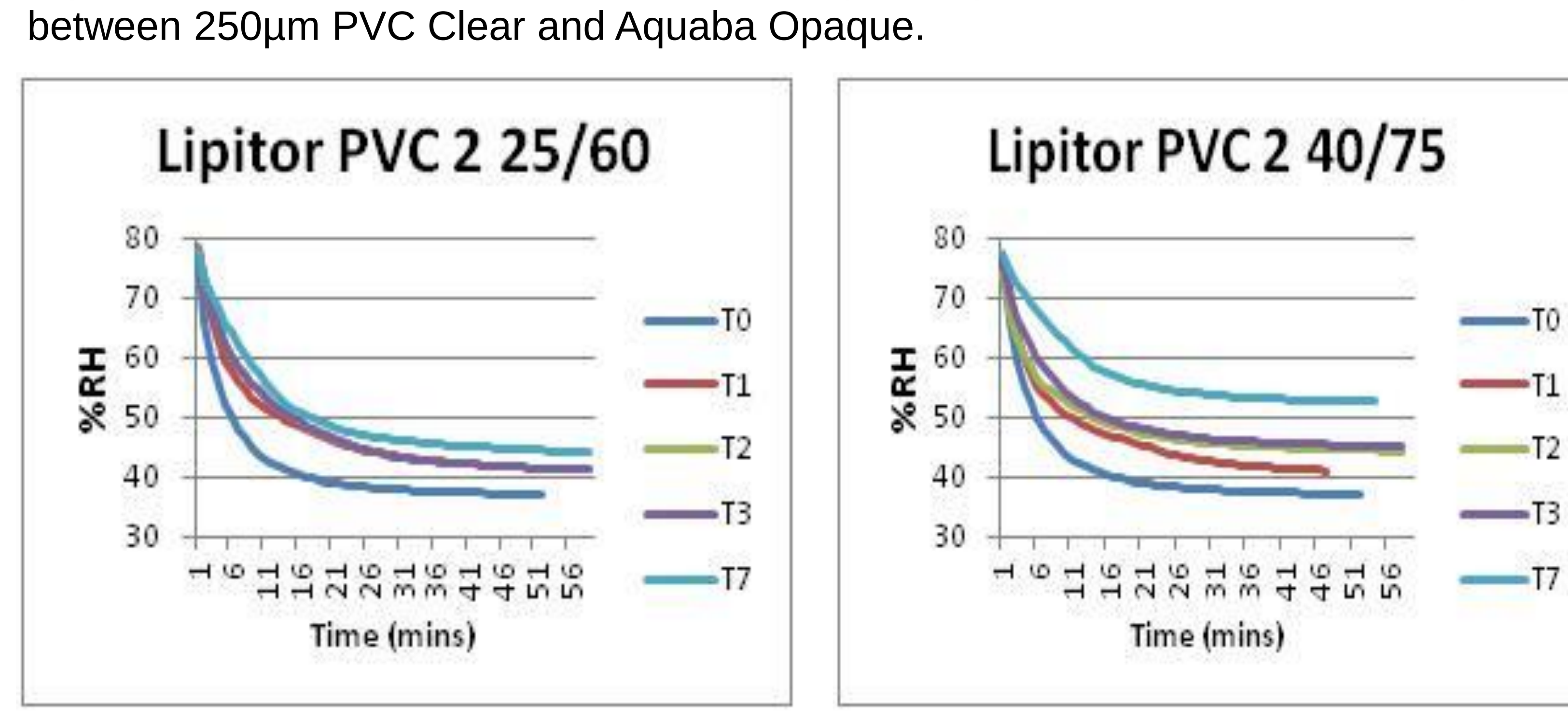

Figure 4. Moisture profiles Lipitor Tablets packed in 250PVC/60PvDC Opaque and stored at 25ºC/60% RH and 40ºC/75% RH

CONCLUSIONS

Moisture Profiling analysis shows that changes in the moisture status of pharmaceutical materials can readily be detected. This new analytical tool was used to investigate the efficiency of barrier properties of different types of PVC blister packaging materials. Data generated from samples stored in controlled humidity cabinets for just 3 days showed differences in the efficiency of the packaging materials to resist moisture ingress.

This study shows that Moisture Profiling has the potential to become a valuable tool for saving time in R&D and Clinical Trial packaging studies.