CONSULTANCY REPORT

Sample Report

[redacted]

Humidity-Control in Foil Pouches using Desiccant Strip Plastic

ADVANCED ● ● ●

BALTIMORE INNOVATIONS

Experts in Humidity and Moisture Control

1 Introduction & Client Requirements

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3 Humidity Inside the Pouch

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1 Introduction & Client Requirements

[redacted] manufacture a range of assays for the pharmaceutical industry. The stability of the reagents inside the testing strips is jeopardised by interactions with any surrounding water molecules in the atmosphere. As such, they intend to pack them in a foil pouch with desiccant.

[redacted] made some preliminary calculations for desiccant requirement giving a shelf life of 3.6 years for a 10 mm x 6 mm x 0.5 mm desiccant strip. This work will provide a more detailed assessment of the pouch humidity for the shelf life.

[redacted] calculation based on a [redacted], provides a good indication but has a few limitations or errors. The MVTR is stated at 25°C/75%, however the storage conditions are given as 30°C/65%. The ingress needs to be scaled up accordingly to account for the higher vapour pressure.

The ingress value through the seal is calculated to be 1.578 x 10^{-8} µg/day. This represents 6 10^{-7} % (or 1 in 1,666,666,667) of the ingress through the foil. This is too small. We note that pouch surface area is proportional to the square of the pouch dimensions, whilst the perimeter is linear with pouch dimensions. Therefore, as the pouch size becomes small, as in this case, the perimeter ingress becomes more significant.

The ingress assumes the interior humidity is perfectly dry and constant for the entire shelf-life. However, the humidity inside the pouch will vary. As the desiccant adsorbs moisture its subsequent adsorption will slow down. When the rate of ingress exceeds the rate of adsorption the pouch humidity will start to rise. As a result, the vapour pressure drop across the boundary will decrease, reducing the rate of ingress. Furthermore, the previous calculation determines the length of time for which the desiccant still has some capacity remaining. However, when the remaining capacity is small, the rate of adsorption will be greatly reduced. As such, it is possible to have an active desiccant inside a high humidity pouch simultaneously. This report illustrates and quantifies these kinetic factors.

2 Analysis of Adsorption

Eight desiccant strip samples of 80mm length were placed in a 25°C/80% environment to measure their moisture uptake. Four of the samples were 0.3mm thick, and four were 0.6mm thick. Giving an aggregate length of 320mm for each thickness. The weight of each desiccant strip was recorded at regular intervals. The moisture adsorbed being the increase from the initial weight.

Figure 2.1 plots the adsorption of moisture by the samples of the desiccant strip against time. The initial rate of adsorption being similar but the *0.6mm sample having greater capacity* as expected.

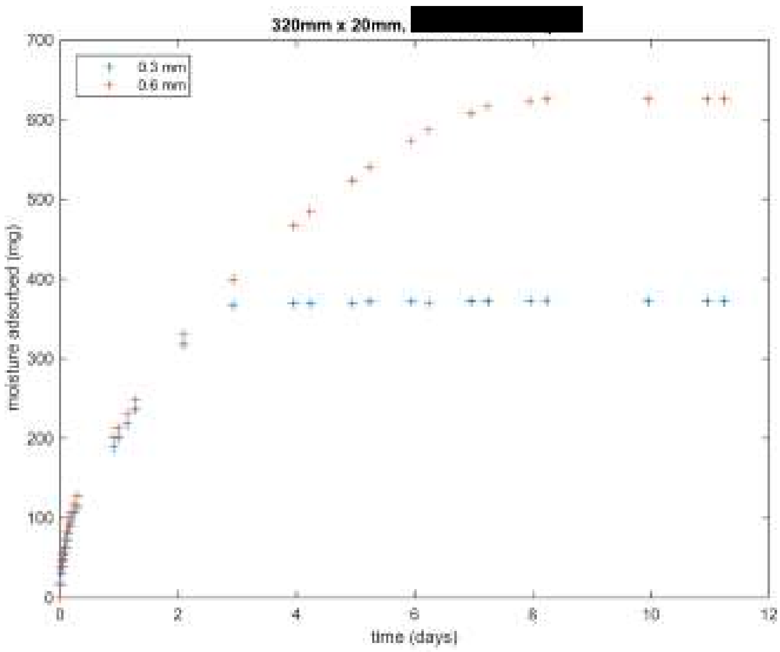

Figure 2.1: Moisture adsorption against time for 320mm lengths of 20mm wide 0.3mm and 0.6mm desiccant strip.

2 Analysis of Adsorption

To better analyse the adsorption behaviour, it is instructive to plot the *moisture adsorbed* as a percentage of the *initial gross dry weight*. **Figure 2.2** shows this desiccant moisture loading. We note the 0.3mm desiccant strip adsorbs moisture quicker than the 0.6mm strip (as a percentage of its own weight). This is due to the 0.6mm strip having a much greater internal capacity that will take longer to become utilised. The 0.3mm sample reaches equilibrium with the environment at around 13.5%, after 3 days.

The 0.6 mm takes longer, around 8 days, as it has a greater internal capacity. It is interesting to note the equilibrium adsorption for the 0.6mm desiccant strip is greater at around 14.5%. This is likely a result of the non-active component weight being similar for both thicknesses, therefore representing a greater dead weight in the 0.3 mm.

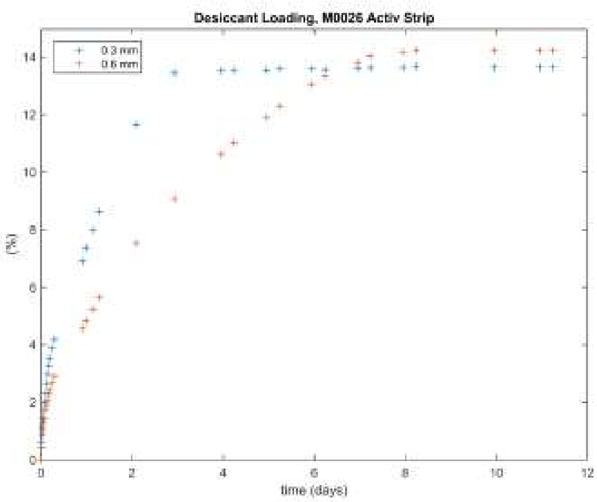

Figure 2.2: Desiccant moisture loading as a percentage of total dry weight for 0.3mm and 0.6mm desiccant strip.

The data in **Fig 2.2** is used to build a kinetic adsorption model for the desiccant strip. This is based on the dimensions of the strip, and will reflect different environmental vapour pressures.

Clearly, for higher humidity conditions, the rate of adsorption will be quicker. Also, the adsorption rate *per gross mass* will be higher, when the surface adsorption represents a greater proportion of the total.

3 Humidity Inside the Pouch

Pouch humidity is a combination of several factors. The rate of adsorption by the desiccant, the rate of ingress into the pouch, the rate of evaporation from the product, and the diffusion of water molecules inside the pouch.

We have established the desiccant adsorption kinetics in the section above. The ingress will depend on the foil properties, the seal and the vapour-pressure drop across the boundary. In house data gives the foil and seal ingress for time and pressure.

Based on data supplied by [redacted] the moisture coming from the product is small and can be confidently neglected from the model.

To determine the movement of the molecules inside the pouch, the diffusion equation is solved, subject to the ingress and adsorption boundary conditions. The air-vapour diffusion coefficient is evaluated at the given temperature, 30°C. The external relative humidity is given as 65%.

3 Humidity Inside the Pouch

The diffusion is shown in figs. 3.1 and 3.2. The left hand rectangle is the desiccant location, and 3-Up test-strip is shown on the right hand side of the pouch.

The figures show *snapshots* of the pouch humidity during the initial head space drying by the desiccant. The red streamlines illustrate the path of the molecules from the pouch boundary forward the desiccant. Two different lengths of desiccant strip are used, 10 mm x 6 mm, and 10 mm x 10 mm. As expected, the longer strip shows superior adsorption.

We note there is little difference in these early stages between the 0.3 mm, and 0.6 mm thick strips. This is expected given the behaviour discussed in the desiccant adsorption section. However, over the shelf-life of the product, the greater capacity of the 0.6 mm strip will be revealed.

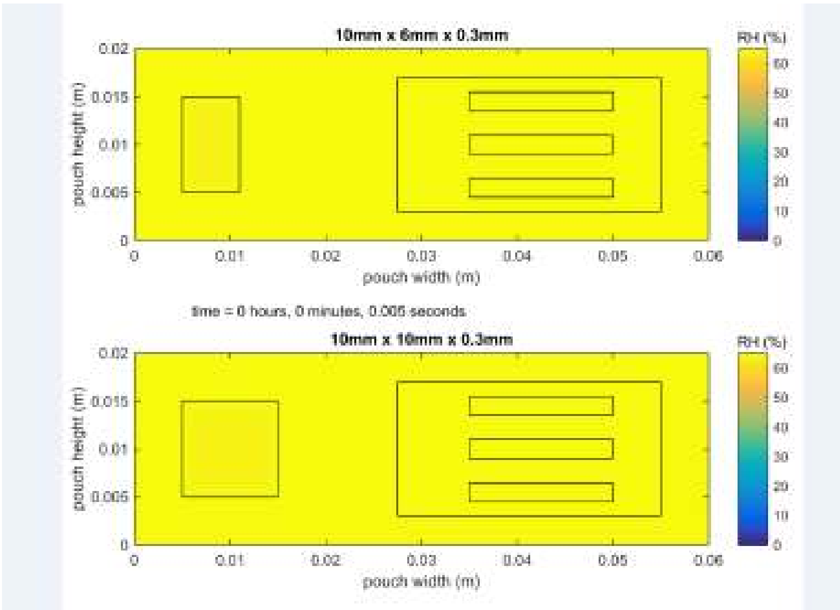

Figure 3.1[a]: Diffusion of water vapour inside the pouch toward two different sized 0.3 mm thick strips. Snapshot [a] for initial state.

3

Humidity Inside the Pouch

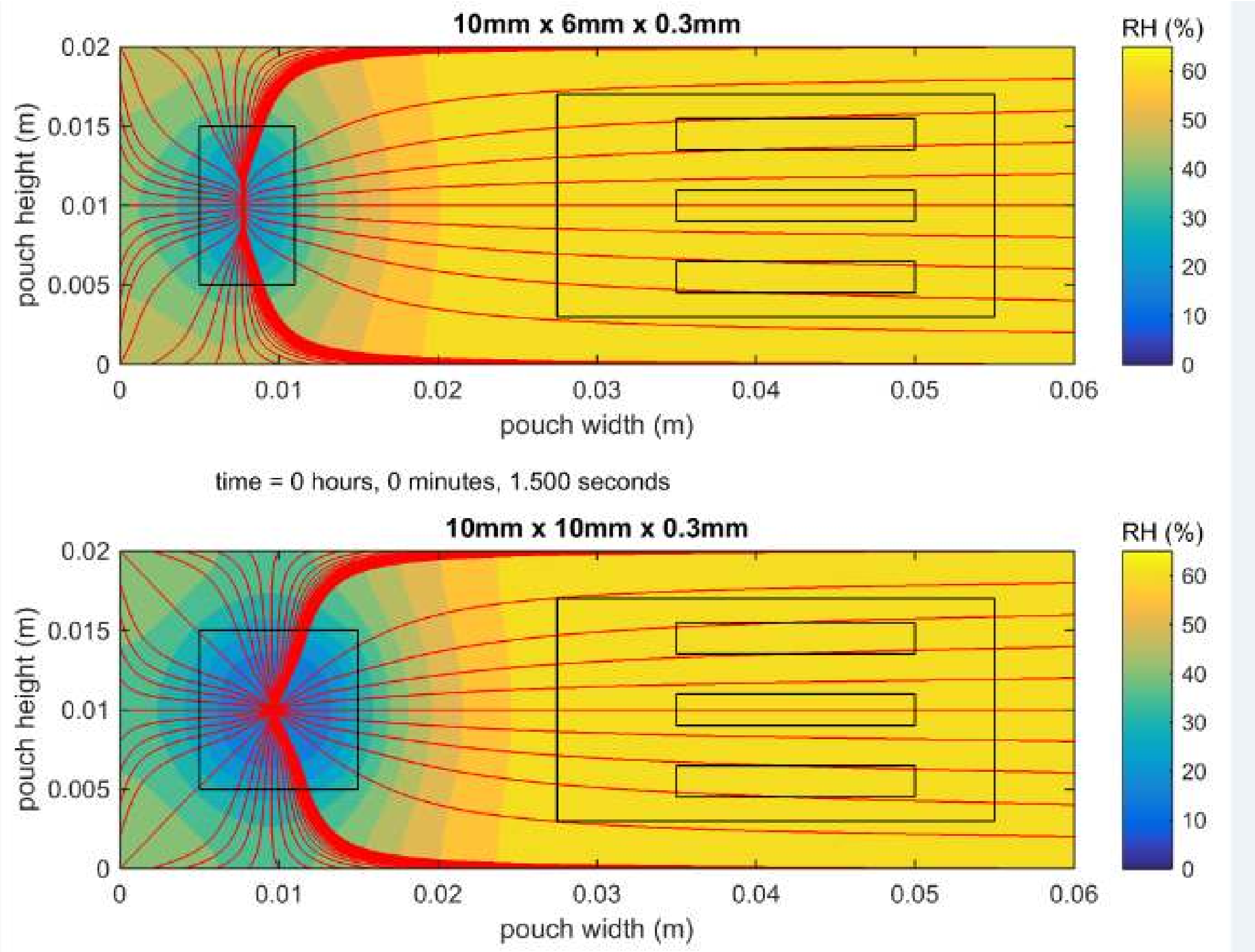

Figure 3.1[b]: Diffusion of water vapour inside the pouch toward two different sized 0.3mm thick strips. Snapshot [b]: after 1.5 seconds.

3 Humidity Inside the Pouch

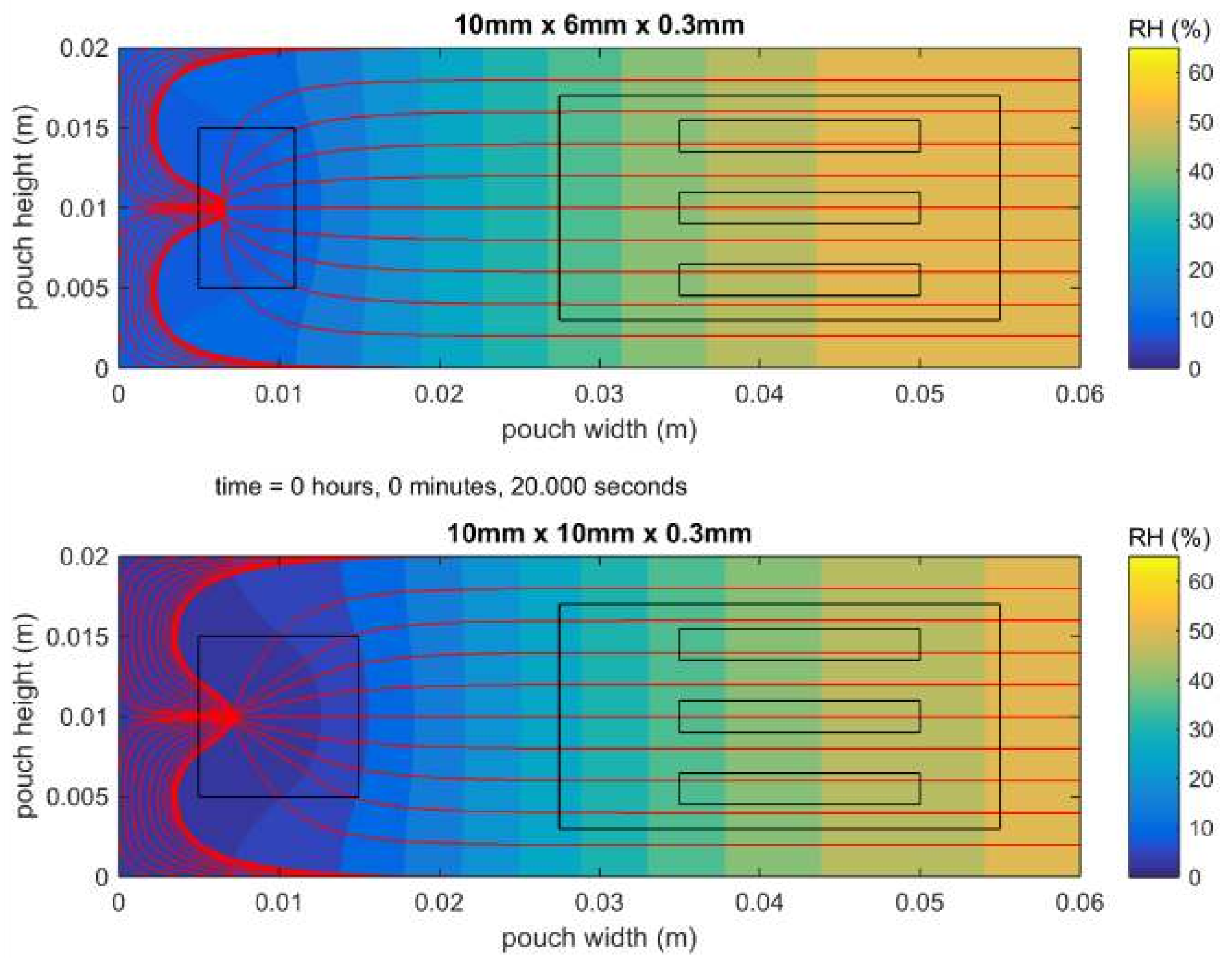

Figure 3.1[c]: Diffusion of water vapour inside the pouch toward two different sized 0.3mm thick strips. Snapshot [c]: after 20 seconds.

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Humidity Inside the Pouch

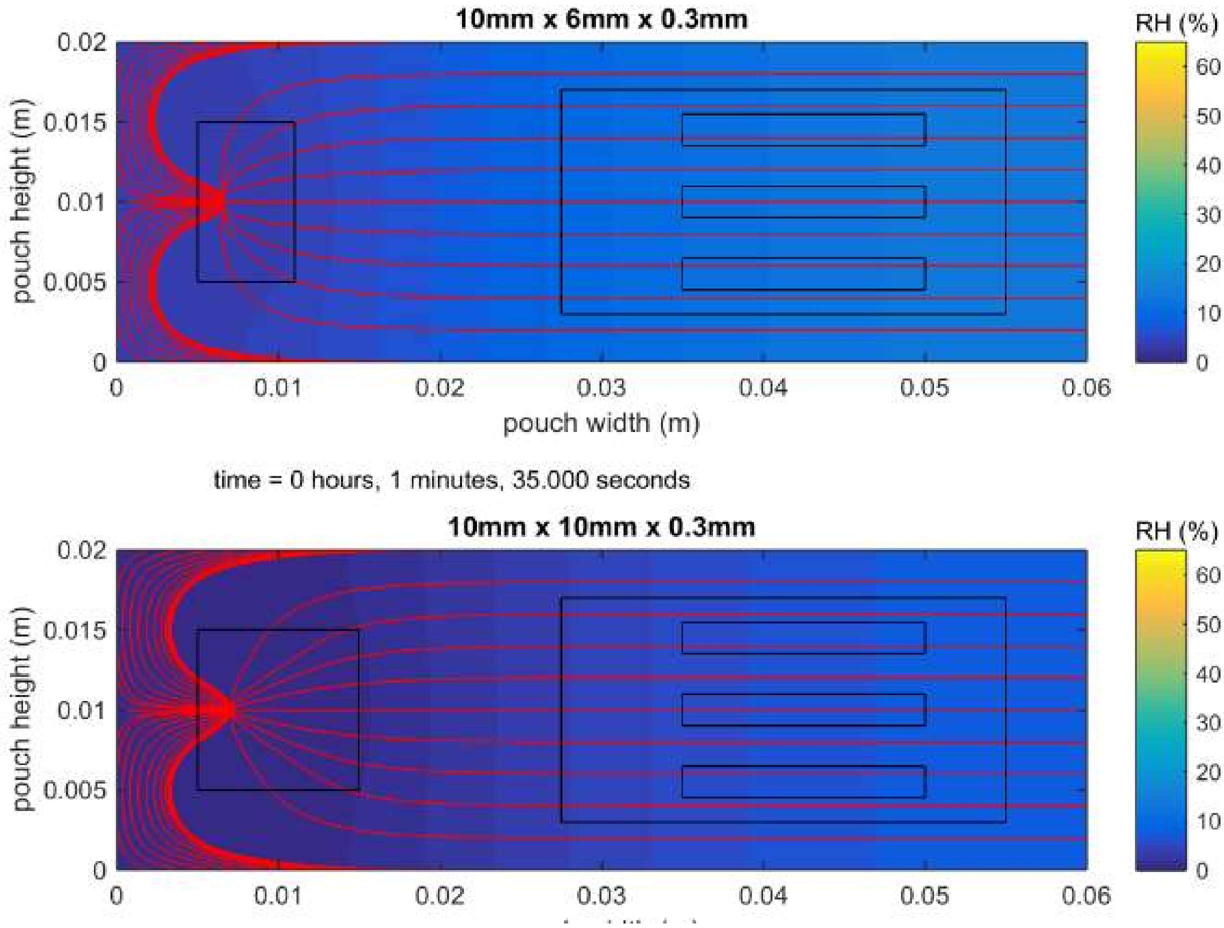


Figure 3.1[d]: Diffusion of water vapour inside the pouch toward two different sized 0.3mm thick strips. Snapshot [d]: after 95 seconds.

3

Humidity Inside the Pouch

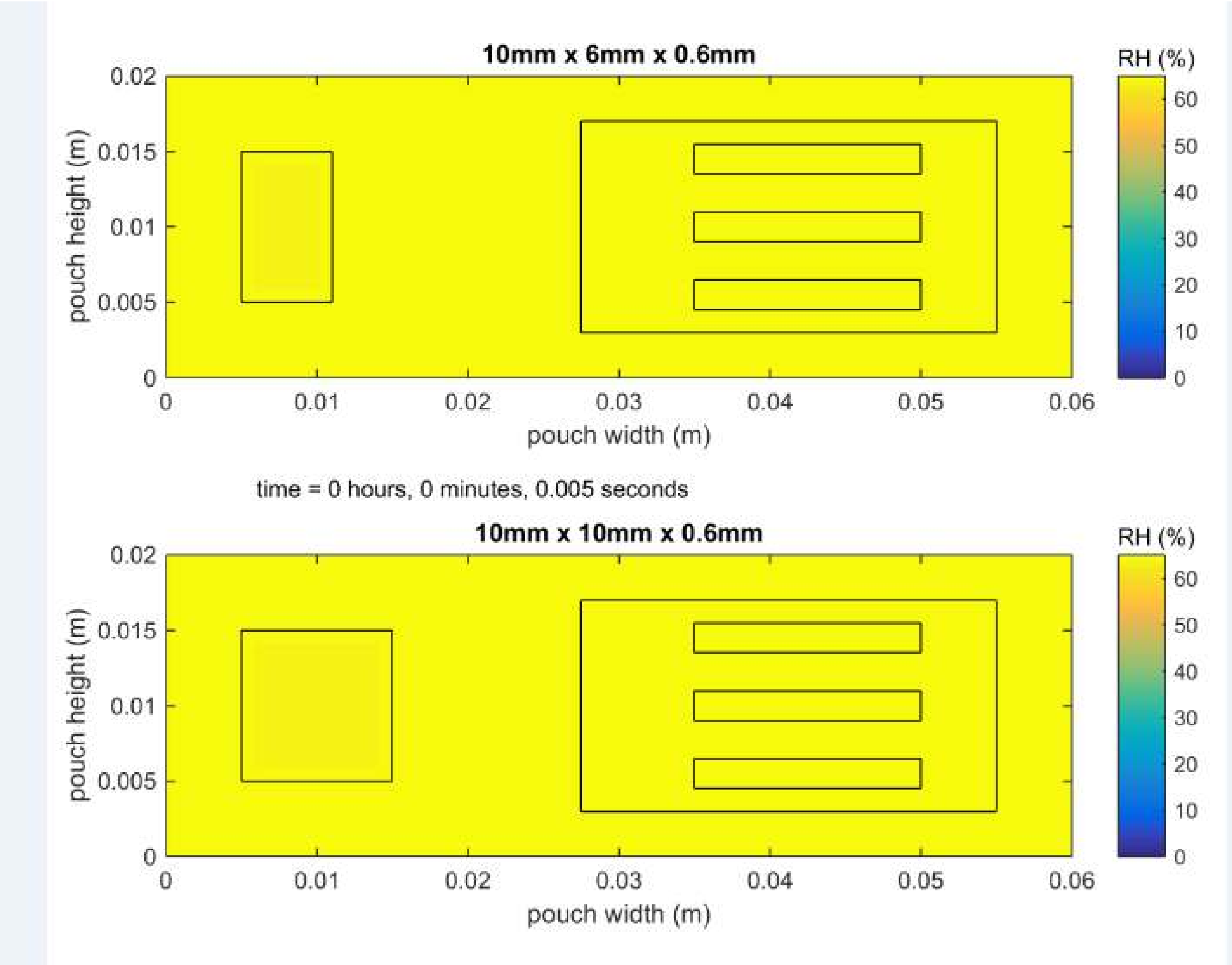


Figure 3.2[a]: Diffusion of water vapour inside the pouch toward two different sized **0.6mm** thick strips. Snapshot [a]: initial state.

3 Humidity Inside the Pouch

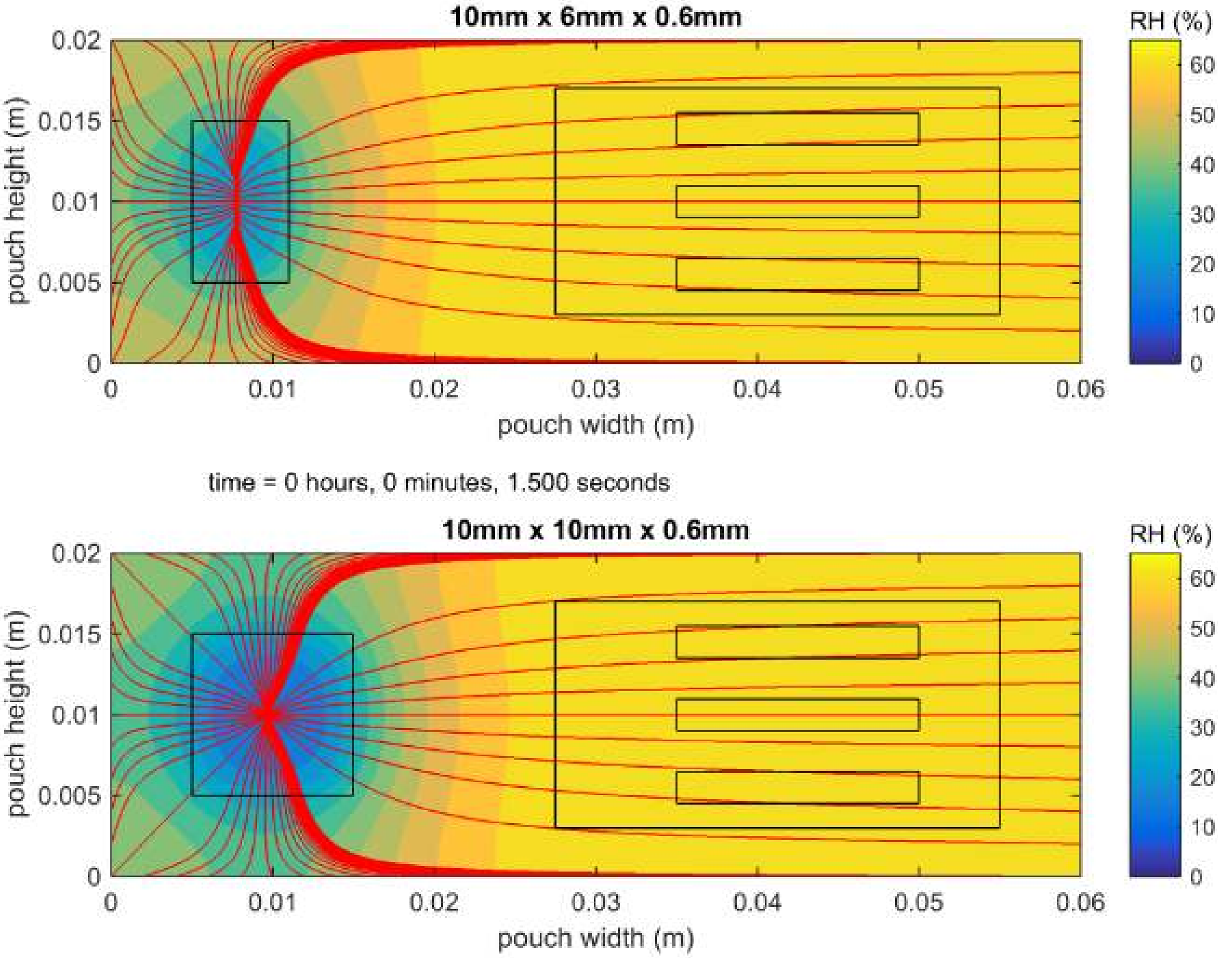


Figure 3.2[b]: Diffusion of water vapour inside the pouch toward two different sized **0.6mm** thick strips. Snapshot [b]: after 1.5 seconds.

3 Humidity Inside the Pouch

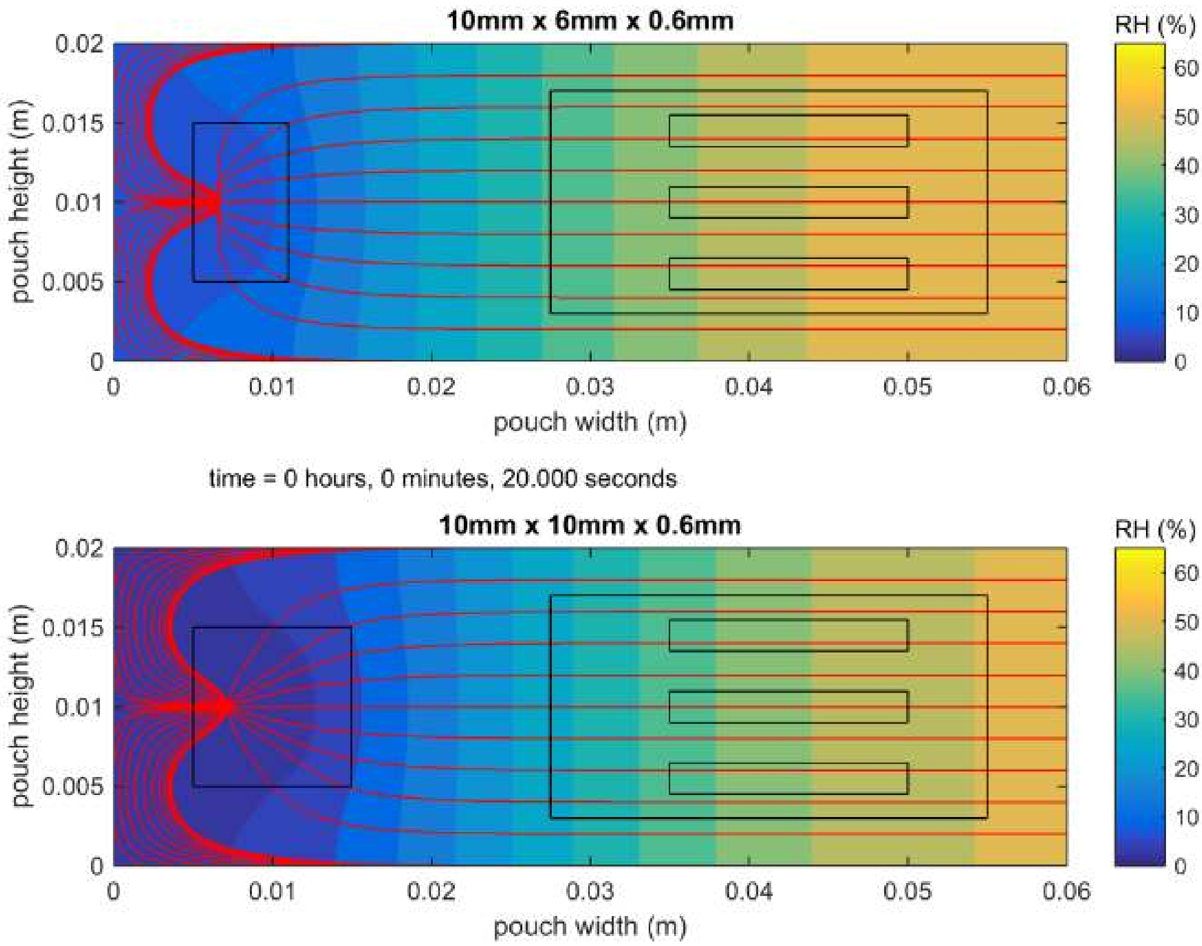


Figure 3.2[c]: Diffusion of water vapour inside the pouch toward two different sized **0.6mm** thick strips. Snapshot [c]: after 20 seconds.

3

Humidity Inside the Pouch

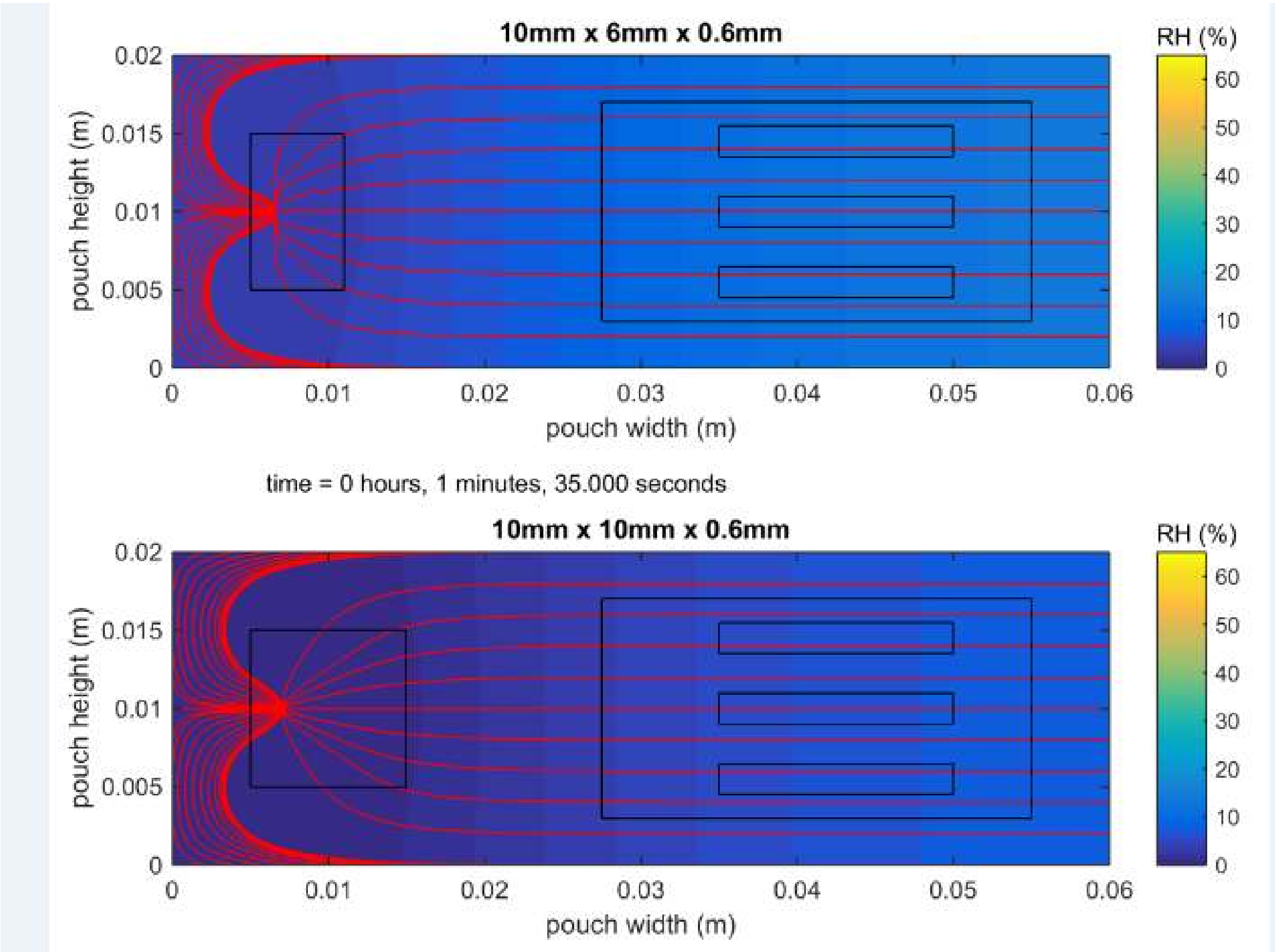


Figure 3.2[d]: Diffusion of water vapour inside the pouch toward two different sized **0.6mm** thick strips. Snapshot [d]: after 95 seconds.

4 Shelf Life Calculations

We now consider the average pouch humidity inside the pouch, over a much greater period of time, reflecting the product shelf life. **Figure 4.1** shows the pouch humidity, ingress, and desiccant adsorption for a 10mm x 6mm desiccant strip in 30°C/65% environment, over 6 years. Results for the 0.3mm and 0.6mm strip are compared. The descending vertical red line on the left axis shows the initial head space drying, the time frame being too small to visualise on this time scale.

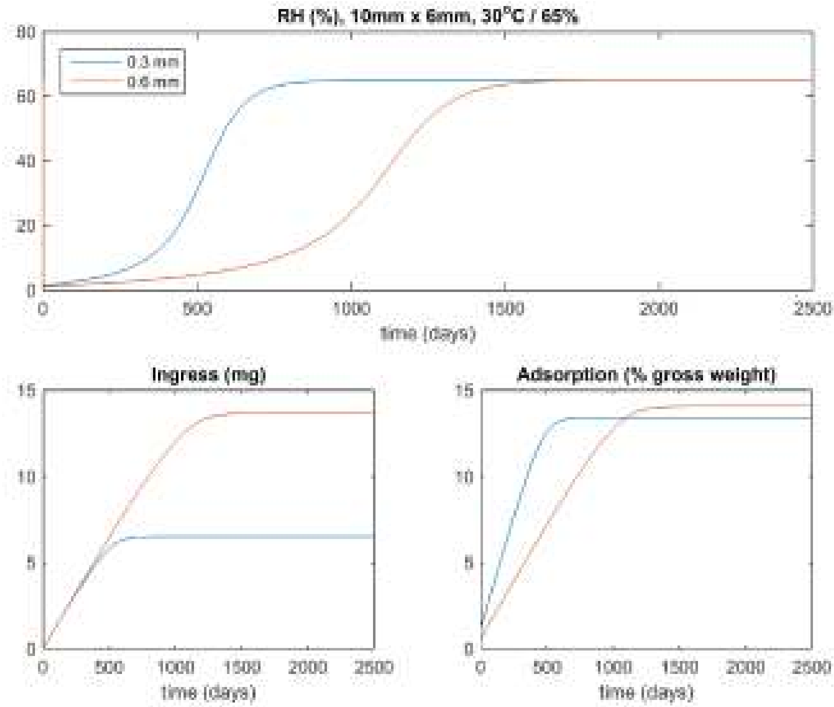


Figure 4.1 - Comparison of mean humidity, ingress, and adsorption inside the pouch for (10mm x 6mm sized) 0.3mm and 0.6mm strips, in a 30°C / 65% RH environment

4 Shelf Life Calculations

We note the humidity starts to rise much sooner for the 0.3mm strip, than the 0.6mm. The deflection points occurring around 450 and 1000 days respectively. The ingress increases linearly whilst the internal humidity is low, then decreases as pouch humidity rises. Eventually the internal and external vapour pressures reach equilibrium resulting in no further ingress.

The adsorption rate behaves as expected. The curves intersection with the vertical axis representing the initial load from the head-space. Again, the time-scale collapses this. The time when the rate of adsorption decreases correlates with the increase in RH in the pouch.

At 30°C/65% the 10mm x 6mm strip *fails too soon*, for both thicknesses, to provide satisfactory shelf-life confidence. The result of increasing the strip length to 10 mm is shown in **Figure 4.2**. The deflection points now occurring at 750, and 1600 days for the 0.3mm and 0.6mm respectively. The 0.3mm time of 750 days is still considered insufficient, whilst the 0.6mm time of 1600 days represents a shelf-life of 4 years with high level of confidence.

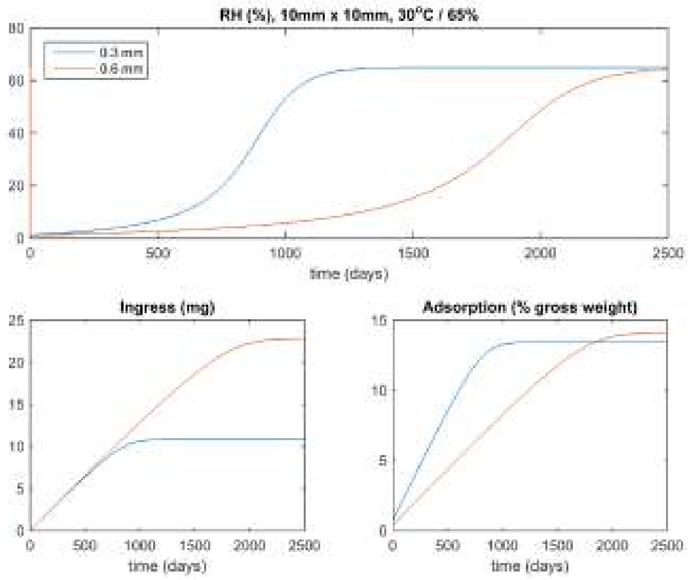


Figure 4.2 - Comparison of mean humidity, ingress, and adsorption inside the pouch for 10mm x 10mm sized 0.3mm and 0.6mm strips in a 30°C / 65% RH environment.

30°C/65% RH represents a significant increase in humidity relative to most average storage conditions. The results for 6mm and 10mm lengths are shown for a more typical environment, 20°C/50%, in figures 4.3 and 4.4.

4

Shelf Life Calculations

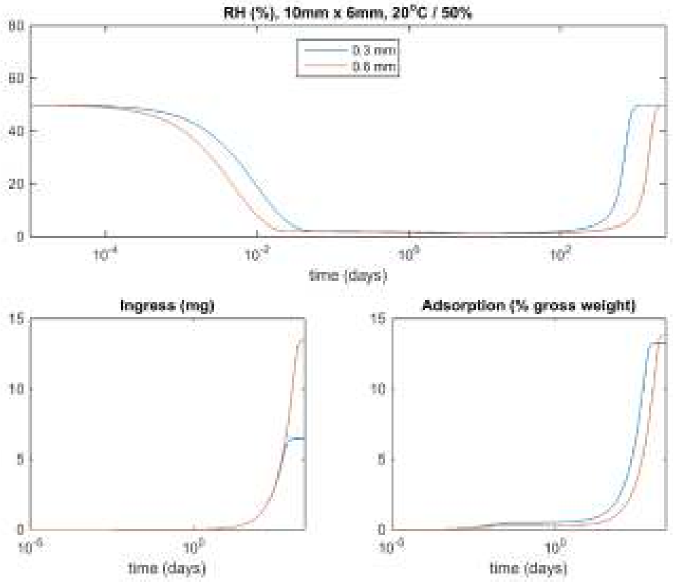
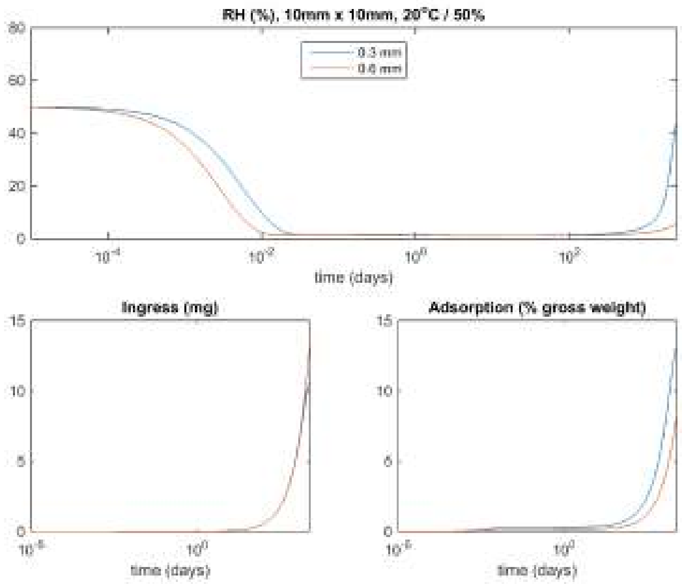


Figure 4.3 – (left) Comparison of mean humidity, ingress, and adsorption inside the pouch for (10mm x 6mm sized) 0.3mm and 0.6mm strips in a 20 °C / 50% RH environment.

Figure 4.4 – (below) Comparison of mean humidity, ingress, and adsorption inside the pouch for 10mm x 10mm sized 0.3mm and 0.6mm strips in a 20°C / 50% RH environment.



We note at the lower humidity conditions the shelf-life is *much greater*. The 10 x 10 x 6mm strip showing no discernible deflection for the 6.8 years plotted. Clearly, the ingress is smaller at the lower vapour pressure condition. At 30 °C and 65% relative humidity, the equivalent ingress value is 0.005 g/m²/day, whilst at 20 °C and 50% relative humidity the equivalent ingress value is only 0.002 g/m²/day.

5

Desiccant Recommendations

2-Up Pouch (70mm x 60mm)

For this pouch, a desiccant with dimensions 20 x 20 x 0.6mm is recommended. The humidity, ingress, and adsorption over a 5 year period (2000 days) is plotted in Figure 5.1.

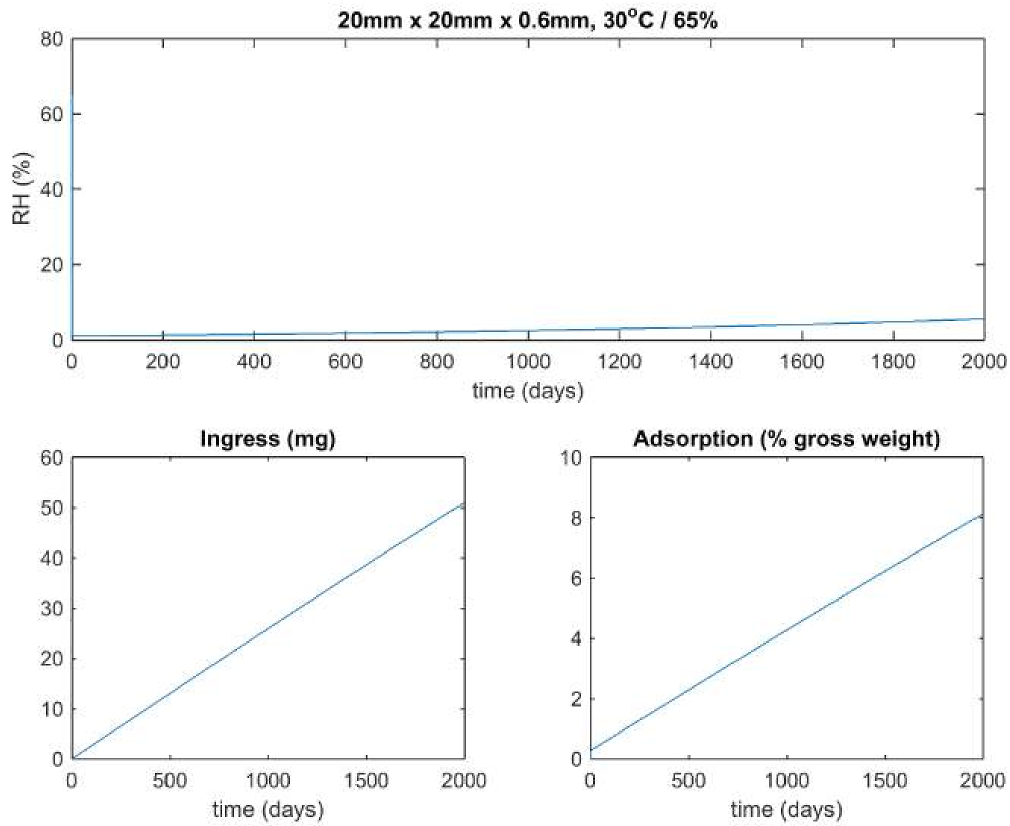


Figure 5.1: Comparison of mean humidity, ingress, and adsorption inside the pouch for 20mm x 20mm x 0.6mm strip in a 30°C / 65% RH environment.

5 Desiccant Recommendations

4-Up Pouch (40mm x 60mm)

For this pouch a desiccant Strip with dimensions 20 x 10 x 0.6mm is recommended. The humidity, ingress, and adsorption over a 5 year period (2000 days) is plotted in Figure 5.2.

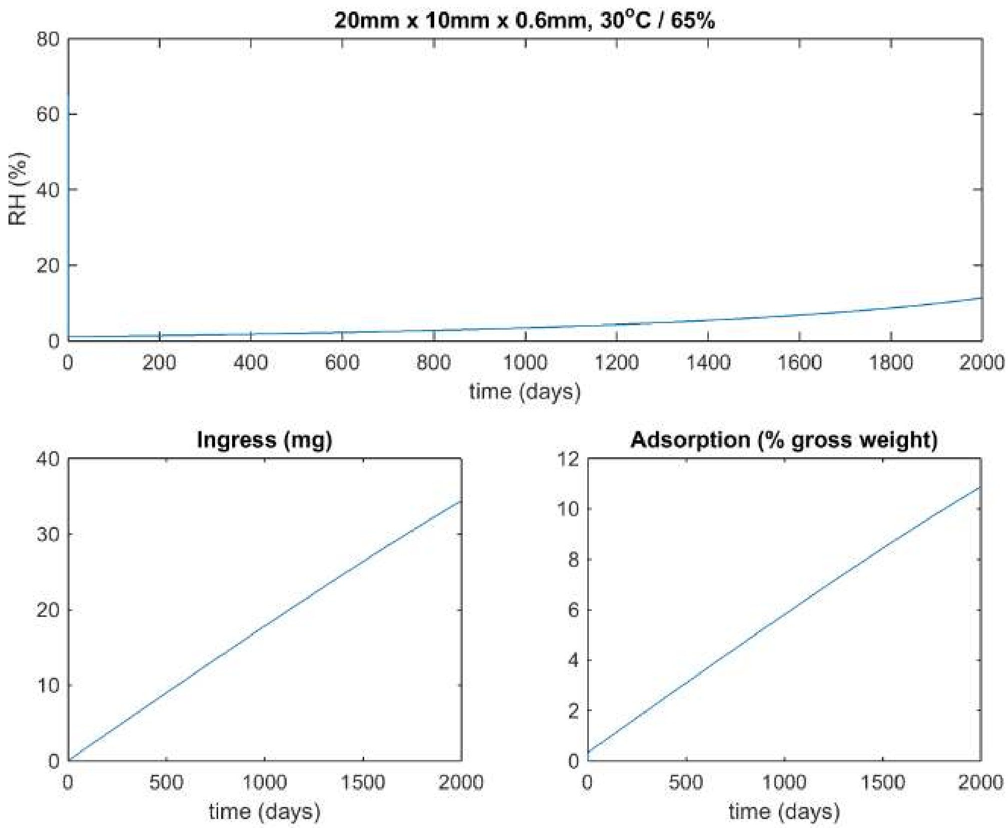


Figure 5.2: Comparison of mean humidity, ingress, and adsorption inside the pouch for 20mm x 10mm x 0.6mm strip in a 30°C / 65% RH environment.

5 Desiccant Recommendations

8-Up Pouch (30mm x 60mm)

For this pouch a desiccant Strip with dimensions 15 x 10 x 0.6mm is recommended. The humidity, ingress, and adsorption over a 5 year period (2000 days) is plotted in Figure 5.3.

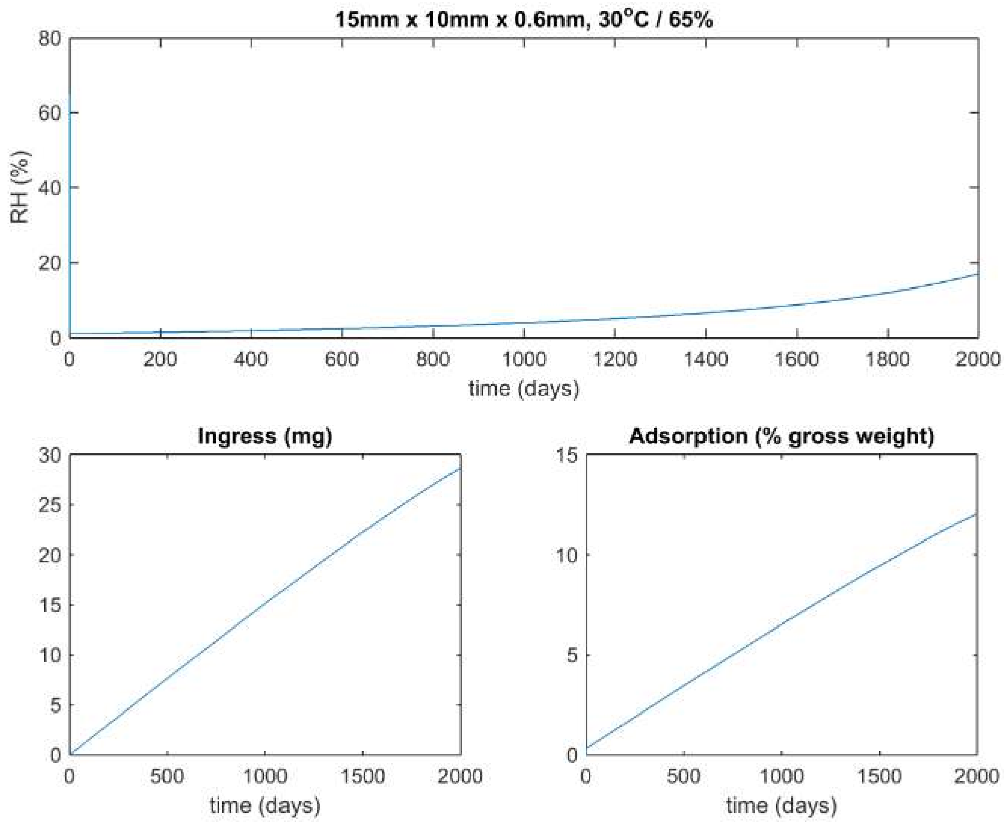


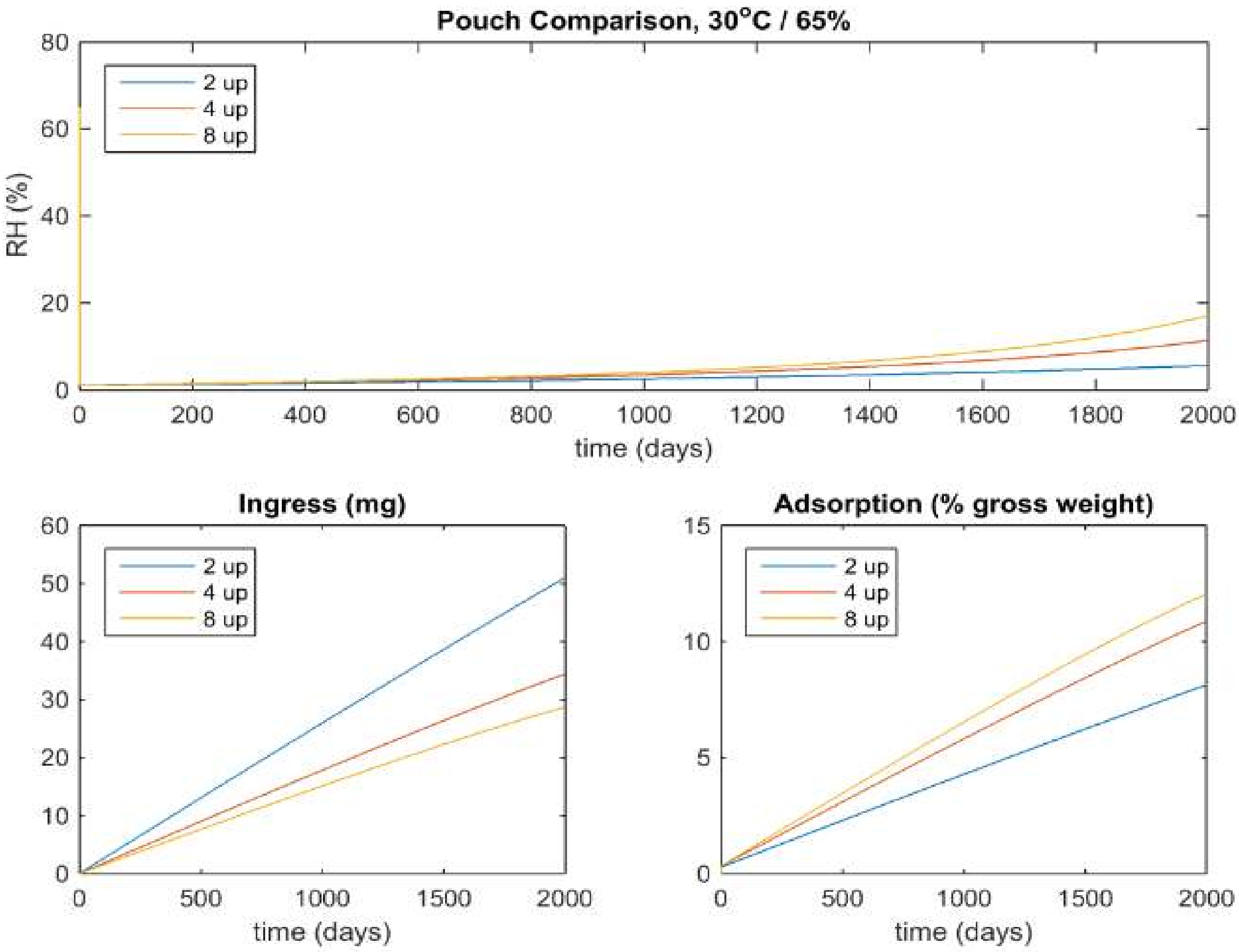
Figure 5.3: Comparison of mean humidity, ingress, and adsorption inside the pouch for 15mm x 10mm x 0.6mm strip in a 30°C / 65% RH environment.

5

Desiccant Recommendations

Overall Comparison of each Pouch's Performance

From the results show in Figure 5.4 (below), we can see that the pouches remain at low relative humidity for the entire period shown. The assays inside each pouch will therefore be ***well protected from any moisture related damage***.



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