It is essential for companies in the pharmaceutical industry to carefully evaluate the effectiveness of the packaging concepts, production methods and materials they use for taking their products to the consumer.

**Blister Pack Studies…**

Generally, a strong focus of attention is directed to the study of blister packs. Typically, the traditional industry-wide evaluation method consists of making blister packs (which generally contain multiple blisters) with the size and packaging material specifications to be tested; however, a desiccant (usually silica gel or magnesium chloride) is placed inside the blister rather than the actual pharmaceutical product. This standard was introduced decades ago by U.S. Pharmacopeia (currently called USP-671) and calls for these blisters to be placed in an environmental chamber at constant temperature and humidity conditions (there are several combinations, but the most common one is 23°C and 75%RH). The weight of the sample blister is then measured at certain intervals of time for 28 days. From the weight gained and the number of individual blisters in the pack, the Water Vapor Transfer Rate (WVTR) is determined in terms of grams of water per day per blister. A typical blister pack with two cavities and silica gel desiccant is shown in **Figure 1**.

![Figure 1. Blisters with Desiccant](image)
By today’s standards, this traditional U.S.P. method is time consuming and prone to errors. Therefore, several companies are improving the effectiveness of their testing by using VTI’s Model SGA Gravimetric Sorption Analyzers to measure the rate of water permeation. Using the SGA instruments, their improved procedure consists of hanging several blisters filled with desiccant inside our sample cavity and monitoring its weight under selected temperature and humidity using our precision microbalance design. Typically, this testing is done at 25°C at 60%RH, 30°C at 65%RH and 40°C at 75%RH and the experiment is run until steady state conditions are reached in each case.

An experiment might last from 3 to 5 days depending on the permeation properties of the particular blister material. This testing protocol is based on the methods issued by the International Community of Harmonization (ICH).

Through the use of VTI’s Sorption Analyzers, the reduction in testing time for blister pack evaluations... reductions typically from 28 days down to the range of 3 to 5 days... represents a major breakthrough in the testing and evaluation of packaging materials. In Figure 2 water permeation data for a 10-blister-pack package is shown. The blisters are made of Aclar and the vapor transmission rate is measured at 30°C and 65% RH.

**Figure 2. Water uptake by 10-cavity blister pack**
Evaluation of entire packages…

VTI’s instruments have also been used for evaluating entire packages to see how they behave under different conditions of temperature and humidity. One example is the behavior of a package of cream sachet with a peel-off lid. The package was tested at 40°C and 35%, 55% and 75%RH. At the lower relative humidity levels, the sachet loses weight (probably both water and alcohol lose), but at 75%RH the process is reversed and the material starts to gain weight. These experiments are most helpful to the manufacturer in selecting storage conditions for their products.

*Figure 3* shows the weight changes for the ointment sachet described above.

![Ointment Sachet under different RH conditions at 40 C](VTI Corporation SGA-100 Data)

*Figure 3. Ointment Sachet at 40° C*
Isotherms for tablets…

Often companies are interested in the water adsorption qualities of the final product…for example, the water adsorption for a specific tablet under different conditions of temperature and RH. Again, the VTI SGA Series of instruments can be used for these evaluations. A water adsorption isotherm for a tablet is given in Figure 4.

For detailed specifications for the Model SGA Series of VTI Instruments used for these various types of evaluations, please refer to our product brochures. Also, VTI now offers a Multi-Sample Analyzer based on the technology of the SGA Series Instruments to handle up to 15 samples at one time for packaging applications. Please contact us for details.

Figure 4. Water adsorption Isotherm for a tablet.