Quality Packaging

pharmaceutical industry

Packaging is an emerging science that has become a great contributor to the success of the pharmaceutical industry. It has become the core sector for marketing and the means by which manufacturers can differentiate their products from those of their competitors. Other than marketing, packaging plays an important role to primarily protect the drug against physical and mechanical damage during transportation, storage and handling (by the pharmacist and patients) as well as providing protection from biological degradation, contamination and from adverse environmental conditions that may alter the properties of the drug. Here we look at the packaging of pharmaceutical products in blister packs and sachets.

Blister Packs

There are two main components that make up blister packs namely the cavity and the lid. The cavity is made of aluminium foil or plastic and the lid from paper, cardboard, plastic or aluminium amongst other materials.

In the pharmaceutical industry blister packs are mainly used to package tablets, pills, granules and capsules. Unit dose drugs for instance benefit from blister packs by having each individual dose enclosed within the blister. By printing the days of the week above each dose, this further improves patient compliance. This packaging system also provides some degree of tamper resistance and therefore avoids accidental opening by children, while at the same time making it easy to open by weaker patients and the elderly. The protective barrier of the blister pack also serves to protect the enclosed dose from the external environment and in so doing, extends the shelf life of the drug. The integrity of the blister pack is therefore important; if there are leaks between two cavities the dose of each cavity will be compromised. As for drugs sensitive to moisture, exposure to the external environment may also compromise its properties.
To ensure the integrity of the blister pack, the force required to extract the tablet must be consistent. Measuring the required force to push through a blister pack is therefore necessary. This measurement can be achieved using a Texture Analyser (see Figure 1).

The Texture Analyser is a very robust and user-friendly instrument that provides accurate and reproducible results within minutes making it effective for use on the production line. With a number of probes and fixtures designed for testing packaging materials, the instrument is capable of measuring seal strength, peel strength, burst strength and crush capabilities of packaging materials. Here we measure the force required to extract a tablet from a blister pack using a hemispherical probe (see Figure 2).

Figure 1
Brookfield CT3 Texture Analysers evaluates the strength of pharmaceutical and cosmetic materials

Figure 2
Brookfield Blister Pack Support Fixture

ISO 9001 CERTIFIED
BROOKFIELD
T: 800.628.8139 / 508.946.6200
www.brookfieldengineering.com

The hemispherical probe simulates the force applied by the fingers to remove a tablet from a blister pack. Probes complimentary to the size and shape of the blister can also be manufactured to meet customer requirements.

During the test, the probe moves downwards over a set distance and as it does so, a compressive force is applied on the blister pack. The compressive force is seen to rise as a result of the resistance exerted by the blister pack. When the blister pack can resist no more, the probe pushes through the lid, forcing the contents of the cavity out the bottom. Figure 3 and 4 show the results using the Texture Analyzer with a blister pack support fixture (TA-BPS).

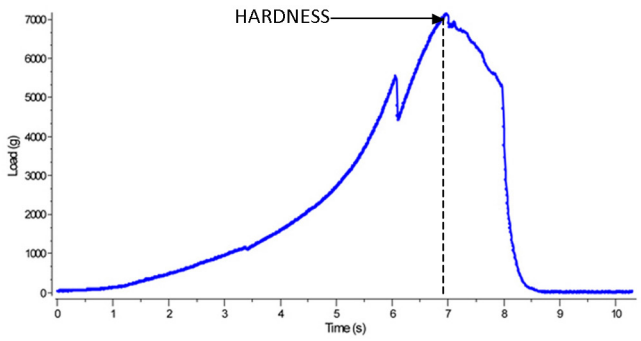

Figure 3
Shows results using the texture analyser with a Blister Pack Support Fixture

Figure 4
Shows the force and work required to extract a hard capsule from a blister pack

Figure 3 shows the maximum force value is a measure of the force required to break the blister pack and release the tablet.

Figure 4 shows an alternative option for displaying the results. Like the load/time graph, the maximum force value is a measure of force required to penetrate and collapse the blister pack. In addition the load/distance graph shows the work done to the blister pack, which is equivalent to the area under the graph from the start of the test to the target distance point (8 mm for this sample).

Hardness (g)	Deformation at Hardness (mm)	Work Done (mJ)
7634 ± 1190.6	7.31 ± 0.5	195.7 ± 9.6

Seal Strength

For manufacturers in the fast moving consumer products arena, packaging their products in sachets is a quick and easy way for consumers to access their product. In the cosmetics and personal care industries, sachets are used for storing make-up, hair care products, hand creams, and many more. Sachets are also a means by which new products can be promoted in the market place.

The aim of packaging a product is to maintain the cleanliness or sterility of the product throughout all stages from the manufacturing plant, to transportation, shelf-life, and storage. For the manufacturer to ensure successful packaging of their products, the integrity of the seal must be assessed.

A seal strength test using a Texture Analyser measures the quality of the seal barrier protecting the product from its external environment. Using the tension testing method, seal strength is measured by the capability of the seal to resist separation. A typical example of a fixture used for this type of tension testing is the dual grip assembly fixture (TA-DGA) (see Figure 5).

The dual grip assembly is a multipurpose fixture used in tensile testing. The grips are 25 mm wide and fitted with rubber inserts to maximise the secure clamping of the sample. These grips are capable of holding rectangular samples up to 5 mm in thickness.

Figure 6 is a typical graph from a tension test using the dual grips with a Texture Analyser to measure the seal strength of a cosmetic sachet.

Figure 5
Brookfield Dual Grip Assembly Fixture

Figure 6
Shows the load verses distance graph for the seal strength of a cosmetic sachet

Figure 6 shows the maximum force value on the graph is a measure of the force required to initiate tearing at the seal. As the seal begins to tear, a plateau is observed followed by a sudden drop in force as the seal is weakened. Further plateaus are observed during the test indicating variation in seal strength as the instrument pulls the seal apart. The area under the graph from the start of the test to the target distance point is a measure of work done to tear apart the seal completely.

A summary of the results for one sachet is shown in the table below:

Sample	Peak Load (g)	Work Done (mj)
Cosmetic Sachet	3715	711.6

Conclusion

The use of Texture Analysers for this type of testing has proliferated for a couple of reasons.

1) The equipment can measure relatively low force levels with good accuracy and repeatability of measurement.

2) The purchase price for a Texture Analyser is very affordable, taking into account special fixtures for each type of test and the training required to become proficient in using the instrument.

Compared to Universal Testers and larger Tension/Compression Testers, the Texture Analyser becomes an easy choice to use, not only in R&D when doing initial characterization work, but ultimately for QC pass/fail on manufactured blister packs and cosmetic sachets.

Authors: Chris Freeman, Sr. Product Manager, Texture Analysers
Dr. Claire Freeman, Lab Tech Specialists
Brookfield Viscometers Limited, Brookfield Technical Centre Stadium Way, Harlow, Essex CM19 5GX England
Tel: (44) 1279/451774 Fax: (44) 1279/451775
Email: c_freeman@brookfieldengineering.com Website: www.brookfield.co.uk