

# Packaging Validation Tests for Medical Blisters and Pouches

## Seal Integrity

- External inspection according to **ASTM F1886**. A relatively simple test regularly used to supplement information gleaned from other seal tests.
- Dye penetration according to **ASTM F 1929**. Dye is injected into sealed packs, ingress into seals is then visually inspected for. Suitable for packs with at least one transparent web or a porous web.
- Hospital environment aerosol test. This test has been validated internally and shown to find channels as small as 0.3mm. It simulates 1 year of storage unprotected on a hospital trolley.
- Leak into a vacuum according to **ASTM F-2095**. A pressure decay test which is very precise, it requires tooling.
- **Calibrated hole test**. In this test impermeable packs are fitted with laser drilled holes of 12.5, 25, or 50 micron diameter. Leak from the packs is then measured using a vacuum decay method and compared to non-perforated packs. MET uses this test for validation and IQ/PQ studies on customer's own machines.
- Hydrogen or CO<sub>2</sub> tracer gas testing. An extremely sensitive test, ideal for 100% testing and locating of the tiniest of holes in non-porous packs.
- Under water (**Blue Dye**) test. An alternative to tracer gas testing for tablet and capsule blister packs.

## Seal Strength

- Burst test according to **ASTM 1140**. A good strength test, which examines the entire seal area, locating the weakest point. Suitable for porous and non-porous packs.
- Seal peel (tensile) test to **ASTM F88**. Measures the force required to peel packs open.

## Shelf Life

- Accelerated ageing according to **ASTM F 1980**. Storage of packs at elevated temperature is used to simulate shelf life ageing in a shorter time period. Suitable for porous and non-porous packs.

## Transport System Validation

- A uniform shipping simulation test according to **ISTA 2A**, testing pack resistance to impact, drops, vibration, heat and humidity.

