

How to Leak Test Sealed Packages

The third in a series of guides intended to help medical device engineers in specific problem areas.

Packaging for medical devices that are sensitive to moisture must provide a barrier to vapour transmission. A barrier is also required if the product contains a volatile component or needs a specific atmosphere for storage. One way to achieve this is by using flexible laminate materials that incorporate an aluminium layer, which acts as the barrier. This type of packaging is also often used for products that are aseptically produced within isolators.

The specification of the packaging material will be governed by the barrier properties that are required. It is also important to verify that the seals on these packages reliably maintain sterility and the requisite atmosphere. Traditionally, this has been done by sealing a dye solution into the packs and placing them in a vacuum chamber. The seals can then be inspected for traces of dye penetration. This method has the disadvantage that the packs that are tested are only samples taken periodically from the production process. An improvement on this test employs a vacuum, but monitors leaks using electronic pressure measurement.

The principle

A nondestructive test can be applied to sealed packs using electronic, vacuum decay leak testing. The pack is placed in a well-fitting chamber, which is sealed around the pack. A vacuum is then drawn into the chamber and the pressure changes monitored over time. Perforations in the pack or seals will be detected as an increase in pressure as the pack leaks into the vacuum. Seals can be stressed by maintaining the pressure over time or by applying sudden shock loading. The system can be calibrated by connecting a known leak into the chamber supply line.

Points to bear in mind

The maximum pressure that can be generated in a vacuum test is one atmosphere and drawing a vacuum is a slightly slower process than pressurising a part. In addition, it may be necessary to hold the pressure for up to 1 min to test creep of the pack welds.

Substantial leaks may be found by evacuating a slave chamber and applying this pressure to the test chamber. Because the volume of the chambers are known, there will be an expected pressure change if the pack is intact. A larger pressure change will occur in the slave chamber if the pack volume is included in the dilution, and this will indicate a gross leak.

The process

A leak test system is required that can keep pace with production. The test process involves the following steps.

- Drop the package into test chamber and close the lid.
- Connect the vacuum pump.
- Isolate the test system and compare vacuum decay to standard decay.
- Eject from test fixture.

A single channel system of this nature should be able to process up to four 10-cm² sachets or bags/min. Multiple loading fixtures can be used to increase the throughput.

The simplest method of calibration is to make up the pneumatic circuit by placing in the chamber a package that is known not to have a leak. A calibrated leak can then be introduced into the circuit, which in turn can be used to calibrate the test system. A calibrated leak consists of a known orifice size through which air flow has been measured at a certain pressure using traceable gauges. Typical packs that can be tested this way include impermeable blister packs such as those used for moisture-sensitive products, impermeable sachets and pouch packs such as

those used for moist products, sealed containers of fluids and tablet blisters. Peel pouches such as Tyvek and paper-backed peel pouches have high permeability and are tested by the burst test method found in ASTM F1140, Standard Test Methods for Internal Pressurisation Failure Resistance of Unrestrained Packages for Medical Applications.

Cost

A robust and accurate single channel test system can be obtained for about £10 000 (approximately €16 000) minimum. Packaging is often a high-speed process and is likely to be more rapid than the number of tests per minute that can be performed by a single-channel machine. The number of tests will depend on the equipment and size of pack; a typical number for medical pouches is likely to be four per min. This will allow a significant sampling plan for most production systems and give a high level of confidence in the quality of the protective atmosphere of the packs. Multiple chamber systems can increase throughput.

Further reading

- ISO 11607 Packaging for Terminally Sterilised Medical Devices.
- ASTM F88 Standard Test Method for Seal Strength of Flexible Barrier Materials
- ASTM F1327-98 Standard Terminology Relating to Barrier Materials for Medical Packaging
- ASTM F2095-01 Standard Test Methods for Pressure Decay Leak Test for NonPorous Flexible Packages With and Without Restraining Plates.

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