

Package Shelf Life Validation



Sterile barrier and packaging system validation is required by ISO 11607-1:2006, *Packaging for terminally sterilized medical devices*. MET can satisfy your needs for testing materials, package integrity and seal strength all combined with ageing studies.

MET's shelf life claims validation protocol is suitable for medical pouches and blisters produced in from any substrate.

Testing commences with a time zero reference to which aged samples are compared. Package integrity and seal strength are tested to ASTM standards along with visual inspection.

Ageing is normally carried out at 55°C, which gives an ageing rate of 1 year of real time equivalent per 6 weeks in the chamber. Other temperatures are available on request.

Testing is carried out in our ISO9000-2001 laboratories using traceable equipment.

Pricing is dependant upon sample sizes and package sizes.

Testing Details

- ❖ **Burst testing** examines the pack seal strength along its entire periphery. It will be carried out according to ASTM F1140-00(2005), Standard Test Methods for Internal Pressurization Failure Resistance of Unrestrained Packages for Medical Applications.
- ❖ **Visual inspection** is carried out according to ASTM F1886-98 (2004), Standard Test Method for Determining Integrity of Seals for Medical Packaging by Visual Inspection.
- ❖ **Dye penetration** testing examines the pack seal integrity along its entire periphery. It will be carried out according to ASTM F1929-98 (2004), Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration.
- ❖ **Accelerated ageing** is carried out according to ASTM F1980-02, Standard Guide for Accelerated Aging of Sterile Medical Device Packages. Storage at 55°C for 6 weeks is equivalent to 1 year real time ageing.