

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 protocol for the validation of shelf-life claims is suited to medical pouches and blisters produced in 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, whereby 6 weeks in the chamber is equivalent to 1 year of real time at ambient conditions, but other temperatures are available on request.

Testing is carried out in our ISO9001:2008 laboratory using traceable equipment.

Pricing is dependant upon sample sizes and package dimensions.

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 is 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.