Shelf Life and Package Performance Testing
OVERVIEW

Package performance testing is used to evaluate the performance of product packaging after being exposed to the manufacturing and distribution processes. The package is expected to maintain product sterility from the time the package is sterilized until the labeled expiration date.

Typical applications of package performance testing are:

- Validation of packaging processes
- Compatibility with the sterilization process
- Transport testing
- Stability testing (Accelerated and real time aging)
- Quality Control

Medical product manufacturers have a responsibility to evaluate the package’s ability to protect the product throughout handling, distribution and within the storage environment. The package must be able to withstand the typical events associated with product distribution without defect or loss of package integrity. Failure to comply with these standards can lead to a loss of sterility for the medical product.


The necessary accelerated and real time aging, transport simulation and package integrity testing is performed at NAMSA’s Irvine, CA facility. As your MRO partner, NAMSA is also able to prepare custom protocols and final summary reports to meet the requirements of regulatory standards.

TESTING

Developing a validation study for a package design or the shelf life of a package involves designing a series of procedures, such as aging, transport simulation and package integrity testing. Sample requirements for the package integrity testing should be based on the acceptable quality limit (AQL) in accordance with ISO 2859-1, ISO 1886 or statistical process control (SPC). Sampling plans shall be based upon statistically valid rationale.

Test Offerings By Program Requirements:

<table>
<thead>
<tr>
<th>Seal Strength Testing</th>
<th>Seal Peel / Tensile Strength ASTM F88</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Burst / Creep Strength ASTM F1140</td>
</tr>
<tr>
<td>Package Integrity Testing</td>
<td>Visual Inspection, ASTM F1886</td>
</tr>
<tr>
<td></td>
<td>Gross Leak Test, Test ASTM F2096</td>
</tr>
<tr>
<td></td>
<td>Vacuum Leak Test ASTM D3078</td>
</tr>
<tr>
<td></td>
<td>Dye Penetration Test ASTM F1929</td>
</tr>
<tr>
<td></td>
<td>Gurley Porosity Testing ISO 11607 annex C, ISO 5636-5, TAPPI T4600cm</td>
</tr>
<tr>
<td>Transportation Simulation Testing</td>
<td>Environmental Conditioning ISTA, ASTM D4332, ASTM F2825, ISO 2233 and other conditioning upon request</td>
</tr>
<tr>
<td>Accelerated Aging / Shelf Life Studies</td>
<td>ASTM F1980, AAMI TIR17 annex G</td>
</tr>
</tbody>
</table>

SEAL STRENGTH TESTING

NAMSA can perform seal strength testing on the package to confirm the processes have not weakened the seals which could cause package failure and loss of sterility.

- Burst and/or Creep Tests ASTM F1140 Internal Pressurization Failure Resistance of Unrestrained Packages
- Seal Peel Tests ASTM F88 Seal Strength of Flexible Barrier Materials or D903 Peel or Stripping Strength of Adhesive Bonds

PACKAGE INTEGRITY TESTING

Sterile barrier system integrity tests are performed to confirm the microbial barrier performance characteristics of the material and seals of the package.
• Visual Inspection, ASTM F1886, Determining Integrity of Seals for Flexible Packaging by Visual Inspection
• Vacuum Leak Test, ASTM D3078, Determination of Leaks in Flexible Packaging by Bubble Emission
• Bubble Emission Test, F2096, Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)

Where applicable sterile barrier system integrity tests are not compatible, microbial barrier performance characteristics may be established by testing the microbial barrier properties of the material and the integrity of the seals separately. This can be done by performing dye penetration of the seals and microbial material permeability tests of the package material.

• ASTM F1929 Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
• Dye penetration only tests the seals and does not test the whole barrier system. This may be added to a test program to confirm the seals are properly sealed or if problems with the seals are suspected.

TRANSPORT SIMULATION TESTS

When considering transport testing, the procedure should be reflective of the steps the shipper will undergo during transit to the final destination. The typical standards used for transport testing are ASTM D4169 – “Standard Practice for Performance Testing of Shipping Containers and Systems”, and ISTA (International Safe Transport Association).

Other standards to consider when performing transport testing are ASTM D7386 - “Performance Testing of Packages for Single Parcel Delivery Systems” and other procedures in device related standards.

NAMSA can perform environmental conditioning to show the package can withstand the extremes of the environment during the transportation process. The materials of the seals may expand and contract at different rates as the temperature and humidity changes. This change may weaken the seals or pull them apart. Although there are many device related standards for conditioning, ISTA 2A “Partial Simulation Performance Test Procedure”, ASTM D4332 – “Practice for Conditioning Containers, Packages or Package Components for Testing”, and ASTM F2825 “Climatic Stressing of Packaging Systems for Single Parcel Delivery” and ISO 2233 – “Packaging -- Complete, filled transport packages and unit loads -- Conditioning for testing” are considered the main standards for conditioning.

AGING ACCELERATED AGING

Manufacturers must demonstrate that the packages maintain sterile properties over the shelf life listed. NAMSA offers real time aging testing as well as accelerated aging which uses exaggerated conditions for establishing the shelf life of a product under an expedited time frame. Accelerated aging data is accepted by regulatory bodies as a conservative estimate of the shelf life until real time aging tests can be completed. Standards NAMSA uses for aging and accelerated aging protocols are ANSI / AAMI / ISO 11607-1, ASTM F1980 and AAMI TIR 17 Annex G.

NAMSA can execute package performance testing on packages after sterilization, aging, transportation simulation, quality control or other processes to show that package integrity and seal strength are retained. Please contact your NAMSA representative for more information.
The MRO® Approach
Regulatory strategy, testing services and clinical research all support the medical product development process. These services must be available when needed, either individually or collectively depending on the stage of the product development process. With NAMSA's MRO® approach to testing and consulting, you maintain project control while gaining the benefit of on-demand external support—whether it’s to extend your in-house capabilities or access specialized expertise at exactly the right time.

We’ve assisted numerous companies from around the world in bringing their great ideas to the patients who need them. We know you’re passionate about developing and producing safe, effective and compliant medical products for global markets so we’ve designed our services, trained our people and maintained our facilities to get you there.

You deserve the best knowledge, integrated services and flawless execution in your chosen partner. NAMSA’s ready.

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