

Packaging System Testing Services for Medical Devices

WuXi AppTec's ISTA-certified laboratory provides medical device manufacturers with an array of testing services for their packaging systems. Testing services can be used to demonstrate compliance with the requirements cited in ANSI/AAMI ISO 11607, Packaging for terminally sterilized medical devices – Part 1 and Part 2. Services include packaging system design qualification testing and Sterile Barrier System (SBS) testing.

WuXi AppTec is a global leader in providing discovery, testing and manufacturing services for the pharmaceutical, biotechnology and medical device industries. Research-driven and customer-focused, with operations in China and the U.S., WuXi AppTec offers a broad and integrated portfolio of services designed to assist our customers with cost-effective and efficient outsourcing solutions.

Sterile Barrier System (SBS) Testing

WuXi AppTec offers a program of SBS services that features integrity evaluations; seal and whole package strength evaluations; and stability testing with accelerated and real-time aging studies.

Available tests include:

SBS Seal and Whole Package Strength Testing

- ASTM F88 – Standard Test Method for Seal Strength of Flexible Barrier Materials
- ASTM F1140 – Standard Test Methods for Internal Pressurization Failure Resistance of Unrestrained Packages for Medical Applications

SBS Integrity Testing

- ASTM F1886 – Standard Test Method for Determining Integrity of Seals for Medical Packaging by Visual Inspection
- ASTM F1929 – Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
- ASTM F2096 – Standard Test Method for Detecting Gross Leaks in Porous Medical Packaging by Internal Pressurization (Bubble Test)

SBS Stability Testing

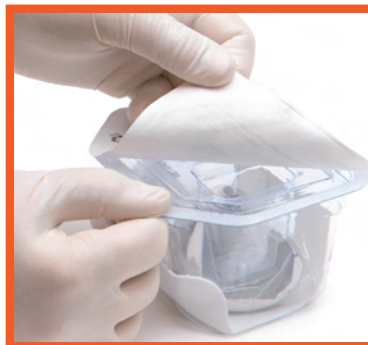
- ASTM F1980-07 – Standard Guide for Accelerated Aging of Sterile Medical Device Packages
- Real-Time Aging Sample Storage and follow up

Packaging System Design Qualification Testing

Available tests include:

- ASTM D4169 – Standard Practice for Performance Testing of Shipping Containers and Systems
- ASTM D7386 – Standard Practice for Performance Testing of Packages for Single Parcel Delivery Systems
- ASTM D4332 – Environmental Conditioning
- ISTA 1 and 2 Series
- ISTA 3A
- ISTA 4AB
- ISTA 7D and 7E
- ISTA Environmental Conditioning

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