

product stability: container closure/package integrity

WuXi AppTec provides manufacturers with a comprehensive menu of sterility assurance services. Our product stability testing and validation program includes integrity and container closure for package systems, as well as transportation and storage evaluations. Our experts will work with you to design customized product-specific testing programs that meet regulatory requirements – for devices, biologics, and combination products.

... for the life of your product



WuXi AppTec's ISTA-certified laboratory offers testing services to ensure seal integrity and packaging compliance, including:

- Determination of expiration dates.
- Proof that the container closure and packaging perform under physical and environmental stress.
- Evidence that the container closure and packaging are compatible with the product and sterilization process.

Our Capabilities

Stability / Accelerated and Real-Time Aging

- Unmatched capacity for a wide range of temperatures and humidity
- Competitive turnaround times (e.g., aging studies are initiated 1-2 days after receipt of samples)

Performance / Transportation Testing

(simulated distribution testing – aka “shake, rattle & roll”)

- Drop Test
- Compression Test
- Low Pressure / High Altitude (LPHA) Test
- Concentrated Impact Test
- Vibration Test

Integrity Testing

(required after each stability and transportation test)

- Package Integrity Test
- Seal Strength Integrity Test
- Container Closure Integrity Test

[See reverse for detailed test listings and the driving regulatory guidances.](#)

Talk to us and find out how our package and seal integrity testing services can work for you.

Contact a WuXi AppTec Account Manager at 888-794-0077 or email: info@wuxiapptec.com

driving regulatory guidance

- ISO 11607 International Organization for Standardization: Packaging for terminally sterilized medical devices
- ANSI American National Standards Institute
- AAMI Association for the Advancement of Medical Instrumentation
- ASTM American Society for Testing and Materials
- CBER Center for Biologics Evaluation and Research
- CDER Center for Drug Evaluation and Research
- ISTA International Safe Transit Association
- USP United States Pharmacopeia
- ICH International Conference on Harmonization: Technical Requirements for Registration of Pharmaceuticals for Human Use
- PDA Parenteral Drug Association
Technical Report 27 (TR 27): Pharmaceutical Package Integrity

available tests include:

Medical Devices

Sterile Barrier System (SBS) Testing

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 F 2096 – Standard Test Method for Detecting Gross Leaks in Porous Medical Packaging by Internal Pressurization (Bubble Test)
- Liquid Dye Immersion with Vacuum

SBS Stability Testing

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

Medical Devices

Packaging System Design Qualification Testing

- 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 and 3F
- ISTA 7D and 7E
- ISTA Environmental Conditioning

Biologics

Stability, Performance and Container Closure Integrity Testing

Container Closure Integrity Testing by Liquid Dye Immersion

- Liquid Dye Immersion with Vacuum

SBS Stability Testing

- Aging/Stability at 25C/60% RH and 40C/75% RH
- Real-Time Aging Sample Storage and follow up

ISTA Thermal Transport Package Testing (Cold-Chain)

- 7D and 7E Profiles
- Custom Profiles

Transportation Testing

- ASTM D4169 – Standard Practice for Performance Testing of Shipping Containers and Systems