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From the Blog

Transport Simulation Testing

March 9th 2026

Medical devices and pharmaceutical products often travel long and complex distribution routes before reaching the point of use. During transportation and storage, packaging systems are exposed to mechanical stresses, environmental fluctuations, and handling events that may challenge their protective performance.

Transport Simulation Testing is a structured validation activity designed to demonstrate that a packaging system can withstand these stresses while maintaining product protection and, for sterile medical devices, sterile barrier integrity. By reproducing distribution hazards under controlled laboratory conditions, manufacturers generate objective evidence that packaging performance remains acceptable throughout the defined distribution lifecycle.

Within regulated environments, Transport Simulation Testing forms a critical component of packaging validation under ISO 11607, and is typically integrated into broader quality and risk management frameworks including ISO 14971, EU MDR requirements, and FDA 21 CFR Part 820.

Regulatory Framework and Technical Standards
For sterile medical devices, packaging validation is governed primarily by ISO 11607 – Packaging for Terminally Sterilized Medical Devices.Two sections of this standard are particularly relevant to distribution testing.

- ISO 11607-1 specifies requirements for packaging materials and sterile barrier systems. It requires that sterility be maintained under defined storage and transport conditions until the point of use.
- ISO 11607-2 addresses validation of packaging processes and requires performance qualification activities that account for hazards encountered during storage, handling, and distribution.

Transport Simulation Testing therefore contributes to the documented evidence demonstrating that the packaging system maintains sterile barrier performance throughout the product lifecycle.

Transport Simulation Standards
Transport Simulation Testing is typically conducted using internationally recognized test protocols such as:

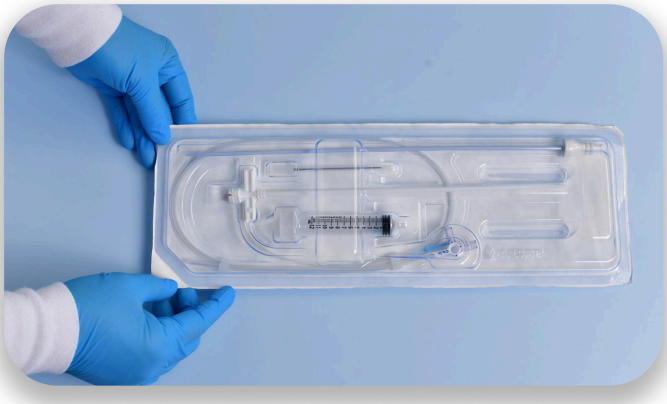
- ASTM D4169 – Performance Testing of Shipping Containers and Systems
- ISTA 2A – Packaged Products for Parcel Delivery Systems
- ISTA 3A – Packaged Products for Parcel Delivery Systems (General Simulation)
- ISTA 3E – Simulation Testing of Unitized Loads

The chosen test sequence must be justified within the validation plan and aligned with the defined distribution model and intended markets.

Post-Test Evaluation and Sterile Barrier Verification
Following completion of Transport Simulation Testing, the packaging system must undergo post-test evaluation to determine whether protective performance has been maintained. For sterile medical devices, evaluation focuses on verification of sterile barrier integrity. Typical post-test assessments include:

Visual Inspection

- Evaluation of packaging materials for punctures, abrasion, seal damage, or structural deformation.
- Seal Strength Testing (ASTM F88)
  - Measures the mechanical strength of packaging seals to ensure they remain within validated specifications.
- Burst or Creep Testing (ASTM F1140 / ASTM F2054)
  - Evaluates the resistance of packaging to internal pressure and potential seal failure.
- Dye Penetration Testing (ASTM F1929)
  - Detects microchannel leaks within seals that could compromise sterile barrier performance.



Definition of the Transport Model
A technically sound Transport Simulation Testing program begins with defining the expected transport profile of the product. This transport model describes the conditions a product may experience between manufacturing and final use. It typically includes:

- Transportation modalities (road, air, sea, or multimodal transport)
- Handling environments (parcel delivery systems, palletized freight, export shipment)
- Climatic exposure conditions
- Storage duration and warehousing conditions
- Stacking configuration and pallet loads
- Worst-case packaging configuration

Worst-case assumptions must be clearly documented and justified to ensure alignment between laboratory simulation and real-world transport conditions. This risk-based approach aligns with ISO 14971 risk management principles, ensuring that packaging validation activities reflect realistic distribution hazards.

Mechanical and Environmental Stressors Simulated
Transport Simulation Testing exposes packaged products to controlled stress conditions representative of real-world distribution hazards. The objective is to evaluate whether the packaging system maintains its protective performance under these simulated conditions.

Random Vibration
Random vibration testing simulates continuous vibration encountered during road, rail, and air transport. These dynamic forces may lead to product movement, packaging fatigue, or internal abrasion. Relevant standards include:

- ASTM D4169 – Distribution Cycle Vibration Profiles
- ASTM D4728 – Random Vibration Testing of Shipping Containers
- ISTA 3A / ISTA 3E – Random vibration simulation procedures

Shock and Drop Events
Handling shocks may occur during manual handling, loading operations, or automated parcel systems. Drop testing reproduces these events to evaluate the resilience of packaging systems to sudden impacts. Common test references include:

- ASTM D5276 – Drop Test of Loaded Containers
- ASTM D6344 – Concentrated Impact Testing
- ISTA 2A / ISTA 3A – Free-fall drop testing

These tests help determine whether packaging structures can absorb impact forces without compromising product protection.

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Acceptance criteria must be defined within the validation protocol prior to testing. Any failure must be investigated through formal quality system procedures, including assessment of impact on sterile barrier integrity and product safety.

Integration with Sterile Barrier Integrity Testing and Environmental Conditioning
Transport Simulation Testing is typically integrated with laboratory services that verify packaging integrity after simulated distribution exposure. Sterile barrier verification ensures that the packaging system continues to function as a microbial barrier after transport stresses. Common test methods include:

- Seal strength testing (ASTM F88)
- Dye penetration testing (ASTM F1929)
- Burst testing (ASTM F1140 / F2054)
- Bubble emission testing

These tests confirm that packaging seals and materials maintain their protective performance.

Validation Timelines and Testing Duration
Transport Simulation Testing is typically conducted within a broader packaging validation program, which may include transport simulation, sterile barrier integrity testing, and shelf-life studies. Lead times depend on protocol complexity, conditioning requirements, and aging studies.

In practice, typical lead times for transport simulation and laboratory verification range between approximately 8 and 12 weeks for a complete validation program. However, the total duration of packaging validation may extend depending on the selected aging strategy.

Accelerated Aging
Accelerated aging studies simulate long-term storage effects using elevated temperatures. These studies are typically conducted according to:

- ASTM F1980 – Standard Guide for Accelerated Aging of Sterile Barrier Systems

Accelerated aging allows manufacturers to simulate shelf-life performance within a shorter timeframe, often within several weeks depending on the claimed shelf life. Accelerated aging data may support initial regulatory submissions while real-time studies continue in parallel.

Real-Time Aging
Real-time aging evaluates packaging stability under actual storage conditions. Standards typically referenced include:

- ASTM F1980 (Real-Time Confirmation Studies)
- ISO 11607 Shelf-Life Requirements

Real-time aging studies may run 12, 24, or 36 months depending on the declared shelf life of the product.

Infrastructure Supporting Packaging Validation
Effective packaging validation requires coordination between sterilization services, laboratory testing, packaging expertise, and logistics infrastructure. Medistri operates a dual-site infrastructure in Switzerland and Hungary, enabling manufacturers to perform packaging validation activities within a controlled regulatory framework.

To learn more about Medistri's Transport Simulation services, visit on our website here or directly contact our team at contact@medistri.com.

– The Medistri Team

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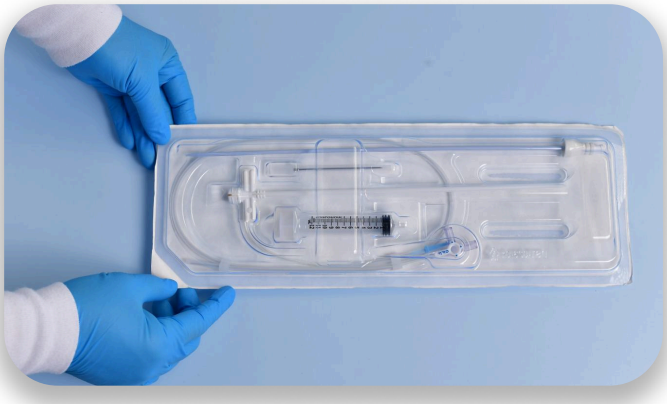

Compression and Stacking Loads
During transport and warehousing, packages may experience vertical loads caused by stacking on pallets or within storage facilities. Compression testing evaluates whether packaging systems can withstand these loads without structural failure. Relevant standards include:

- ASTM D642 – Compression Resistance of Shipping Containers
- ASTM D4169 – Stacking Load Simulation
- ISTA 3E – Palletized load compression testing

This testing is particularly important for palletized distribution systems and extended warehouse storage.

Environmental Conditioning
Products distributed globally may pass through different climate zones and environmental conditions. Environmental conditioning replicates these exposures under controlled laboratory conditions. Typical standards include:

- ASTM D4332 – Conditioning Containers, Packages, or Packaging Components
- ISTA 3A Environmental Conditioning Profiles
- ASTM F2825 – Climatic Stressing of Packaging Systems for Medical Devices

Environmental conditioning may simulate:

- Temperature extremes
- Relative humidity variation
- Thermal cycling
- Atmospheric pressure changes associated with air transport

Environmental conditioning is often performed prior to or during mechanical testing to replicate realistic distribution scenarios.

Integration into the Packaging Validation Lifecycle
Transport Simulation Testing represents one element within the broader packaging validation lifecycle. A complete packaging validation program typically includes:

- Packaging process validation (IQ / OQ / PQ)
- Transport simulation testing (ASTM D4169 / ISTA protocols)
- Environmental conditioning (ASTM D4332)
- Sterile barrier integrity testing (ASTM F88, F1140, F1929)
- Accelerated aging studies (ASTM F1980)
- Real-time shelf-life studies

The resulting dataset demonstrates that the packaging system maintains required performance characteristics throughout sterilization, storage, distribution, and use.