AdeptGroup

ENGINEERING EXCELLENCE

Single Parcel Test Comparison

MEDICAL DEVICE TESTING

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Adapt Testing Protocols

Package Performance Testing Standard

As of 2019, ISTA 2A is no longer a recognized package performance testing standard by either the International Organization for Standardization (ISO) or the U.S. Food and Drug Administration (FDA).

Though many medical device companies have historically relied on ISTA 2A for their package performance testing needs, submissions in 2020 will no longer accept ISTA 2A as a viable package performance testing standard.

More modern testing standards developed by both International Safe Transit Association (ISTA) and ASTM International (ASTM) allow manufacturers to customize some testing criteria, such as levels, sequences, and orientations, to better evaluate specific, real-world conditions of their packaging and distribution environments.

This ability to adapt portions of the testing protocol to suit specific needs has brought these newer standards to the forefront and caused ISTA 2A to fall out of favor.

Package Performance Testing

ISO11607-1:2019 (Packaging for terminally sterilized medical devices – Part 1:

Requirements for materials, sterile barrier systems and packaging systems) lists four (4) key testing requirements for packaging materials, pre-formed sterile barrier systems, sterile barrier packaging systems and packaging systems that are intended to maintain sterility of terminally sterilized medical devices until the point of use.

1. **Performance Testing** – Distribution simulation to demonstrate that the packaging system provides protection through the hazards of handling, distribution and storage
2. **Package Strength Testing** – Physical tests to demonstrate the mechanical performance of the sterile barrier system (i.e. seal strength, burst testing)
3. **Package Integrity Testing** – Physical tests to demonstrate the sterility and integrity of the sterile barrier system (i.e. dye penetration of seals)
4. **Stability Testing** – Simulation tests to demonstrate the sterile barrier system maintains integrity over the anticipated shelf life of the product

Performance Testing relates specifically to challenging the sterile barrier packaging system to repeatable/controlled simulation of the distribution environment. Though the requirements include assessment and exposure to expected environmental conditions (sterilization and distribution humidity and temperature levels), this discussion will focus primarily on the physical distribution tests for non-cold chain products.

Recognized Package Performance Testing Standards

As of the time of this writing, both ISO and FDA recognized standards are as follows:

ISO 11607-1:2019 (ANNEX B – STANDARDIZED TEST METHODS, GUIDES AND PROCEDURES THAT CAN BE USED TO DEMONSTRATE CONFORMITY WITH THE REQUIREMENTS OF 11607-1)

- D4169-16 Standard Practice for Performance Testing of Shipping Containers and Systems
- D7386-16 Standard Practice for Performance Testing of Packages for Single Delivery Systems
- ISTA 3 Series, including ISTA 3A, ISTA 3B and ISTA 3E
- ISTA 4AB Enhanced Simulation Performance Tests
- ISO 4180 Packaging

FDA – RECOGNIZED CONSENSUS STANDARDS FOR PACKAGE PERFORMANCE TESTING

- D4169-16 Standard Practice for Performance Testing of Shipping Containers and Systems
- D7386-16 Standard Practice for Performance Testing of Packages for Single Delivery Systems
- ISTA 3 Series, including ISTA 3A, ISTA 3B and ISTA 3E

INTERNATIONAL SAFE TRANSIT ASSOCIATION (ISTA)

The International Safe Transit Association (ISTA) is a nonprofit member-driven association. The Board of Directors generates new standards. There is no formal balloting process including outside experts or non-member industry experts. ISTA has over 750 member companies that include manufacturing, packaging suppliers, carriers, universities and independent test labs. Member companies within ISTA define testing procedures and condition to ensure how different packages perform in transit and distribution and the conditions they may be subjected too. ISTA testing can consist of actual testing condition or simulated testing, based upon the known transportation levels.

AMERICAN SOCIETY FOR TESTING AND MATERIALS (ASTM)

ASTM International creates “consensus standards” developed by a large group of experts and are democratically approved. Three groups review the standards (Task Group, Subcommittee, Main Committee). Any issues put forth during the review process are addressed before approval. Most of the testing of the ASTM standards are meant to look at specific tests (Drop, Vibration, Shock) and not the overall packaging system. The exceptions to this methodology are ASTM D4169 and D7386.

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Distribution Channels

Single Parcel Testing

Single Parcel: Individual packages that are not sent as part of a skid or pallet containing a single item, usually done with services from UPS, FedEx, etc. This is generally considered a “worst case” distribution environment since these packaged products are manually handled multiple times, may be stacked/shipped multiple times in any orientation and stacked below any other mixed commodities to the full height of the vehicle in use.

Unitized load: One or more packaged products, typically on a skid or pallet, secured together or restrained for distribution as a single consolidated load. This method is considered much less severe in comparison to Single Parcel.

The majority of medical devices in the U.S. are shipped through multiple distribution channels. A typical packaged device is often shipped as a unitized load to sterilization and again to a distribution center. At the distribution center, product may be configured and/or consolidated in multiple ways as required for downstream distribution, with the final leg often as single parcel.

The importance of understanding your specific products potential distribution flow is critical in justifying the performance testing standards selected and executed for verification testing. Since most domestically produced products are eventually shipped as single parcel somewhere through the distribution channels, an appropriately recognized single parcel test standard is often required.

Single Parcel Test Standards Comparison

ISTA:

ISTA 2A (2011) Partial Simulation Performance Tests: As the title states, this is not considered a full simulation testing series, it is a combination of the most basic test series (ISTA 1) and the recognized performance test series found in ISTA 3A.

- Only simulates some actual transport hazards
- Does not necessarily comply with carrier packaging regulations
- Useful for comparing relative performance between package designs/configurations
- Drop heights are excessive in comparison to other test series discussed in this paper.
- Most importantly – NOT recognized by FDA or ISO

ISTA 3A (2018) General Simulation Performance Tests: This test series is specific to individually packaged products shipped through a parcel delivery system (FedEx, UPS, etc.). The tests are specific to four different common packaging styles/configurations (standard, small, flat, elongated).

- "Standard" packaging style/configuration is the most common
- Covers packages weighing 150 lbs or less
- Includes a Top Load Vibration sequence which is controversial in reflecting real-life damage reports.

ASTM:

ASTM D4169 (2016) Performance Testing of Shipping Containers and Systems: This testing standard is divided into 15 Distribution Cycles (DC), including a cycle (DC 2) for user specified (custom) development. The most common cycle within the medical device industry is DC 13 (Air and motor freight, single package up to 150 lb).

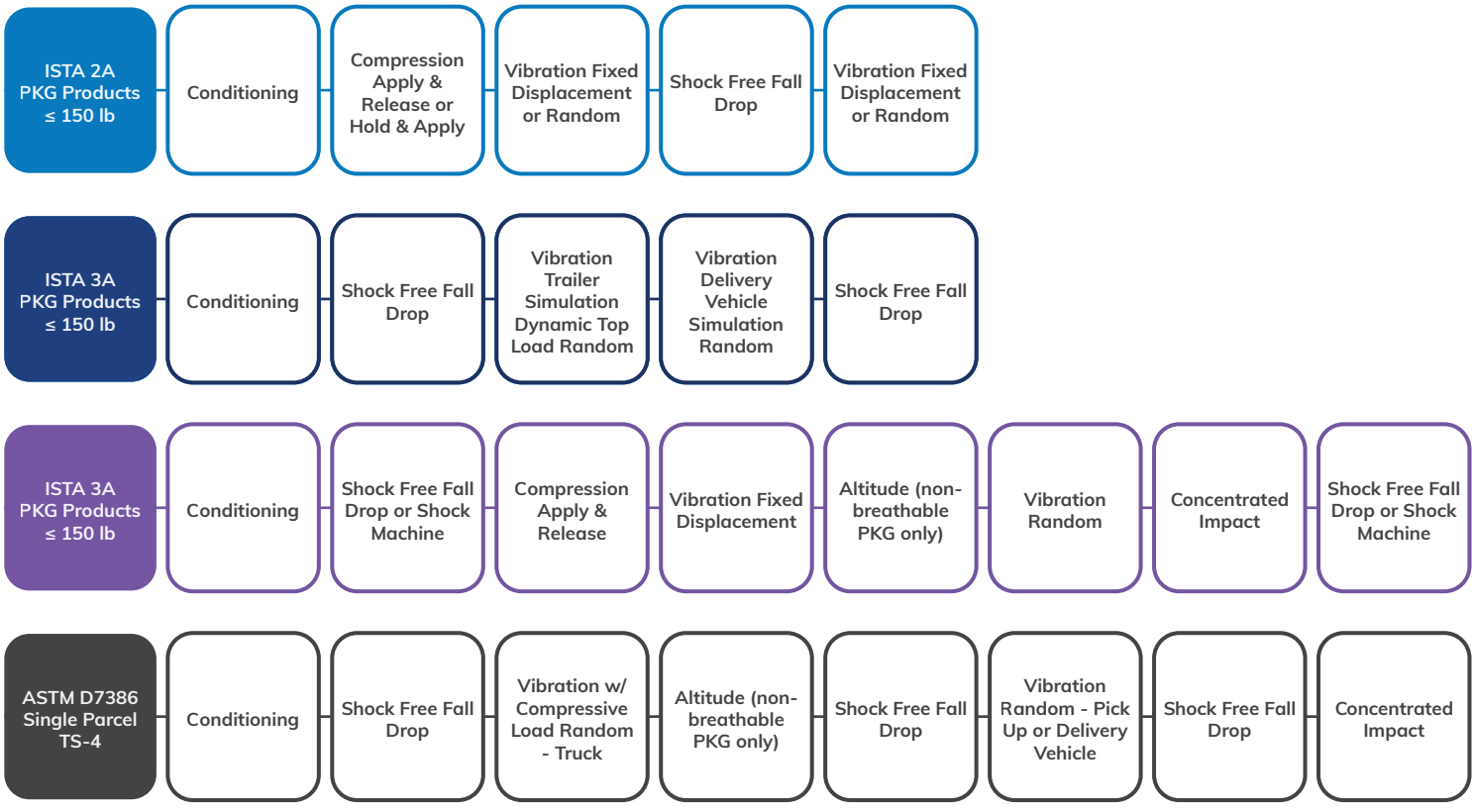
- Each test series is broken into three Assurance Levels (AL) for selection of test intensity (ALI highest, ALIII lowest). ALII is suggested unless known conditions dictate otherwise.
- Its compressive loading formula is controversial in reflecting real life damage reports. Some users justify reducing this test from ALII to ALIII to reflect real-life historical data.
- Includes a Concentrated Impact test which is controversial in its usefulness, since low weighted corrugated boards (under 44 ECT) will suffer punctures
- Includes both random truck and random air vibrational tests. The random air profile is controversial in reflecting real-life historical data
- Most-used test standard in medical device industry

Single Parcel Test Standards Comparison

ASTM D7386 (2016) Performance Testing of Packages for Single Parcel Delivery Systems: This testing standard is divided into 4 test sample (TS1 small, TS2 large/flat, TS3 long/narrow, TS4 all others).

- Similar to ISTA 3A with additional elements that align with ASTM D4169
- TS4 style/configuration most common
- Includes a Top Load Vibration sequence which is controversial in reflecting real-life damage reports
- Includes a Concentrated Impact test which is controversial in its usefulness, since low weighted corrugated boards (under 44 ECT) will suffer punctures
- Not commonly used in medical device industry for formal verifications
- Very useful for development and/or failure analysis

A side-by-side comparison of each test series is shown below. ISTA 2A is included in this analysis to aid in understanding the upcoming regulatory impacts.



Considerations Before Changing a Package Performance Test Standard

If the situation arises that you wish to or need to change the package performance test you are currently using, there are a few things to consider.

First, why are you considering the change? Is it because of a change to the form, fit or function of the product? Is it because it is a new product or brands? Is it in regard to a regulatory concern or function? These are all acceptable changes and reasons to consider for changing.

Second, consider which test standard best aligns to the distribution life cycle your packaged product will be subjected too. This includes the transportation, environmental conditions and shelf life. You may have started with one over ten (10) years ago and now there are better distribution cycles and standards that align more closely with your life cycle.

Third, has the acceptance criteria or criticality of defects changed either in a higher or lesser classification? Did the packaged product previously need to be a sterile barrier and now it is just to be used as a non-sterile product? Was it previously to be used in a retail environment (OTC) and now it is strictly a prescription or clinical environment?

Fourth, standardize the testing standards within a company based upon growth and mergers/acquisitions. With so many companies merging to being acquired, it is not cost-effective or resource-effective to test multiple packaged products to different standards. A review of the current testing and standards is necessary to determine which standard to follow.

The key to making your decision is a complete and thorough packaging audit/comparison. This is where you review the entire packaging and product life cycle and make note of all areas that affect or have input into the product/package. This will include a “birth to grave” review for design inputs and outputs and a process review. These are best completed by an outside group that is trained and has completed these audits/comparisons previously, with positive results. Having an expert in this process gives your product, package, structure and distribution process a review with an unbiased and “fresh perspective” can gain you a better testing profile and in many cases, a healthy cost savings to the bottom line.

Single Parcel Test Comparison

Get in Touch

Partnering with Experts

Changing package performance test standards can be a complex, but sometimes necessary process.

It requires having a comprehensive understanding of regulatory requirements, distribution environments and validation and testing. The Adept Group team has over a decade of experience helping the most iconic life sciences brands engineer, audit and qualify packaging to meet the highest testing standards. Our clients have leveraged our unique blend of expertise, tools and resources to help them increase speed to market, reduce risk and ensure compliance.

If you need assistance validating, qualifying or testing your packaging, contact our team today.