

AdeptPackaging
PACKAGING ENGINEERS & CONSULTANTS

A Guide to Successful Distribution Qualification

The Path to Effective Packaging

An Adept Packaging White Paper

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Why Distribution Testing?

-  Reduce Product Loss
-  Increase Customer Satisfaction
-  Maintain Product Functionality
-  Validate Strength of Package Design
-  Uncover Package Areas of Weakness
-  Meet Regulatory Requirements

As the ecommerce market continues to grow, supply chains become more complex, and regulations in industries such as life sciences become increasingly demanding, executing a reliable distribution qualification process is an

imperative step towards a satisfied consumer or user. It is the duty of manufacturers and retailers to ensure that their products arrive at the consumer in safe working condition, and one of the most effective ways to do that is through distribution qualification.

In order for a manufacturer to assure their product makes it through the distribution environment unscathed, the distribution qualification process must ensure that the packaging provides adequate protection through the distribution environment. Because each combination of product and distribution environment is unique, there is no “one size fits all” distribution test. Manufacturers must ensure the test is representative and takes into account the many factors that affect the package throughout the distribution environment. A poorly designed system may not represent the distribution environment correctly, resulting in an incorrect simulation and inaccurate test results.

This white paper gives guidelines for building a robust system and examines the following areas:

- I. **The Concepts Within Distribution Qualification**
- II. **Understanding the Distribution Environment**
- III. **Utilizing ISTA's Distribution Testing Series**
- IV. **Establishing a Testing Approach**
- V. **Evaluating Test Results**

I. **The Concepts Within Distribution Qualification**

The terms used in distribution qualification such as integrity testing, conditioning, and simulation can be confusing. Before a distribution qualification is undertaken, there must be an understanding of the basic concepts.

What is a Distribution Test?

A **Distribution Test** is a test that reproduces the environment the product will go through when it is sent from its point of manufacture to the user. A distribution test may use the actual channels that the product will use, e.g. planes, ships, and trucks.

A **Distribution Simulation Test** is a test that uses laboratory equipment to represent the conditions of the environment the product will go through during its trip to the user. The use of laboratory equipment ensures that the test is repeatable. A simulation test is usually more cost effective and quicker than putting samples through actual channels. A simulation can ensure that worst case conditions are applied to the samples.

Distribution tests and distribution simulation tests are merely methods of conditioning the test samples in a way that represents the hazards of the environment. Examples of conditioning are vibration, temperature, and impact. A distribution test alone does not verify that the packaging is suitable for the environment. It is the testing that is executed after the distribution testing that provides the pass/fail data.

Types of Tests

Inspection is a visual observation of the product and packaging following the distribution testing. During inspection, the inspector records observations of damage or deterioration caused by the hazards within the environment.

Integrity Testing is used to determine whether packaging is providing a protection to the product against contamination. Examples of integrity testing are internal pressurization testing and dye leak testing. If a product is required to be sterile when used, integrity tests are used to assess whether sterility has been compromised during distribution testing.

Strength Testing is an evaluation of the force required to separate two or more components of a package. The conditions in an environment, e.g. temperature and humidity, can affect materials such as adhesives, which will impact the packaging strength.

Product Testing is the evaluation of whether a product is working safely and effectively. Product tests may include closure removal torque tests or electronic tests.

Qualification is a data-driven assessment whether packaging provides satisfactory protection to the product through the distribution channels.

A combination of inspection, integrity, strength and product testing, amongst other verification tests, must be conducted after the distribution test or distribution simulation test to determine whether the packaging is qualified.

Distribution Qualification Process

A distribution qualification process is a system that plans and executes the activities to accurately assess an environment, determine success criteria and develop representative test plans to give a high level of confidence that the results can be used to make predictions within a population. The process will contain methods, operating procedures, templates, and instructions to make each package qualification as accurate and efficient as possible

II. Understanding the Distribution Environment

Evaluating the factors that will be experienced throughout the distribution environment will ensure the manufacturer is choosing a test which will produce results indicative of real world package performance. The variability and level of exposure to the four main shipping hazards present in any distribution environment is one of the largest challenges throughout distribution. The four main hazards are vibration, shock, compression, and atmospheric conditions. There are many ways to determine the level of hazards. One way is to use sensors placed in packages that are then sent on the actual distribution channel, i.e. on a ship or on an airplane. Other methods used to determine levels of the hazard include researching temperature extremes for regions and using carrier information for distribution data, such as temperatures in delivery trucks.

It is also important to understand the sensitivities of the product. For example, most drug products have a temperature range that they must stay within to ensure the product lasts up to its expiration date. If a product must be refrigerated between 3-7C, it must be shipped in a temperature-controlled environment. In some cases, it is not enough to put a product in a refrigerated truck. Packaging must also be sufficient to supplement moving from the manufacturer to the truck, the truck to the distributor and so on. Understanding the sensitivities of the product, and therefore the risk level of making errors with testing, will dictate certain aspects of the distribution qualification such as samples sizes and reliance on simulation to test the effect of temperature extremes.

Once the product and its distribution environment are fully understood, the tests must be selected or designed to simulate the distribution environment. ISTA (International Safe Transit Association) has developed a series of ANSI accredited tests to assist companies in accurately evaluating how well their product withstands its distribution environment.

III. Utilizing ISTA's Distribution Testing Series

ISTA uses a combination of tests to gauge package performance and each series offers a different level of testing depending on what the manufacturer needs and what their purpose is for performing the test.

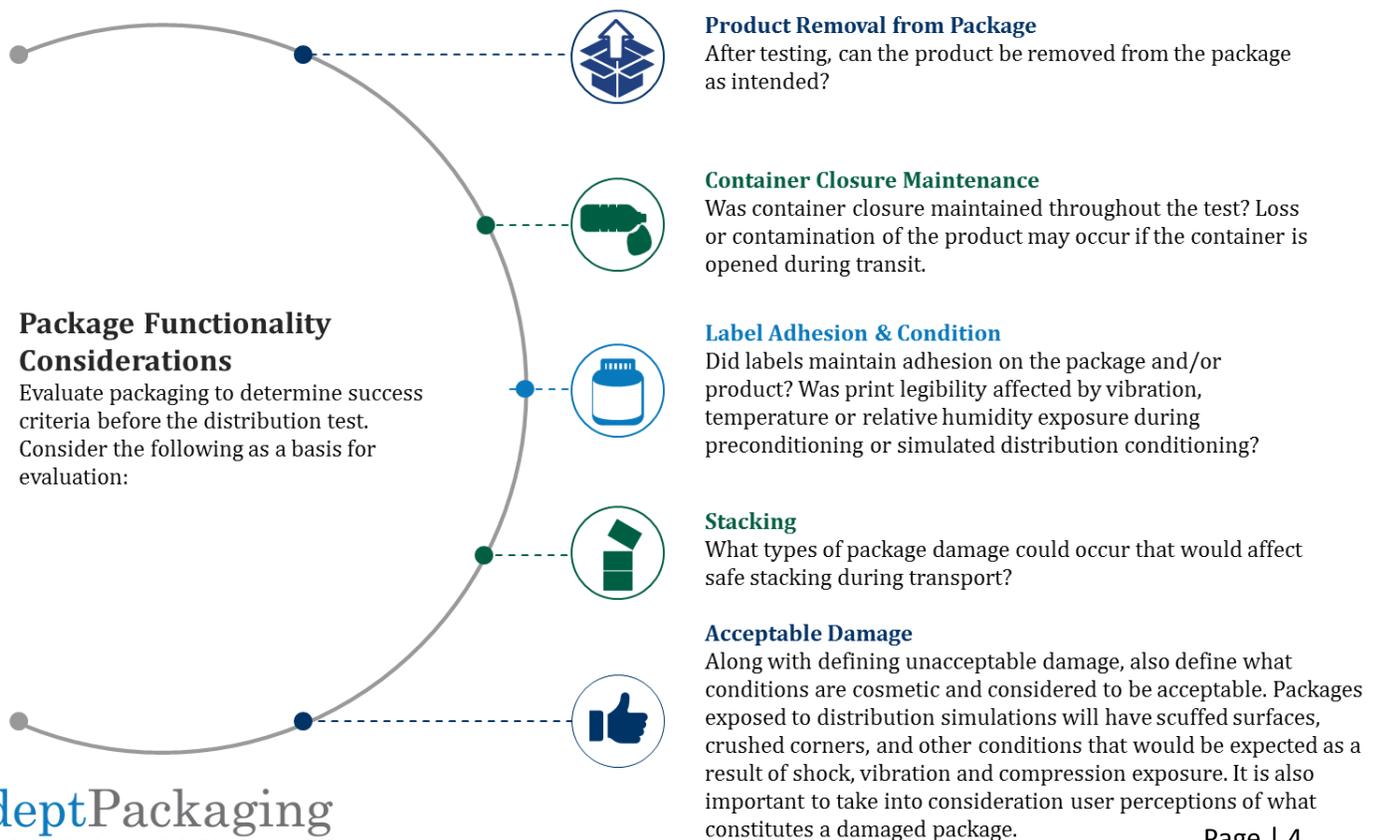
ISTA's Series 2: Partial simulation tests. These tests focus on at least one of the four hazards that were mentioned before: vibration, shock, compression or atmospheric conditions, as well as basic elements of the Series 1 integrity tests.

ISTA's Series 3: General simulation tests. Series 3 is the most comprehensive testing series offered by ISTA. It is designed to provide simulations of all of the elements experienced throughout a distribution environment, as well as sequence testing when combining these elements. Procedures for these were developed using reference studies and industry research to determine actual hazard levels that exist in a distribution environment. These tests are often the best method for determining under which conditions a packaging is failing to protect the product, or where the issues are in the distribution chain. ISTA works to correlate the data to ensure it is representative of what carriers are seeing in the real world.

Utilizing an ISTA series test can lessen the amount of decision making required to determine correct simulation, but it is up to the manufacturer to decide which ISTA series applies to their product. Guidelines for test selection can be used to assist with the selection process. In some cases, a combination of the distribution environment and the product sensitivity requires that distribution testing and simulations are tailored for the specific use. There are ASTM standards for conditioning and testing packaging that can be applied, however the tester will need to determine simulation conditions using the information gained during environment research.

IV. Establishing Success Criteria

Once the appropriate test is identified, manufacturers must define acceptable outcomes of the testing in terms of packaging integrity, packaging strength, acceptable damage to packaging and product, and product functionality. Package damage may include conditions affecting package functionality, which compromise product protection, aesthetics, dispensing, handling, or identification prior to distribution test execution. Clearly defining what constitutes damage to the package and product will prevent questions and delays when the test has been completed. Doing this work up front and gaining agreement with stakeholders will ensure recommendations from data assessment are not challenged. A common occurrence of not establishing success criteria is having to repeat testing, which is an inefficient activity.



Manufacturers must determine pass/fail criteria before completing the test. As different companies are willing to accept different levels of risk, it is important to determine criteria that can be used to measure the success of the test prior to conducting it. Both the package and the product should be considered when determining this criteria and specifications set for what is acceptable and unacceptable for each.

As part of the success criteria for packaging and product a product functionality checklist can be developed to ensure consistency in the inspection process. This checklist should include:



Once packaging and product expectations are set, it's time to perform the test.

V. Evaluating Test Results

One of the main problems with distribution simulation testing is that product and packaging has to be transported to and from the test site. Additional damage could occur before and after the distribution simulation test takes place. To lessen risk, the manufacturer should plan to spend time at the lab to observe distribution simulation testing. This allows the manufacturer to ensure that product arrived at the lab in good condition, and the manufacturer can assess the quality of the packaging and product immediately following the testing. When observing the test and performing inspections, details of the inspection results should be recorded, including the location and type of damage if any is identified. This information can help to determine the root cause of any unacceptable results or establish the need for design modifications to prevent future package performance issues, especially if the same type of damage is seen on multiple test samples.

In addition to observing the package performance during simulated distribution, observations during test sample preparation and set up may be valuable as well. Consider the following:

- ✓ When test samples were prepared, were any problems apparent during assembly, loading or closing the package?
- ✓ If the packages were palletized, were issues with load stability apparent?
- ✓ Did the size of the package make it difficult to handle during testing?
- ✓ Could any design features be added to make handling of a larger package easier?

Test data from integrity and other tests has to be prepared in a way that can be compared to the success criteria. The preparation and the statistical analysis methods used for evaluation should be established as part of the success criteria to ensure that results are not groomed to meet desired outcomes rather than actual outcomes.

Partnering for an Effective Packaging System

In order to qualify packaging for distribution and satisfy consumers, packaging systems need to continue to be effective once they've been through the distribution environment. Following the guidelines in this white paper will help manufacturers establish a system for distribution qualification that produces reliable results that can be used to make decisions on the suitability of packaging with a high confidence level. Adept Packaging has developed Distribution ProTrack as a system that can be used by life sciences organizations to confidently qualify packaging material in distribution channels. In addition to the guidelines above, Distribution ProTrack identifies decision points, describes SOPs, and provides templates to improve accuracy and speed to market.

Adept Packaging's team of industry experts is the largest in the world, providing services and tools to effectively execute projects, fix issues, improve internal capabilities and deliver on objectives. Over 100 national and global food & beverage, CPG and life sciences companies trust Adept's combined 850 years of experience for everything they need to optimize their packaging function, from staffing and engineering services to business process tools and serialization expertise.

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