

ISTA 7 Series
Development
Test
Procedure

VERSION
DATE
Last
TECHNICAL
Change:
MARCH 2007

Last
EDITORIAL
Change:
JANUARY
2010

For complete
listing of
Procedure
Changes and
Version Dates
go to
www.ista.org

Preface

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ISTA 7 Series tests are package development tests.

- Test elements may come from ISTA Series 1, 2 or 3 tests, **and**
- They may or may not evaluate the protection afforded packaged-products.

There are three sections: Overview, Testing and Report

- **Overview** provides the general knowledge required before going into the testing laboratory **and**
- **Testing** presents the specific instructions to do the testing in the laboratory **and**
- **Report** indicates what data shall be recorded to submit a test report to ISTA.

Two systems of weights and measures are presented in ISTA test procedures. They are the English system (Inch-Pound) and the international system (Metric). Inch-Pound units are shown first with Metric units in brackets, except in some tables where they are shown separately. In the case of temperatures, °C is shown first and °F is in brackets.

- Either system may be used as the unit of measure (standard units), **but**
- The standard units chosen shall be used consistently throughout the procedure.
- Units are converted to two significant figures **and**
- Not exact equivalents.

VERY IMPORTANT:

The entire document shall be read and understood before proceeding with a test.

**2010: LAST YEAR OF PUBLICATION
FOR PROCEDURE 7D**

ISTA, in cooperation with the Pharmaceutical Cold Chain Interest Group (PCCIG), is completing an extensive survey of temperature ranges found in the U.S. parcel delivery distribution environment. This data will be used to create a new ISTA Procedure, which will supersede 7D. Procedure 7D will be supported for one year after publication of the new Procedure.

OVERVIEW FOR PROCEDURE 7D

Test Procedure 7D is a development test to evaluate the effects of external temperature exposures of individual packaged-products shipped through a parcel delivery system.

- It can be used for the development of temperature controlled transport packages made of any material.
- It can be used for individual or comparative performance analysis of standard or insulated transport packages against normally encountered conditions.
- It is designed to measure the relative ability of a package to protect a product when exposed to test cycles that simulate both the range and time of exposure to ambient temperature conditions.
- The product and package are considered together and not separately.
- It is not intended to evaluate the protection afforded packaged-products from shock, vibration and/or compression.

CAUTION:

The cycle profiles in 7D are general simulations not intended to represent the worst case thermal exposure in the small parcel shipment environment. Many variables affect the thermal and distribution performance of a package and the ambient exposure profile extremes found in the distribution environment for each distribution situation, therefore,

- If testing is for compliance with specific government, industry, laboratory, validation or regulatory standards or guidelines that would supplement or supersede this procedure **or**
- If the value of the product **or**
- the liability of damage is significant,
- **It is the responsibility of the user to know that ISTA strongly recommends that Focused Simulation Performance Guide 5B be used to develop specific focused profiles to be used in place of the generalized profile examples illustrated in Procedure 7D.**

Other ISTA Procedures may be appropriate for different conditions or to meet different objectives.

- It is recommended that once a package demonstrates acceptable thermal performance in a series of screening or exploratory ISTA 7D general simulation tests, a distribution test series be conducted that simulates the extremes expected to be encountered in the transit environment.
- For packaged-products that may be transported in a small parcel delivery system consider ISTA General Simulation Performance Test Procedure 3A.

Refer to *Guidelines for Selecting and Using ISTA Procedures and Projects* for additional information.

Scope

Test Procedure 7D covers the thermal performance testing of packaged-products to evaluate the effects of external temperature exposure. The test method is suitable for testing analysis of packaged-products with and without temperature stabilizers (e.g. refrigerants, eutectic solutions), and with or without external temperature controlled packaging (e.g. insulated containers).

Product Damage
Tolerance and
Package
Degradation
Allowance

The shipper shall determine the following prior to testing:

- exact product temperature limits, high and/or low for the product **and**
- any acceptable time limits for excursions above or below the temperature limits.

For additional information on this determination process refer to *Guidelines for Selecting and Using ISTA Procedures and Projects*.

Samples

Samples should be the untested actual package and product, but if one or both are not available, the substitutes shall be as identical as possible to actual items.

Substituted products should be as close as possible in regard to content, composition, thermal mass, consistency (e.g. liquid, powder, or paste), and other physical properties, and be packaged in the product specific primary package.

It is recommended that the simulated packaged-product tested be as close as possible in its specific heat to the actual product so that changes in temperature of both materials would occur at the same rates.

If a refrigerant or temperature stabilizer is used, it shall be the exact type that will be used by the shipper.

Number of samples required:

One sample is required for the tests in this procedure.

Replicate Testing Recommended:

To permit an adequate determination of representative performance of the packaged-product, ISTA:

- Requires the procedure to be performed one time, **but**
- Recommends performing the procedure three or more times using new samples with each test.

NOTE:

Packages that have already been subjected to the rigors of transportation cannot be assumed to represent standard conditions. In order to insure testing in perfect condition, products and packages shipped to certified laboratories for testing must be:

- over-packaged for shipment to the laboratory **or**
- repackaged in new packaging at the laboratory.

Test Sequence

The tests shall be performed on each test sample in the sequence indicated in the following table:

| Sequence # | Test Category | Test Type | Test Level | For ISTA Certification |
|------------|-----------------------------|-------------|--|------------------------|
| 1 | Temperature Preconditioning | Temperature | Storage conditions for the product and each package element for 24 hrs. min. | Optional |
| 2 | Shock Conditioning | Drop | Height varies with packaged-product weight | Optional |
| 3 | Atmospheric | Temperature | 1 st Cycle Period of selected Test Profile | Required |
| 4 | Vibration Conditioning | Random | Overall G _{rms} level of 1.15 | Optional |
| 5 | Atmospheric | Temperature | 2 nd Cycle Period of selected Test Profile | Required |
| 6 | Shock Conditioning | Drop | Height varies with packaged-product weight | Optional |
| 7 | Atmospheric | Temperature | Remaining Cycle Periods of selected Test Profile | Required |

Equipment
Required
Atmospheric
Conditioning

Temperature Conditioning:

- Draft-free Room or Chamber and Control apparatus complying with the apparatus section of ASTM D 3103.
 - Temperature Indicators complying with the apparatus section of ASTM D 3103.
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Equipment
Required
Shock
(Optional)

Optional Free Fall Drop Test:

- Free Fall Drop Test System complying with of the apparatus section of ASTM D 5276.
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Equipment
Required
Vibration
(Optional)

Optional Random Vibration Test:

- Random Vibration Test System complying with the apparatus section of ASTM D 4728.