

ISTA 7 Series
Development
Test
Procedure

VERSION
DATE
Last
TECHNICAL
Change:
MARCH 2007

Last
EDITORIAL
Change:
JANUARY
2012

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.

OVERVIEW FOR PROCEDURE 7D

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

- 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 of 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 a worst case temperature exposure. The profiles listed in this procedure are not based on current data-based research. 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, it is the responsibility of the user to know and understand those requirements and use the proper procedure accordingly
- ISTA strongly encourages the use of ISTA 7E over Procedure 7D. ISTA 7E was developed after a comprehensive survey of temperature ranges found in the parcel delivery system and is considered to be the best and most current simulation of the thermal environment.

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 in the form of a distribution test series, be conducted that simulate other distribution hazards, such as shock, vibration and compression 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.
- ISTA 7E should be considered for thermal testing of insulated shipping containers in the parcel delivery system.

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

USE OF ISTA 7E OVER PROCEDURE 7D

ISTA, in cooperation with the Pharmaceutical Cold Chain Interest Group (PCCIG), has completed an extensive survey of temperature ranges found in the U.S. parcel delivery distribution environment. This data has been used to develop **ISTA 7E, Testing Standard for Thermal Transport Packaging Used in Parcel Delivery System Shipment**, which should be considered for use in lieu of Procedure 7D. 7E is not available in the Resource Book but is available for a separate purchase from ISTA. Full details on ISTA 7E can be found on the ISTA website:

<http://www.ista.org/pages/procedures/ista-standards.php>

Scope

Test Procedure 7D covers the thermal performance testing of packaged-products to evaluate the effects of external temperature exposure.

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	Atmospheric	Temperature	1 st Cycle Period of selected Test Profile	Required
3	Atmospheric	Temperature	2 nd Cycle Period of selected Test Profile	Required
4	Atmospheric	Temperature	Remaining Cycle Periods of selected Test Profile	Required

EQUIPMENT REQUIRED FOR PROCEDURE 7D

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.