



Standard Test Methods for Pressure Decay Leak Test for Flexible Packages With and Without Restraining Plates¹

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1. Scope

1.1 These test methods cover the measurement of leaks in nonporous film, foil, or laminate flexible pouches and foil-sealed trays, which may be empty or enclose solid product. If product is enclosed, seals or surfaces cannot be in contact with water, oils, or other liquid.

1.2 These test methods will detect leaks at a rate of 1×10^{-4} sccs (standard cubic centimetres per second) or greater, in flexible packages. The limitation of leak rate is dependent on package volume as tested.

1.3 The following test methods are included:

1.3.1 *Test Method A*—Pressure Decay Leak Test for Flexible Packages Without Restraining Plates

1.3.2 *Test Method B*—Pressure Decay Leak Test for Flexible Packages With Restraining Plates

1.4 These test methods are destructive in that they require entry into the package to supply an internal pressure of gas, typically air or nitrogen, although other gases may be used. The entry connection into the flexible package must be leak-tight.

1.5 For porous packages, see 9.3.

1.6 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.*

2. Referenced Documents

2.1 *ASTM Standards*:²

D4332 Practice for Conditioning Containers, Packages, or Packaging Components for Testing

E177 Practice for Use of the Terms Precision and Bias in

¹ These test methods are under the jurisdiction of ASTM Committee F02 on Flexible Barrier Packaging and are the direct responsibility of Subcommittee F02.40 on Package Integrity.

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² For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

ASTM Test Methods

E691 Practice for Conducting an Interlaboratory Study to Determine the Precision of a Test Method

F17 Terminology Relating to Flexible Barrier Packaging

2.2 *Other Document*:

ANSI/AAMI/ISO 11607–1:2006 Packaging for Terminally Sterilized Medical Devices—Part 1: Requirements for Materials, Sterile Barrier Systems, and Packaging Systems³

3. Terminology

3.1 *Definitions of Terms Specific to This Standard*:

3.1.1 *integrity*—the unimpaired physical condition of the package. This implies that there are no leaks in the seals or body materials.

3.1.2 *leak*—See Terminology F17.

3.1.3 *nonporous*—types of materials that are not purposely designed to transfer gases through their matrix.

3.1.4 *restraining plates*—plates of rigid material, for example, aluminum, that are used to restrict the movement of the package during inflation.

3.1.5 *seal*—See Terminology F17.

3.1.6 *standard cubic centimetre per second (sccs)*—the flow rate of a gas (air) at standard conditions of 20°C (68°F) and 101.3 kPa (14.7 psig) (1 atmosphere or 760 mm Hg).

3.1.6.1 *Discussion*—Conditions may be varied depending on the source of data. Always check the definition being used.

4. Summary of Test Method

4.1 Detection of leak paths in flexible packages that have nonporous material surfaces and seals can be accomplished by pressurization of the package to a fixed pressure, shutting off the pressure and connecting a pressure transducer. Observed changes in pressure indicate the presence of leakage paths in the package seals or pinholes in the surfaces. This leak may be represented in decay pressure units or calculated leak rate units. To accomplish this technique, a leak-tight measuring

³ Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, <http://www.ansi.org>.