



Standard Test Method for Nondestructive Detection of Leaks in Packages by Vacuum Decay Method¹

This standard is issued under the fixed designation F 2338; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ϵ) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 *Test Packages*—Packages that can be nondestructively evaluated by this test method include:

1.1.1 Rigid and semi-rigid non-lidded trays.

1.1.2 Trays or cups sealed with porous barrier lidding material.

1.2 *Leaks Detected*—This test method is capable of detecting package leaks using an absolute or differential pressure transducer leak detector. The sensitivity of a test is a function of the sensitivity of the transducer, the package design, the design of the package test fixture, and critical test parameters of time and pressure. Types and sizes of leaks that may be detected for various package systems, as well as test sensitivities are described below. These data are based on precision and bias confirmation studies.

1.2.1 *Trays or Cups (Non-lidded)*—Hole or crack defects in the wall of the tray/cup of at least 50 μm in diameter can be detected at a Target Vacuum of $4 \cdot 10^4$ Pa (400 mbar) using an absolute pressure transducer test instrument.

1.2.2 *Trays Sealed with Porous Barrier Lidding Material*—Hole or crack defects in the wall of the tray/cup of at least 100 μm in diameter can be detected. Channel defects in the seal area (made using wires of 125 μm in diameter) can be detected. Severe seal bonding defects in both continuous adhesive and dot matrix adhesive package systems can be detected. Slightly incomplete dot matrix adhesive bonding defects can also be detected. All porous barrier lidding material packages were tested at a Target Vacuum of $4 \cdot 10^4$ Pa (400 mbar) using an absolute pressure transducer test instrument. Using a calibrated volumetric airflow meter, the sensitivity of the test for porous lidded packages is shown to be approximately $10^{-2} \text{ Pa} \cdot \text{m}^3 \cdot \text{s}^{-1}$.

1.3 *Test Results*—The test results are qualitative (Accept/Reject). Acceptance criteria for test results are established from quantitative baseline vacuum decay measurements obtained from control, non-leaking packages.

1.4 *Standard Value Units*—The values used in this test method are stated in SI units and are to be regarded as standard units. Values in parentheses are for information only.

1.5 *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

D 996 Terminology of Packaging and Distribution

E 691 Practice for Conducting an Interlaboratory Study to Determine the Precision of a Test Method

F 17 Terminology Relating to Flexible Barrier Materials

F 1327 Terminology Relating to Barrier Materials for Medical Packaging

3. Terminology

3.1 *Definitions*—For definitions used in this test method, see Terminologies D 996, F 17, and F 1327.

3.2 *Definitions of Terms Specific to This Standard:*

3.2.1 *baseline vacuum decay, n*—the extent of vacuum change within the test chamber over time demonstrated by a control, non-leaking package.

3.2.2 *control, non-leaking packages, n*—packages without defects and properly sealed according to manufacturer's specifications with non-defective lidding materials.

3.2.3 *semi-rigid trays or cups, n*—trays made of material that retain shape upon deflection. For example, thermoformed PETE or PETG trays are considered semi-rigid trays.

3.2.4 *spotty or mottled seals, n*—an incomplete adhesive bond made between a package tray or cup and porous lidding material that can be visibly identified by a distinctive pattern of dots, spotting or mottling on the tray sealing surface after the lid is removed.

3.2.5 *volumetric airflow meter, n*—a calibration tool that can be used to provide an artificial leak of known volumetric airflow rate into the test chamber for verification of instrument sensitivity. Airflow meters should be calibrated to NIST standards. The operational range of the meter should reflect the desired limit of sensitivity for the intended leak test.

¹ This test method is under the jurisdiction of ASTM Committee F02 on Flexible Barrier Materials and is the direct responsibility of Subcommittee F02.60 on Medical Device Packaging.

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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.