



Standard Test Method for Using Aerosol Filtration for Measuring the Performance of Porous Packaging Materials as a Surrogate Microbial Barrier¹

This standard is issued under the fixed designation F2638; 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.

^{ε1} NOTE—The research report designation was added editorially in November 2016.

1. Scope

1.1 This test method measures the aerosol filtration performance of porous packaging materials by creating a defined aerosol of 1.0 μm particles and assessing the filtration efficiency of the material using either single or dual particle counters.

1.2 This test method is applicable to porous materials used to package terminally sterilized medical devices.

1.3 The intent of this test method is to determine the flow rate through a material at which maximum penetration occurs. The porous nature of some materials used in sterile packaging applications might preclude evaluation by means of this test method. The maximum penetration point of a particular material could occur at a flow rate that exceeds the flow capacity of the test apparatus. As such, this test method may not be useful for evaluating the maximum penetration point of materials with a Bendtsen flow rate above 4000 mL/min as measured by ISO 5636–3.

1.4 The values stated in SI units are to be regarded as the standard. The values given 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.*

¹ This test method is under the jurisdiction of ASTM Committee F02 on Primary Barrier Packaging and is the direct responsibility of Subcommittee F02.15 on Chemical/Safety Properties.

Current edition approved May 1, 2012. Published June 2012. Originally approved in 2007. Last previous edition approved in 2007 as F2638 – 07. DOI: 10.1520/F2638-12E01.

2. Referenced Documents

2.1 *ASTM Standards*:²

E177 Practice for Use of the Terms Precision and Bias in ASTM Test Methods

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

2.2 *ISO Standard*:³

ISO 5636–3 Paper and Board—Determination of Air Permeance (Medium Range)—Part 3: Bendtsen Method

3. Terminology

3.1 *Definitions*:

3.1.1 *challenge aerosol*—a sufficient quantity of aerosolized 1.0 μm particles that enable effective particle counting in the filtrate aerosol.

3.1.2 *filtrate aerosol*—particles that remain aerosolized after passage through the test specimen.

3.1.3 *maximum penetration*—the highest percent concentration of particles in the filtrate aerosol when a specimen is tested over a range of pressure differentials or air flow rates.

3.2 *Abbreviations and Symbols*:

Symbol	Unit	Description
C_S	n	Average particle count of the challenge aerosol when using a single particle counter (Method A).
C_F	n	Average particle count of the filtrate aerosol.
C_C	n	Average particle count of the challenge aerosol.
C_{LR}	N	Average particle count of the filtrate aerosol prior to correction for dilution.

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.

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