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Standard Guide for Integrity Testing of Porous Barrier Medical Packages[1]

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1. Scope

1.1 This guide covers general procedures for conducting controlled tests for determining the integrity of porous barrier medical packages. These procedures are intended to be a guide in determining overall package integrity and are not intended to be used by themselves in determining component material suitability. Material specifications should be written for each component, and a complete battery of tests should be performed to determine its suitability.

1.2 *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:*

D 903 Test Method for Peel or Stripping Strength of Adhesive Bonds[2]

D 996 Terminology of Packaging and Distribution Environments[3]

D 3078 Test Method for Determination of Leaks in Flexible Packaging by Bubble Emission[3]

D 4169 Practice for Performance Testing of Shipping Containers and Systems[3]

D 4332 Practice for Conditioning Containers, Packages, or Package Components for Testing[3]

E 122 Practice for Choice of Sample Size to Estimate a Measure of Quality for a Lot or Process[4]

E 515 Test Method for Leaks Using Bubble Emission Techniques[5]

E 1316 Terminology for Nondestructive Examinations[5]

F 17 Terminology Relating to Flexible Barrier Materials[3]

F 88 Test Method for Seal Strength of Flexible Barrier Materials[3]

F 1140 Test Methods for Failure Resistance of Unrestrained and Nonrigid Packages for Medical Applications[3]

F 1327 Terminology Relating to Barrier Materials for Medical Packaging[3]

F 1608 Test Method for Microbial Ranking of Porous Packaging Materials (Exposure Chamber Method)[3]

F 1886 Test Method for Determining Integrity of Seals for Medical Packaging by Visual Inspection[3]

F 1929 Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration[3]

F 1980 Guide for Accelerated Aging of Sterile Medical Device Packages[3]

3. Terminology

3.1 *Definitions:*

3.1.1 Applicable definitions and terminology may be found in Terminologies D 996, E 1316, F 17, and F 1327.

4. Significance and Use

4.1 Maintaining the integrity of a porous barrier medical package is critical to the delivery of a sterile product. This guide provides for the evaluation of the integrity of porous barrier medical packages, using established test methods. Damaged packages, substandard materials, inadequate seals, or a combination thereof, may cause a package to fail during manufacture, sterilization, distribution, storage, or use. When using the tests presented in this guide as part of a qualification test plan, process validation plan, or quality control program, some of the factors to consider are as follows:

4.1.1 *Porosity*—Porous barrier materials are designed to allow for the transmission of gases. Their porosity rates, consistency, uniformity, and the effect that coatings or labels have on their overall porosity can change the uniformity of performance characteristics and results.

4.1.2 *Leaks*—Small leaks may be hard to detect. The effects of the porous barrier material, the product, entrapped air, and the test parameters selected, may be significant and make the detection of small leaks very difficult.

4.1.3 *Physical Handlings*—The number and severity of physical handlings during manufacture, sterilization, and distribution.

4.1.4 *Sealing Process*—The parameters and tolerances such as temperature, dwell time, and pressure.

4.1.5 *Distribution Requirements*.

4.1.6 *Shelf Life Requirement*, utilizing real time or accelerated aging techniques.

4.1.7 *Maintenance of Package Integrity*—The requirements

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[2] *Annual Book of ASTM Standards*, Vol 15.06.

[3] *Annual Book of ASTM Standards*, Vol 15.09.

[4] *Annual Book of ASTM Standards*, Vol 14.02.

[5] *Annual Book of ASTM Standards*, Vol 03.03.

associated with the maintenance of package integrity need to be defined.

4.1.8 *Sterilization Process*—The sterilization process chosen may indicate the type of tests to be performed. For instance, in the case where there are substantial pressure changes during the sterilization process, it will be necessary to examine the package seals for degradation or failure from the affects of the pressure changes. Certain types of sterilization processes can degrade the packaging materials. The affect this has on the package integrity needs to be evaluated.

4.2 The evaluation of sterile package integrity is accomplished by the following:

4.2.1 Determining seal or closure integrity by demonstrating that the seal is impermeable and continuous through the use of tests, such as vacuum (Test Method D 3078), leak (Test Method E 515), visual examination (Test Method F 1886), and dye penetrant (Test Method F 1929).

4.2.2 Determining the microbial barrier property characteristics of the packaging materials (Test Method F 1608).

4.3 The testing of the seal's strength or its ability to hold the package together, through burst (Test Methods F 1140, Method A), creep (Test Methods F 1140, Method B), or tensile tests (Test Methods D 903 and F 88) can result in a measure of the package's ability to maintain its integrity. *Seal strength tests should not be considered as package integrity tests*. They can be used as an indicator of a package's ability to withstand the stresses of manufacturing and sterilization processes, distribution and storage environments, and as a mechanism for establishing process envelopes and for checking process controls.

4.4 *Aging and Dating Claim Verification*—When dating claims are made in the product labeling and verification of such claims with respect to the ability of the primary sterile barrier package to maintain integrity for that stated period is desired, reference Guide F 1980.

5. Procedure

5.1 *Test Plan*—A test plan should be prepared which is appropriate for the package and product being evaluated. The test plan should normally include sections such as purpose, scope, references, test sample, and test procedure. The test plan should be written to document what is being tested, why the test is being performed, what elements are to be tested, exactly how to perform the test either directly stated or by reference to ASTM or other standardized test(s), and the anticipated scope of the testing. Reference should be made to any previous testing or other documentation which is relevant. The information contained in the test plan should be thorough enough that it can be used as a processing guide to explain exactly how to prepare the test samples and how to perform the test. It should contain specific sample preparation instructions. If required, pass/fail criteria should be specifically stated. A rationale supporting specific pass/fail criteria may also be included. A test report (Section 6) should be prepared including the results.

5.2 *Test Procedure*—Tables 1 and 2, show the type of test, the ASTM test method (if currently available), and a description of the test. For conditioning of packages prior to testing, refer to Practice D 4332. Packages may also be prestressed with rough handling distribution by subjecting them to specified distribution cycles and assurance levels in accordance with Practice D 4169 [for example, Distribution Cycles (DC) #3, single package environmental (not unitized or palletized), and DC #13 Air (intercity) and motor freight (local) single package up to 100 lb/45.4 kg, using Assurance Level I for the test intensity]. When determining the number of sample packages to test, Practice E 122 may be helpful.

TABLE 1 Guide to Testing the Integrity of Porous Barrier Medical Packages

Vacuum[A]	D 3078[B]
Leak[A]	E 515[C]
Visual Examination	F 1886
Dye Penetrant	F 1929
Accelerated Aging	F 1980
Material Microbial Challenge	F 1608

[A] When performing Test Method D 3078 or E 515, it should be cautioned, that any submersion of porous packaging materials in any liquid, such as water, and subjecting them to pressure or vacuum, may cause bubbles or penetration of that liquid. Unless the operator is cautioned or correctly trained in what to expect, test results can be erroneously reported and incorrectly interpreted. The listed standards do not sufficiently address how to specifically handle porous materials.

[B] This test method covers the determination of gross leaks in heat-sealed flexible packages and may be used to evaluate the performance of heat-sealed packages.

[C] This test method covers procedures for detecting or locating leaks, or both, by bubble emission techniques. A quantitative measure is not practical with these procedures and the sensitivity is dependent on the particular technique.

TABLE 2 Guide to Testing the Strength of Porous Barrier Medical Packages

Type of Test	ASTM Standard
Burst (Internal Pressure)	F 1140, Method A[A]
Creep (Internal Pressure)	F 1140, Method B[B]
Seal Strength	F 88[C]
Peel Strength	D 903[D]

[A] This test method covers the procedures for determination of the ability of package materials or seals, or both, to withstand internal pressurization to the point of bursting.

[B] This test method covers the procedures for determination of the ability of package materials or seals, or both, to withstand and hold a specified internal pressure.

[C] This test method covers the measurement of the seal strength of flexible barrier materials.

[D] This test method covers the determination of the comparative peel or stripping characteristics of adhesive bonds when tested on standard-sized specimens and under defined conditions of pretreatment, temperature, and testing machine speed.

6. Report

6.1 The test report should describe the test with sufficient detail for analysis at some time in the future and should include the following:

6.1.1 An overview statement documenting why the test was performed, what was being tested (including pass/fail criteria), how it was tested, how the test was evaluated, and the scope of the test results. Deviations between any written test plan and the actual tests performed should be noted (see 5.2).

6.1.2 A conclusion statement documenting the outcome of the test relative to the reason why the test was being performed and comparing the results to the pass/fail criteria. Include any

observations or comments which are relative to the testing and supported by factual data.

6.1.3 A supporting data section which contains the information gathered during the testing and which supports the conclusion and observations presented. As applicable, the supporting data section should include material lot numbers, assembly job numbers, equipment used, processing parameters, parts lists, material specifications, inspection reports, number of packages tested, number of failures (if any), and any other related information which is pertinent.

7. Precision and Bias

7.1 The precision and bias statements are contained in the individual test methods referenced in this guide.

APPENDIXES

(Nonmandatory Information)

X1. HELIUM GAS LEAK DETECTION

X1.1 Efforts are presently in process within ASTM Committee F02 to develop a test method for use with recently available equipment for evaluating the seals of porous blister packages and pouches and the nonporous materials in those packages for integrity or leaks. The test is nondestructive and is based on sensing of a trace gas (helium) as it leaks from a breach in the seal or a leak in the nonporous material. In this test method, a temporary adhesive tape is used to mask the face of the porous barrier material. Tracer gas is delivered to the outside of the porous barrier material through a port in the temporary adhesive tape. The tracer gas passes into the package nondestructively through the porous barrier material. The *tracer gas profile* of the outside of the package is mapped using a tracer gas detector whose sampling probe is deployed on a three-axis translation stage. As of the date of this ballot revision, the process has progressed to the point of several reviewed drafts of a proposed test method and a planned round robin study.

X2. INTERNAL PRESSURIZATION TEST

X2.1 This test is being developed within Subcommittee F02.60. The principal behind this proposed method is to form a controlled pressure differential by inflating a porous package to just below the bubble point of the porous material while submerging the sample under the surface of a water filled container. The sample is observed for streams of bubbles that indicate a leak at that point in the sample.

X3. MICROBIAL CHALLENGE TESTING

X3.1 No whole package microbial challenge test has been found to be appropriate for all packages. Test parameters such as the microbial challenge concentration and dispersion, humidity, and pressure are difficult to control with the variety of package sizes, shapes and materials produced in the medical device industry. These test parameters would have to be customized for the type of package being evaluated. Other factors that discourage the standardization of a single test for all types of packages include the effects of static charges, test sensitivity limitations, methods for package decontamination and assay following microbial challenge, time required to obtain results, and the level of expertise needed to perform the test. The current industry consensus approach for evaluation of packaging and packaging materials is generally to qualify porous packaging materials with a microbial challenge, and then to use physical test methods for evaluating the integrity of the final package. ASTM Subcommittee F02.60 is currently evaluating a microbial challenge test for porous materials for the purpose of standardization.