Designation: F2097 – 16

Standard Guide for Design and Evaluation of Primary Flexible Packaging for Medical Products[1]

This standard is issued under the fixed designation F2097; 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 This guide provides directions for the design and evaluation of primary flexible packages for medical products. The package materials must be selected appropriately for manufacturing process, end use, and the product being packaged.

1.2 This guide provides a compendium of test methods, practices, and procedures. Specific individual test methods must be selected based on the pertinent characteristics of the specific product to be packaged and the purpose for testing, research and development, or compliance. Not all test methods will be applicable.

1.3 This guide does not address acceptability criteria, which need to be determined jointly by the package producer and the medical products manufacturer.

1.4 This guide does not assess the product to be packaged or the sterilization method to be used.

1.5 The units cited in the referenced standard should be used.

2. Referenced Documents

2.1 *ASTM Standards:*[2]

D374 Test Methods for Thickness of Solid Electrical Insulation (Withdrawn 2013)[3]
D589 Test Method for Opacity of Paper (15° Diffuse Illuminant ***A***, 89 % Reflectance Backing and Paper Backing) (Withdrawn 2010)[3]
D638 Test Method for Tensile Properties of Plastics
D645/D645M Test Method for Thickness of Paper and Paperboard (Withdrawn 2010)[3]
D726 Test Method for Resistance of Nonporous Paper to Passage of Air (Withdrawn 2009)[3]
D882 Test Method for Tensile Properties of Thin Plastic Sheeting
D1003 Test Method for Haze and Luminous Transmittance of Transparent Plastics
D1434 Test Method for Determining Gas Permeability Characteristics of Plastic Film and Sheeting
D1709 Test Methods for Impact Resistance of Plastic Film by the Free-Falling Dart Method
D1777 Test Method for Thickness of Textile Materials
D1894 Test Method for Static and Kinetic Coefficients of Friction of Plastic Film and Sheeting
D1922 Test Method for Propagation Tear Resistance of Plastic Film and Thin Sheeting by Pendulum Method
D1938 Test Method for Tear-Propagation Resistance (Trouser Tear) of Plastic Film and Thin Sheeting by a Single-Tear Method
D2019 Test Method for Dirt in Paper and Paperboard (Withdrawn 2010)[3]
D2457 Test Method for Specular Gloss of Plastic Films and Solid Plastics
D3078 Test Method for Determination of Leaks in Flexible Packaging by Bubble Emission
D3079 Test Method for Water Vapor Transmission of Flexible Heat-Sealed Packages for Dry Products
D3335 Test Method for Low Concentrations of Lead, Cadmium, and Cobalt in Paint by Atomic Absorption Spectroscopy
D3420 Test Method for Pendulum Impact Resistance of Plastic Film
D3718 Test Method for Low Concentrations of Chromium in Paint by Atomic Absorption Spectroscopy
D3776 Test Methods for Mass Per Unit Area (Weight) of Fabric
D3985 Test Method for Oxygen Gas Transmission Rate Through Plastic Film and Sheeting Using a Coulometric Sensor
D4169 Practice for Performance Testing of Shipping Containers and Systems
D4279 Test Methods for Water Vapor Transmission of Shipping Containers—Constant and Cycle Methods

[1] This guide is under the jurisdiction of ASTM Committee F02 on Flexible Barrier Packaging and is the direct responsibility of Subcommittee F02.50 on Package Design and Development.

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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.

[3] The last approved version of this historical standard is referenced on www.astm.org.

D4321 Test Method for Package Yield of Plastic Film
D4332 Practice for Conditioning Containers, Packages, or Packaging Components for Testing
D4754 Test Method for Two-Sided Liquid Extraction of Plastic Materials Using FDA Migration Cell
D5264 Practice for Abrasion Resistance of Printed Materials by the Sutherland Rub Tester
D7386 Practice for Performance Testing of Packages for Single Parcel Delivery Systems
E398 Test Method for Water Vapor Transmission Rate of Sheet Materials Using Dynamic Relative Humidity Measurement
F17 Terminology Relating to Flexible Barrier Packaging
F88 Test Method for Seal Strength of Flexible Barrier Materials
F99 Guide for Writing a Specification for Flexible Barrier Rollstock Materials
F151 Test Method for Residual Solvents in Flexible Barrier Materials (Withdrawn 2004)[3]
F372 Test Method for Water Vapor Transmission Rate of Flexible Barrier Materials Using an Infrared Detection Technique (Withdrawn 2009)[3]
F392 Test Method for Flex Durability of Flexible Barrier Materials
F748 Practice for Selecting Generic Biological Test Methods for Materials and Devices
F813 Practice for Direct Contact Cell Culture Evaluation of Materials for Medical Devices
F895 Test Method for Agar Diffusion Cell Culture Screening for Cytotoxicity
F904 Test Method for Comparison of Bond Strength or Ply Adhesion of Similar Laminates Made from Flexible Materials
F1140 Test Methods for Internal Pressurization Failure Resistance of Unrestrained Packages
F1249 Test Method for Water Vapor Transmission Rate Through Plastic Film and Sheeting Using a Modulated Infrared Sensor
F1306 Test Method for Slow Rate Penetration Resistance of Flexible Barrier Films and Laminates
F1307 Test Method for Oxygen Transmission Rate Through Dry Packages Using a Coulometric Sensor
F1443 Practice for Using 0.008-in. (0.203-mm) Aperture Reflectometers as Test Instruments for Measuring Visual Image Quality of Business Copy Images
F1608 Test Method for Microbial Ranking of Porous Packaging Materials (Exposure Chamber Method)
F1884 Test Methods for Determining Residual Solvents in Packaging Materials
F1886 Test Method for Determining Integrity of Seals for Medical Packaging by Visual Inspection
F1921 Test Methods for Hot Seal Strength (Hot Tack) of Thermoplastic Polymers and Blends Comprising the Sealing Surfaces of Flexible Webs
F1927 Test Method for Determination of Oxygen Gas Transmission Rate, Permeability and Permeance at Controlled Relative Humidity Through Barrier Materials Using a Coulometric Detector
F1929 Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
F1980 Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
F2029 Practices for Making Heatseals for Determination of Heatsealability of Flexible Webs as Measured by Seal Strength
F2054 Test Method for Burst Testing of Flexible Package Seals Using Internal Air Pressurization Within Restraining Plates
F2095 Test Methods for Pressure Decay Leak Test for Flexible Packages With and Without Restraining Plates
F2096 Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)
F2203 Test Method for Linear Measurement Using Precision Steel Rule
F2217 Practice for Coating/Adhesive Weight Determination
F2250 Practice for Evaluation of Chemical Resistance of Printed Inks and Coatings on Flexible Packaging Materials
F2251 Test Method for Thickness Measurement of Flexible Packaging Material
F2252 Practice for Evaluating Ink or Coating Adhesion to Flexible Packaging Materials Using Tape
F2227 Test Method for Non-Destructive Detection of Leaks in Non-sealed and Empty Packaging Trays by CO_2 Tracer Gas Method
F2228 Test Method for Non-Destructive Detection of Leaks in Packaging Which Incorporates Porous Barrier Material by CO_2 Tracer Gas Method
F2338 Test Method for Nondestructive Detection of Leaks in Packages by Vacuum Decay Method
F2391 Test Method for Measuring Package and Seal Integrity Using Helium as the Tracer Gas
F2475 Guide for Biocompatibility Evaluation of Medical Device Packaging Materials
F2476 Test Method for the Determination of Carbon Dioxide Gas Transmission Rate (CO_2TR) Through Barrier Materials Using An Infrared Detector
F2559 Guide for Writing a Specification for Sterilizable Peel Pouches
F2622 Test Method for Oxygen Gas Transmission Rate Through Plastic Film and Sheeting Using Various Sensors
F2638 Test Method for Using Aerosol Filtration for Measuring the Performance of Porous Packaging Materials as a Surrogate Microbial Barrier
F2714 Test Method for Oxygen Headspace Analysis of Packages Using Fluorescent Decay
F2824 Test Method for Mechanical Seal Strength Testing for Round Cups and Bowl Containers with Flexible Peelable Lids
F2825 Practice for Climatic Stressing of Packaging Systems for Single Parcel Delivery
F2981 Test Method for Verifying Nonporous Flexible Barrier Material Resistance to the Passage of Air
F3004 Test Method for Evaluation of Seal Quality and Integrity Using Airborne Ultrasound

F3039 Test Method for Detecting Leaks in Nonporous Packaging or Flexible Barrier Materials by Dye Penetration
F3136 Test Method for Oxygen Gas Transmission Rate through Plastic Film and Sheeting using a Dynamic Accumulation Method

2.2 *EN/ISO Standards:*[4]

EN 868/1 Annex C Gurley, Schopper, Dye Penetration
ISO 2556 Plastics—Determination of Gas Transmission Rate of Films and Thin Sheets Under Atmospheric Pressure—Manometric Method
ISO 5636–5 Paper and Board—Determination of Air Permeance (Medium Range)—Part 5: Gurley Method
ISO 10993 Biological Evaluation of Medical Devices
ISO 11607–1 Packaging for Terminally Sterilized Medical Devices, Annex C
ISO 15105–1 Plastics—Film and Sheeting—Determination of Gas Transmission Rate—Part 1: Differential-Pressure Method
ISO 15105–2 Plastics—Film and Sheeting—Determination of Gas Transmission Rate—Part 2: Equal-Pressure Method

2.3 *Military Specification:*[5]

Mil Spec 36954C Bacterial Filtration Efficiency

2.4 *TAPPI Standards:*[6]

TAPPI T 404 Tensile Breaking Strength and Elongation of Paper and Paperboard
TAPPI T 437 Dirt in Paper and Paperboard
TAPPI T 460 Air Resistance of Paper (Gurley Method)
TAPPI T 494 Tensile Breaking Properties of Paper and Paperboard (Using Constant Rate of Elongation Apparatus)
TAPPI T 536 Resistance of Paper to Passage of Air (High Pressure Gurley Method)
TAPPI T 547 Air Permeance of Paper and Paperboard (Sheffield Method)

2.5 *ISTA Procedures:*[7]

ISTA 3A Packaged Products for Parcel Delivery System Shipments 70 kg (150 lb) or Less (standard, small, flat, or elongated)
ISTA 3E Unitized Loads of Same Product
ISTA 4AB Packaged-Products for Shipment in Known Distribution Channels
ISTA 6–FEDEX-A FedEx Procedures for Testing Packaged Products Weighing Up to 150 lbs

3. Terminology

3.1 *Definitions of Terms Specific to This Standard:*

3.1.1 *barrier requirements, n*—the need to promote or inhibit moisture, gas, or light, or a combination thereof, while maintaining necessary levels of sterility.

3.1.2 *durability requirements, n*—material properties relevant to the ability of the package to protect the product.

3.1.3 *integrity and seal requirements, n*—the ability of the package to prevent inadvertent escape of contents or entrance of outside substances while preserving intended opening for use features.

3.1.4 *package performance, n*—the ability of the packaging system, including the sterile barrier system and protective packaging, to withstand the hazards of handling, distribution, and storage.

3.1.5 *printing requirements, n*—the printed ink properties needed to ensure physical and chemical resistance to degradation.

3.1.6 *processing requirements, n*—the material characteristics needed to ensure the consistent and reliable production of the package.

3.1.7 *safety requirements, n*—safeguard product against contamination and deleterious health effects.

3.1.8 *visibility and appearance requirements, n*—the desired package aesthetics needed to permit or inhibit viewing of the product or to enhance product presentation.

3.2 For other terms used in this guide, see Terminology F17.

4. Significance and Use

4.1 This design and evaluation guide describes multiple categories for evaluating flexible medical packages and packaging materials. These include safety, barrier properties, durability, package and seal integrity, visibility and appearance, processing, printing ink properties, and package performance.

4.2 The intent of this design and evaluation guide is to evaluate all cited categories and select those that are applicable. Once the product has been characterized and the sterilization methodology has been defined, there are numerous sets of requirements for any specific package. This design and evaluation guide provides an avenue for assessing these requirements and choosing test methods for both evaluating the package design and monitoring package compliance.

NOTE 1—Many of the standards included in this guide are consensus standards that are recognized by the United States Food and Drug Administration (FDA). Selection and use of a U.S. FDA recognized consensus standard is voluntary and the sole responsibility of the user in determining its applicability. For further information, consult the U.S. FDA Medical Device Standards Program at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm.

4.3 Product characterization shall include mass or weight, geometry (length and width, height, and shape) and product composition.

4.4 All categories must be considered for applicability.

4.5 The Summary of Test Methods for Medical Packaging Design and Evaluation (Fig. 1) provides a compact graphical presentation of the test methods referenced in this guide.

4.6 *Test Description and Applicability* (see Table 1):

4.6.1 Table 1 lists the test methods commonly used to evaluate flexible medical packaging. The test methods are used in two phases.

[4] Available from International Organization for Standardization (ISO), 1 rue de Varembé, Case postale 56, CH-1211, Geneva 20, Switzerland, http://www.iso.ch.
[5] Available from Standardization Documents Order Desk, Bldg. 4 Section D, 700 Robbins Ave., Philadelphia, PA 19111-5094, Attn: NPOPS.
[6] Available from Technical Association of the Pulp and Paper Industry (TAPPI), 15 Technology Parkway South, Norcross, GA 30092, http://www.tappi.org.
[7] Available from International Safe Transit Association (ISTA), 1400 Abbot Rd., Suite 160, East Lansing, MI 48823-1900, http://www.ista.org.

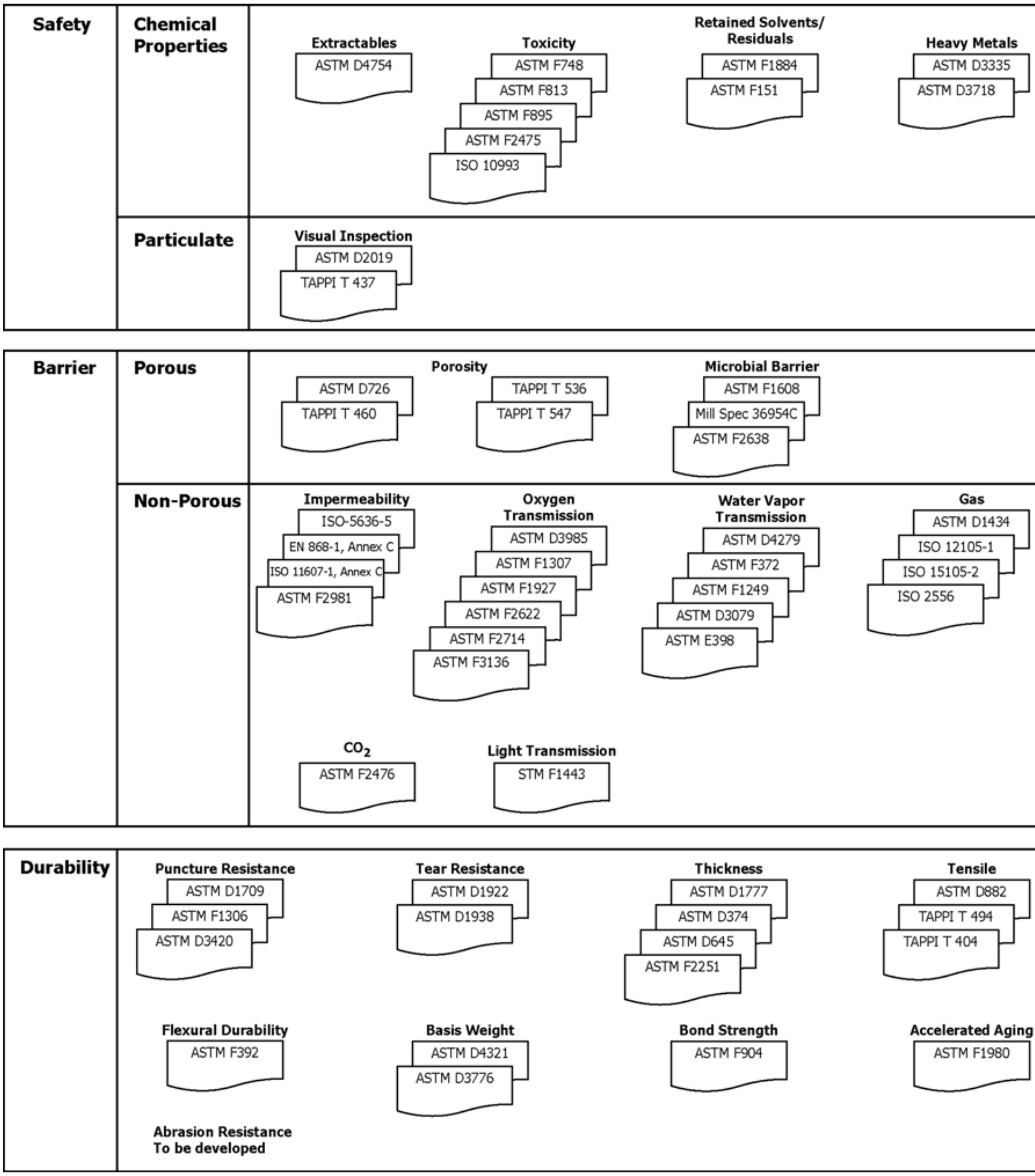

FIG. 1 Summary of Test Methods for Medical Packaging Design and Evaluation

4.6.1.1 *Package Design: Characterization of the Materials and Evaluation of the Resultant Package*—This is referred to as "R&D Evaluation" in Table 1. Testing during this phase is characterized by the generation of quantitative data on the performance of the component materials and the package assembly. These test methods are lengthy, making them inappropriate for the manufacturing environment where rapid response is required for process control. Often, they are expensive and require specialized equipment not readily available at a medical packaging or device manufacturing facility.

4.6.1.2 *Package Compliance: Routine Monitoring of Adherence to Specifications*—This is referred to as "Compliance Testing" in Table 1. Testing during this phase must be rapid, inexpensive, and readily implemented in a manufacturing environment. The objective is not to develop design data, but to ensure that the design specifications are being met. These test methods do not necessarily make direct measurements of critical values, but detect variations in material, process, or product that are indicative of all critical characteristics.

4.6.2 It is important to note that no individual test method is entirely predictive of final package performance. Filled packages must be evaluated under conditions of use.

4.7 Once the design of the package and/or packaging materials has been determined, it may be appropriate to create a package and/or material specification. Guides F99 or F2559 may provide useful guidance.

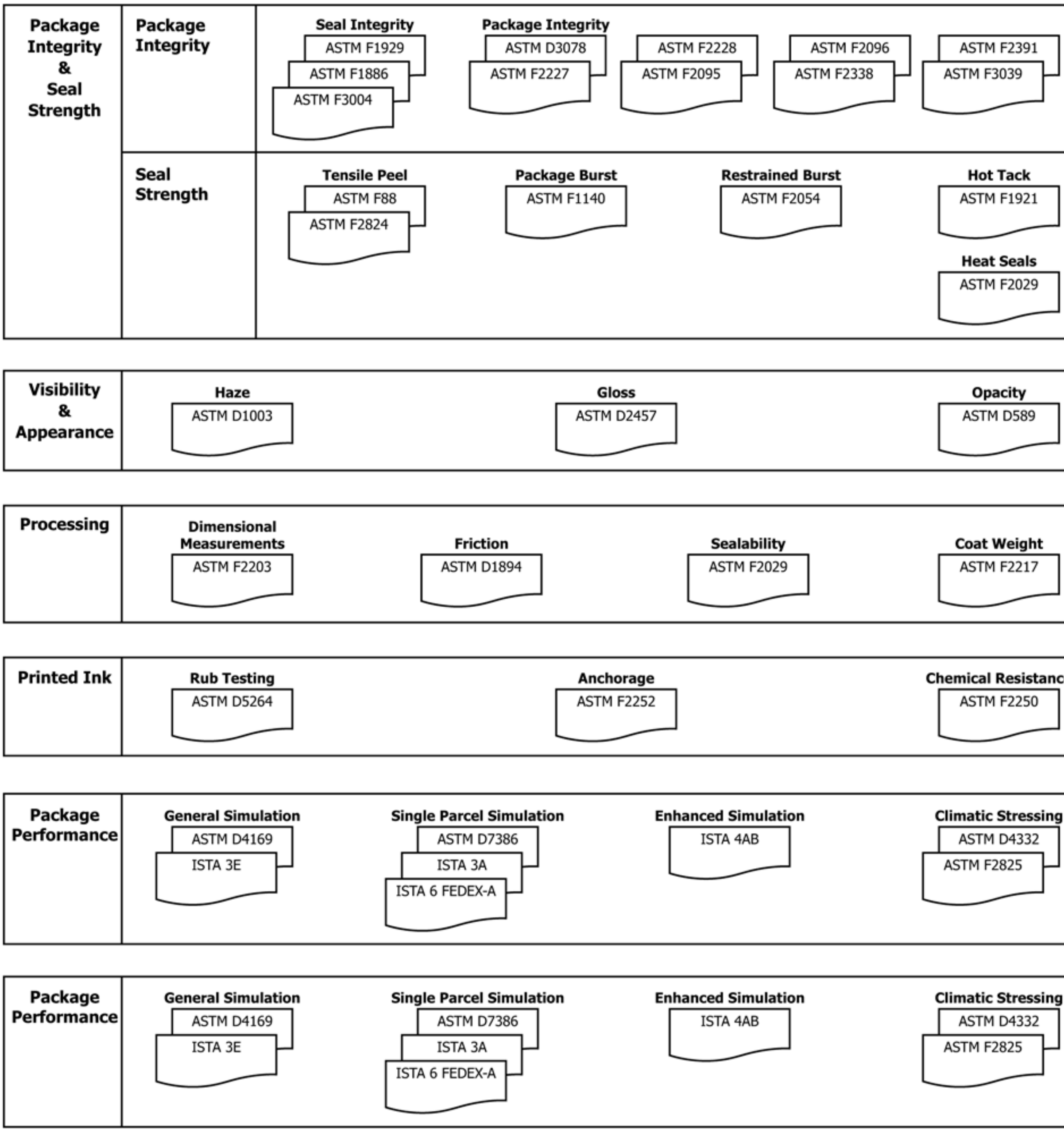

FIG. 1 Summary of Test Methods for Medical Packaging Design and Evaluation *(continued)*

TABLE 1 Test Description and Applicability Table

Test	Test Method	Description	Applicability
		Safety Requirements	
		Chemical Properties	
Extractibles Usage R&D evaluation	ASTM D4754	This test method covers the use of the FDA migration cell in the extraction of components and permits quantitation of individual migrants from plastic materials by suitable extracting liquids, including liquid foods and food-stimulating solvents. This test method provides a two-sided, liquid extraction test for plastic materials that can be formed into film, sheet, or disks.	This test method has been applied to a variety of migrant/polymer systems in contact with numerous foods and food simulants. Though most of the migrants examined were radiolabeled, the use of the FDA cell has been validated for migration studies of unlabeled styrene from polystyrene. This test method has been shown to yield reproducible results under the conditions for migration tests requested by the FDA. However, if the data is to be submitted to the FDA, it is suggested that their guidelines by consulted. Because it employs two-sided extraction, this test method may not be suitable for multilayered plastics intended for single-sided food contact use. The size of the FDA migration cell as described may preclude its use in determining total nonvolatile extractives in some cases.
Toxity Usage R&D evaluation	ASTM F748	This practice recommends generic biological test methods for materials and devices according to end-use applications. Tests include those performed on materials, end products, and extracts. Rationale and comments on current state of the art are included for all test procedures described. Biological evaluation of materials and devices, and related subjects such as pyrogen testing and batch testing of production lots are also discussed.	The biocompatibility of materials used in single-component or multicomponent medical devices for human use depends to a large degree on the particular nature of the end-use application. It is not possible to specify a set of biocompatibility test methods which will be necessary and sufficient to establish biocompatibility for all materials and applications. While chemical testing for extractable additives and residual monomers or residues from processing aids is necessary for most implant materials, such testing is not included as a part of this practice. The reader is cautioned that the area of materials biocompatibility testing is a rapidly evolving field, and improved methods are evolving rapidly, so this practice is by necessity only a guideline. These test protocols are intended to apply to materials and medical devices for human application.
Toxity Usage R&D evaluation	ASTM F813	This practice describes a reference method of direct contact cell culture testing that may be used in evaluating the cytotoxic potential of materials for use in the construction of medical materials and devices. This practice may be used either directly to evaluate materials or as a reference against which other cytotoxicity test methods may be compared.	This practice tends to be used less frequently due to the risk of inducing a response from mechanical damage due to direct placement of the sample onto the cell layer. This practice may be suitable for products which have leachates that are not able to diffuse through agar and are not too heavy.
Toxicity Usage R&D evaluation	ASTM F895	The agar diffusion assay is an indirect contact test in which the test material is placed onto an agar layer that protects the cells. This test method is commonly used to evaluate the response of small samples that have at least one flat surface such as elastomeric closures.	This is one of a series of reference test methods for the assessment of cytotoxic potential, employing different techniques. Assessment of cytotoxicity is one of several tests employed in determining the biological response to a material, as recommended in Practice F748. This test method is appropriate for materials in a variety of shapes and for materials that are not necessarily sterile. This test method would be appropriate in situations where the amount of material is limited. For example, small devices or powders could be placed on the agar and the presence of a zone of inhibition of cell growth could be examined. While the agar layer can act as a cushion to protect the cells from the specimen, there may be materials which are sufficiently heavy to compress the agar and prevent diffusion or to cause mechanical damage to the cells. This test method is not appropriate for leachables that are not water soluble because they may not diffuse through agar or agarose and thus not be detected. This test method would not be appropriate for these materials. The L 929 cell line was chosen because it has a significant history of use in assays of this type. This is not intended to imply that its use is preferred; only that the L 929 is an established cell line, well characterized and readily available, that has demonstrated reproducible results in several laboratories.
Toxicity Usage R&D evaluation	ASTM F2475	This guide provides information to determine the appropriate testing for biocompatibility of packaging materials used to contain a medical device.	This method applies to packaging for medical devices.

TABLE 1 *Continued*

Test	Test Method	Description	Applicability
Biocompatibility Usage R&D evaluation	ISO 10993	This entails a series of standards for evaluating the biocompatibility of a medical device prior to clinical study. Part 1 of the Standard uses an approach to test selection thatis very similar to the Tripartite Guidance.	When selecting the appropriate tests for biological evaluation of a medical device, one must consider the chemical characteristics of device materials and the nature, degree, frequency, and duration of its exposure to the body. Note: FDA has made several modifications to the testing required by ISO 10993–Part 1.
Retained solvents Usage R&D evaluation Compliance testing	ASTM F1884	This test method covers determination of the amount of residual solvents released from within a packaging material contained in a sealed vial under a given set of time and temperature conditions and is a recommended alternative for Test Method F151. This test method covers a procedure for quantifying volatile compounds whose identity has been established, and are retained in packaging materials.	This test method does not address the determination of total retained solvents in a packaging material. Techniques such as multiple headspace extraction can be employed to this end. For purposes of verifying the identity of or identifying unknown volatile compounds, the analyst is encouraged to incorporate techniques such as gas chromatography/mass spectroscopy, gas chromatography/infrared spectroscopy, or other suitable techniques in conjunction with this test method. This is an off-line head space analysis. It is sensitive to technique and sampling equipment resulting in large variations (~25 %) between laboratories. It is a simplified version of Test Method F151 providing about the same level of accuracy. This method differs from Test Method F151 in that it specifies certain conditions. Test Method F1884, for example, specifies a preheat condition of 90°C for 20 min. Test Method F151 defines a procedure for determining optimum heating time and temperature conditions for the preheat. Because solvents will escape from surface wraps on a roll of film, this test should be performed immediately after manufacturing to provide an indication of solvent levels in the inner wraps of the roll of film.
Retained solvents Usage R&D evaluation Compliance testing	ASTM F151	This test method provides an index for comparing the level of solvents retained in flexible barrier materials of the same construction, which result from casting, coating, printing, or laminating operations. This test method does not yield absolute quantitative measurements of solvents retained in flexible barrier materials.	This method is essentially identical to Test Method F1884 except for a complicated determination of the optimum heating time and temperature for the films in the head space container. There is no improvement in the interlaboratory variation. All other comments under Test Method F1884 apply equally to Test Method F151.
Heavy metals Usage R&D evaluation	ASTM D3335	This test method covers the determination of lead contents between 0.01 and 5 %, cadmium contents between 50 and 150 ppm (mg/kg), and cobalt contents between 50 and 2000 ppm (mg/kg) present in the nonvolatile portion of liquid coating or contained in dried films by means of atomic absorption.	Higher levels of all three elements can be determined by this test method, provided that appropriate dilutions and adjustments in specimen size and reagent quantities are made. This test method is not applicable to the determination of lead in samples containing antimony pigments (low recoveries are obtained). If lead is present in the sample to be analyzed in the form of an organic lead compound at a concentration greater than 0.1 %, small losses of lead may occur, resulting in slightly poorer precision.
Heavy metals Usage R&D evaluation	ASTM D3718	This test method covers the determination of the content of chromium (including chromium oxide) in the range from 0.005 to 1.0 % present in the solids of liquid coatings or in dried films obtained from previously coated substrates by means of atomic absorption.	Higher concentrations of chromium can be determined by this test method provided that appropriate dilutions and adjustments in specimen size and reagent quantities are made.
Particulate			
Visual inspection Usage Compliance testing	TAPPI T 437	This test method is suited for the visual estimation of dirt in paper or paperboard in terms of equivalent black area. Dirt in paper or paperboard is defined as any foreign matter embedded in the sheet, which, when examined by reflected, not transmitted, light has a contrasting color to the rest of the surface and has an equivalent black area of 0.04 mm^2 or over.	This test method can be used to size characteristics other than dirt. Frequently used for estimation of gels, fisheyes, ink splashes, and other visual defects.
Visual inspection Usage Compliance testing	ASTM D2019	This test method is intended for the numerical estimation of dirt in paper or paperboard in terms of equivalent black area. This test method is satisfactory only for the estimation of visual characteristics and it may be entirely inadequate when nonvisual effects such as grittiness of dirt are of importance. This is ASTM's version of TAPPI T 437. It refers to the TAPPI Dirt Estimation Chart.	This test method can be used to size characteristics other than dirt. Frequently used for estimation of gels, fisheyes, ink splashes, and other visual defects.

TABLE 1 *Continued*

Test	Test Method	Description	Applicability
		Barrier Requirements	
		Porous	
Porosity Usage R&D evaluation Compliance testing	ASTM D726	This test method is applicable in papers that permit the passage of up to 25 mL of air/0.785 in.^{2} in 15 s.	This test method cannot be used in those cases where the paper cannot be clamped securely against surface and edge leakage, such as, crepe or corrugated papers. For testing porous and semiporous paper, refer to TAPPI T 460, and T 536, respectively. Since the three test methods (D726, T 460, and T 436) do not give the same results, it is recommended that a specific method be agreed upon in specifications covering paper between the seller and the purchaser, and that the test method be chosen to conform to the principle range.
Porosity Usage R&D evaluation Compliance testing	TAPPI T 460	This test method references the use of a Gurley densometer that measures the amount of time required for a certain volume of air (100 cm^3) to pass through a test specimen of a given area. The air pressure is generated by a gravity-loaded cylinder that captures an air volume within a chamber using a liquid seal. The pressurized volume of air is directed to the clamping gasket ring, which holds the test specimen. Air that passes through an area of the test specimen of 6.4 cm^2 (1 in.^{2}) escapes to atmosphere through the holes in the downstream clamping plate.	The pressure differential used in this test method is 1.22 kPa. The recommended range of time measured is from 5 to 1800 sec/100-mL cylinder displacement. For more impermeable materials the time requirements become so excessive that other techniques are preferable. Since this test method measures air passage through the specimen, as well as, leakage across the surface, it is unsuitable for rough-surfaced materials that can not be securely clamped in the mechanism and may allow significant surface and edge leakage. For measurement of materials at higher pressure (3 kPa) refer to TAPPI T 536. To measure materials at pressures up to 9.85 kPa, TAPPI T 547 references the use of a Sheffield tester which measures the amount of air passing through a material of a given area over a specific time period.
Porosity Usage R&D evaluation Compliance testing	TAPPI T 536	This test method measures the amount of time required for a certain volume of air to pass through a test specimen of a given size. This test method measures at a higher pressure differential (3 kPa) and is recommended for papers that require 10 or more seconds for 10 mL of air to pass through.	This test method cannot be used in those cases where the paper cannot be clamped securely against surface and edge leakage, such as, crepe or corrugated papers. Since the three test methods (D726, T 460, and T 536) do not give the same results, it is recommended that a specific test method be agreed upon in specifications covering paper between the seller and the purchaser, and that the test method be chosen to conform to the principle range.
Porosity Usage R&D evaluation Compliance testing	TAPPI T 547	This method is used to measure the air permeance of a circular area of paper using a pressure differential of approximately 10 kPa (1.5 psig).	In order to accommodate a wide range of paper products, rubber clamping plates are available for five commonly used orifice diameters: 9.5 mm (0.375 in.), 19.1 mm (0.75 in.), 38.1 mm (1.5 in.), 57.2 mm (2.25in.), and 76.2 mm (3.00 in.). The air flow range for this method is 0 to 3348 mL/min (0 to 400 Sheffield units). Instruments are available with either variable flowmeters (glass tubes with internal tapers and floats) or electronic mass flowmeters.
Microbial barrier Usage R&D evaluation	ASTM F1608	This test method is used to determine the passage of airborne bacteria through porous materials intended for use in packaging sterile medical devices. This test method is designed to test materials under conditions that result in the detectable passage of bacterial spores through the test material.	A round-robin study was conducted with eleven laboratories participating. Each laboratory tested duplicate samples of six commercially available porous materials to determine the LRV. Materials tested under the standard conditions described in this test method returned average values that range from LRV 1.7 to 4.3. Results of this round-robin study indicate that caution should be used when comparing test data and ranking materials, especially when a small number of sample replicates are used. In addition, further collaborative work should be conducted before this test method would be considered adequate for purposes of setting performance standards.
Microbial barrier Usage R&D evaluation	Mil Spec 36954C	This test method is performed at high flow rates. The challenge particles are microbial clusters with a mean diameter of 3 µm. Removal of challenge particles is therefore almost entirely by impaction.	Test methods based on this specification are intended to evaluate materials for use in surgical masks. This test method is not applicable for materials intended for low flow rate, barrier applications such as medical packaging where particulate removal is almost exclusively a diffusion mechanism.

TABLE 1 *Continued*

Test	Test Method	Description	Applicability
Microbial barrier Usage R&D evaluation	ASTM F2638	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. The intent of this test method is to determine the flow rate through a material at which maximum penetration occurs.	This test method is applicable to porous materials used to package terminally sterilized medical devices. 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 material with a Bendtsen flow rate above 4000 mL/min as measured by ISO 5636-3.
		Nonporous	
Impermeability Usage R&D evaluation	ISO 5636/5 EN 868-1, Annex C ISO 11607–1, Annex C	Each of these test methods includes the use of a permeability tester to determine the ability of a material to inhibit the passage of air.	These test methods have similar test instruction for impermeability. All reference testing with Gurley Densometer. EN 868-/1 includes another permeance tester and a dye penetration test as options.
Impermeability Usage R&D evaluation	ASTM F2981	This test method provides a means to verify that a flexible barrier material is nonporous by challenging a material with a given volume of air under pressure over a specific time period.	This material challenge is presented in ISO-11607-1, Annex C as a normative test method to demonstrate that a material is nonporous and satisfies the microbial barrier requirements. This test method is not intended to measure the diffusion properties of a material nor to identify or quantify the presence of pinhole damage to the design that may result in leaks.
Oxygen transmission Rate Usage R&D evaluation	ASTM D3985	This test method covers a procedure for determination of the steady-state rate of transmission of oxygen gas through plastics in the form of film, sheeting, laminates, coextrusions, or plastic-coated papers or fabrics. It pr ovides for the determination of oxygen gas transmission rate (O_2 GTR), permeance of the film to oxygen gas (PO_2), and oxygen permeability coefficient (PO_2) of homogeneous materials. Transmitted oxygen is used to generate a current through a load resistor to produce an output voltage proportional to the oxygen content of the carrier gas.	This test method uses coulometric sensors to determine the steady state transmission rate through plastic film and sheeting. Suitable for product development. Generally, it is not used for process or quality control except in circumstances where materials may be compromised by cracking.
Oxygen transmission Rate Usage R&D evaluation	ASTM F1307	This test method covers a procedure for the determination of the steady-state rate of transmission of oxygen gas into packages. It employs a coulometric oxygen sensor and associated equipment in an arrangement similar to that described in Test Method D3985.	This method is applicable to packages that in normal use will enclose a dry environment.
Oxygen transmission Rate Usage R&D evaluation	ASTM F1927	This test method covers a procedure determination of the rate of transmission of oxygen gas, at a steady state, at a given temperature and percent relative humidity through film sheeting, laminates, co-extrusion, orplastic-coated papers or fabrics. By controlling humidity, it extends Test Method D3985, which addresses zero humidity or assumed humidity. It provides for the determination of oxygen gas transmission rate, the permeance of the film to oxygen gas, the permeation coefficient of the film to its thickness, and oxygen permeability coefficient in the case of homogeneous materials at a given temperature and relative humidity level.	By controlling the relative humidity of the purge gases, the test environment will more closely simulate actual shelf conditions. This test method uses coulometric sensors to determine the steady state transmission rate through plastic film and sheeting. This method is suitable for product development.
Oxygen gas transmission rate Usage R&D evaluation	ASTM F2622	This test method covers a procedure for determination of the steady-state rate of transmission of oxygen gas through plastics in the form of film, sheeting, laminates, coextrusions, or plastic-coated papers or fabrics. It provides for the determination of (*1*) oxygen gas transmission rate (O_2GTR), (*2*) the permeance of the film to oxygen gas (PO_2), and (*3*) oxygen permeability coefficient ($P'O_2$) in the case of homogeneous materials.	This method allows for the use of various sensors, devices, and procedures and applies to non-porous materials that are to be tested with or without humidity. The Precision and Bias section of this method compares select instruments with other sensors to the instruments specifically described in ASTM D3985.
Oxygen transmission rate Usage R&D evaluation	ASTM F3136	This test method covers a procedure for determination of the transmission rate of oxygen gas through plastics in the form of film, sheeting, laminates, coextrusions, coated or uncoated papers or fabrics. The oxygen sensor incorporates a fluorophore that fluoresces in response to a certain wavelength of light, but is quenched in the presence of oxygen. The oxygen quenching effect is calibrated to oxygen concentration.	This test method tests samples dry and therefore does not provide information about the effect of humidity on the oxygen transmission rate of the sample.

TABLE 1 *Continued*

Test	Test Method	Description	Applicability
Oxygen Headspace Usage R&D evaluation	ASTM F2714	This test method covers a procedure for using fluorescent decay to determine the oxygen concentration in the headspace within a sealed package without opening or compromising the integrity of the package. It requires that chemically coated components be placed on the inside surface of the package before closing. As this test method determines the oxygen headspace over time, the oxygen permeability can easily be calculated as ingress per unit time as long as the volume of the container is known.	The package must be either transparent, translucent, or a transparent window must be affixed to the package surface without affecting the package's integrity.
CO_2 transmission rate Usage R&D evaluation	ASTM F2476	This method covers a procedure for determination of the steady-state rate of transmission of carbon-dioxide gas through plastics in the form of film, sheeting, laminates, coextrusions, or plastic-coated papers of fabrics. It provides for the determination of carbon dioxide gas transmission rate, the permeance of the film to carbon dioxide gas, and carbon dioxide permeability coefficient in the case of homogeneous materials. Transmitted carbon dioxide gas is measured by an infrared detector where an electrical output is produced whose magnitude is proportional to the amount of CO_2 flowing into the detector per unit of time.	This method measures carbon dioxide gas transmission rate in a dry (relative humidity less than 1%) environment. This test method is suitable for product development.
Gas transmission rate Usage R&D evaluation	ASTM D1434	This test method covers the estimation of the steady-state rate of transmission of a gas through plastics in form of film, sheeting, laminates, and plastic-coated papers of fabrics. This test method provides for the determination of (*1*) gas transmission rate, (*2*) permeance, and, in the case of homogeneous material, (*3*) permeability. A sample is mounted in a gas transmission cell so as to provide a semibarrier between the two chambers. One chamber contains the test gas at a specific high pressure, and the other chamber at a lower pressure, receives the permeating gas. Two procedures are provided to determine the gas permeability characteristics. The first is a manometric test method where changes in the pressure differential between the chambers are measured. The second is a volumetric method where the transmission of the gas through the test specimen is indicated by a change in volume.	This method provides semiquantitative estimates for the gas transmission of single pure gases through film and sheeting. The permeances measured by this procedure exhibit a strong dependence on the procedure being used, as well as on the laboratory performing the test. Agreement with other methods is sometimes poor and may be material-dependent.
Gas transmission rate Usage R&D evaluation	ISO 15105–1	ISO 15105–1 specifies a method for determining the gas transmission rate of any plastic material in the form of film, sheeting, laminate, coextruded material, or flexible plastic-coated material under differential pressure.	This method applies to non-porous materials that are to be tested dry (without humidity).
Gas transmission rate Usage R&D evaluation	ISO 15105–2	ISO 15105–2 specifies a method for determining the gas transmission rate of any plastic material in the form of film, sheeting, laminate, coextruded material, or flexible plastic-coated material under equal pressure.	This method applies to non-porous materials that are to be tested dry (without humidity).
Gas transmission rate Usage R&D evaluation	ISO 2556	ISO 2556 specifies a method for determining the gas transmission rate of any plastic material in the form of film, sheeting, laminate, coextruded material, or flexible plastic-coated material using two types of suitable test apparatus. The plastic test specimen separates two chambers, the one contains the test gas at atmospheric pressure, the other of known initial volume has the air pumped out until the pressure is practically zero. The quantity of gas which passes through the specimen from one chamber to the other is determined as a function of time by measuring the increase in pressure occurring in the second chamber by means of a manometer.	This method applies to non-porous materials that are to be tested dry (without humidity).
Water vapor Transmission rate Usage R&D evaluation	ASTM D3079	This test method covers the determination of the amount of water vapor transmission for flexible heat-sealed packages by weight gain of a desiccant. Measurements of mass are taken at intervals over at least a month to determine the average rate of mass change.	This method measures the water vapor barrier properties of a package. With proper precautions and background experience, reproducible results can be obtained. This method is not used for process or quality control. Given the length and accuracy of this test method, instrumentation methods such as Test Methods F372 and F1249 are generally preferred.

TABLE 1 *Continued*

Test	Test Method	Description	Applicability
Water vapor Transmission rate Usage R&D evaluation	ASTM D4279	This test method measures the water vapor transmission rate (WVTR) by weight gain of a desiccant. These test methods cover the determination of water vapor transmission rates for bulk shipping containers in two methods: for reclosable containers and containers not designed for reclosing. Details are given for the constant and cycle test methods of test atmosphere.	Intended for use on fully configured containers either as packed or after performance tests such as drop, impact, or vibration. It is not suitable as a material test. It is intended for relatively large packages. Where smaller packages or greater accuracy is required, Test Method F895 or D1251 should be considered.
Water vapor Transmission rate Usage R&D evaluation	ASTM E398	This test method covers dynamic evaluation of the rate of transfer of water vapor through a flexible barrier material and allows conversion to the generally recognized units of water vapor transmission as obtained by various other test methods. This test method is unique in that it closely duplicates typical product storage where a transfer of moisture from a package into the environment is allowed to proceed without constantly sweeping the environmental side with dry gas (as is done in Test Methods F1249 and F372.)	This test method is limited to flexible barrier sheet materials composed of either completely hydrophobic materials, or combinations of hydrophobic and hydrophilic materials having at least one surface that is hydrophobic. The minimum test value obtained by this test method is limited by the leakage of water vapor past the clamping seals of the test instrument—approximately 0.01 g/24 h-m^2. This test method is not suitable for referee testing at this time, but is suitable for control testing and material comparison.
Water vapor Transmission rate Usage R&D evaluation	ASTM F372	This test method covers a rapid procedure for determining the WVTR of flexible barrier materials in film or sheet form. Calibration is by desiccant weight gain. A dry chamber is separated from a wet chamber of known temperature and humidity by the barrier material to be tested. The time for a given increase in water vapor concentration of the dry chamber is measured by monitoring the differential between two bands in the infrared spectral region, one in which water molecules absorb and the other where they do not. This information then is used to calculate the water vapor movement through a known area of barrier material.	Determines the WVTR of a film by infrared adsorption using a Mocon ERD-1 infrared Diffusometer. This test method is suitable for product development and quality or process control during film manufacturing. This test method is applicable to sheets and films up to 3 mm in thickness, consisting of single-layer or multilayer synthetic or natural polymers and metal foils including coated materials. Values for water vapor permeance and water vapor permeability must be used with caution. Suitable for product development, it is generally not used for process or quality control except in circumstances where brittle barrier coated materials may be compromised by cracking.
Water vapor Transmission rate Usage R&D evaluation	ASTM F1249	This test method provides for the determination of water vapor transmission rate (WVTR), the permeance of the film to water vapor, and for homogeneous materials, water vapor permeability coefficient. A dry chamber is separated from a wet chamber of known temperature and humidity by a barrier material to be tested. The dry chamber and the wet chamber make up a diffusion cell in which the test film is sealed. The diffusion cell is placed in a test station where the dry chamber and the top of the film are swept with dry air. Water vapor diffusing through the film mixes with the air and is carried into a pressure modulated infrared detector. Results from the test film are compared to results from a reference film to calculate the WVTR of the material being tested.	Similar to Test Method F372 but written around a generic infrared sensor. Calibration is with a reference film of known transmission rate rather than gravimetric methods. Values for water vapor permeance and water vapor permeability must be used with caution. The inverse relationship of WVTR to thickness and the direct relationship of WVTR to the partial pressure differential of water vapor may not always apply. This test method is applicable to sheets and films up to 3 mm (0.1 in.) in thickness, consisting of single-layer or multilayer synthetic or natural polymers and foils, including coated materials. Suitable for product development, it is not used generally for process or quality control except in circumstances where brittle barrier coated materials may be compromised by cracking.
UV Barrier Usage R&D evaluation		Spectra	
Light transmission Usage R&D evaluation	ASTM F1443	This is a contact transmission densitometer. It will quantify the amount of light penetrating a film and will detect anything that can cause optical density to vary. Operating range is from 0 to >10^5	Because this is a contact densitometer it is not suitable for determining haze or clarity. This test method can be used to determine the amount of material, such as an ink or vapor deposited aluminum, on a film.
		Durability Requirements	
Puncture resistance Usage R&D evaluation	ASTM D1709	This test method defines two methods and two techniques for employing the test methods to cover the determination of the energy that causes plastic film to fail under specified conditions of impact of a free-falling dart. The two test methods cover different size of dart and distance dropped. The techniques are related to the manner in which the testing shows at what point 50 % of the samples pass. The results are equivalent.	Suitable for heavier weight/stronger materials that cannot be punctured by the apparatus used in Test Method D3420. Slippage of the sample in the clamp at impact is a source of significant test variability. This test method may be used to evaluate changes in material properties from such factors as time, strength, storage conditions, etc. It may be used to compare and contrast materials; further steps would be needed to correlate these relative numbers to end-use applications.

TABLE 1 *Continued*

Test	Test Method	Description	Applicability
Puncture resistance Usage R&D evaluation	ASTM F1306	This test method permits flexible barrier films and laminates to be characterized for slow rate penetration resistance to a driven probe. This test method is performed at 23/–2°C, by applying a biaxial stress at a single test velocity on the material until perforation occurs. The force, energy, and elongation to penetration are determined.	This is strictly a material characteristic and in many instances has little if any relationship to performance in the packaging environment. This test method may be used to evaluate changes in material properties from such factors as time, strength, storage conditions, etc. It may be used to compare and contrast materials; further steps would be needed to correlate these relative numbers to end-use applications. This test method could be used to address concerns over sharp edged products packaged in thin flexible material penetrating the integrity. This test method will create a relative number for penetration resistance but does not address abrasion.
Puncture resistance Usage R&D evaluation	ASTM D3420	This test method covers the determination of resistance of film to impact-puncture penetration. It uses a swinging pendulum to deliver an impact to a sample held in a circular clamp. Two methods are cited: *A*-Dynamic Ball Burst Tester, and *B*-Spencer test for larger samples utilizing a modified Elmendorf. These two methods are not comparable.	For lightweight films and papers. Slippage of the sample in the clamp at impact will produce an erroneously high value. For heavier materials use Test Methods D1709. This test method may be used to evaluate changes in material properties from such factors as time, strength, storage conditions, etc. It may be used to compare and contrast materials, further steps would be needed to correlate these relative numbers to end use applications.
Tear resistance Usage R&D evaluation	ASTM D1922	This test method covers the determination of the average force to propagate tearing through a specified length of plastic film or nonrigid sheeting. After the tear has been started using an Elmendorf-type tearing tester, two specimens are cited, a rectangular type and one with a constant radius testing length. The latter shall be the preferred or referee specimen.	Because of difficulties in selecting uniformly identical specimens, the varying degree of orientation in some plastic films, and the difficulty found in testing highly extensible or highly oriented materials, or both, the reproducibility of the test results may be variable and, in some cases, misleading. This test method may be used to evaluate changes in material properties from such factors as time, strength, storage conditions, etc. It may be used to compare and contrast materials, further steps would be needed to correlate these relative numbers to end use applications. Provisions are made in the test method to compensate for oblique directional tearing which may be found with some materials.
Tear resistance Usage R&D evaluation	ASTM D1938	This test method covers the determination of the force necessary to propagate a tear in plastic film and thin sheeting (thickness of 1 mm (0.04 in.) or less) by a single-tear method.	This is a low speed (10 in./min) tear performed in a load frame. This measures the force to propagate a razor cut. It is not indicative of the force required to initiate a tear. This test method may be used to evaluate changes in material properties from such factors as time, strength, storage conditions, etc. It may be used to compare and contrast materials, further steps would be needed to correlate these relative numbers to end use applications.
Flexural durability Usage R&D evaluation	ASTM F392	This practice covers conditioning of flexible barrier materials for the determination of flex resistance. Subsequent testing can be performed to determine the effects of flexing on material properties.	Flex failure is determined by measuring the effect of the flex conditioning on the barrier and/or mechanical performance of the structure. The property to be evaluated determines the appropriate conditioning level. This practice is valuable in determining the resistance of flexible-packaging materials to flex-formed pinhole failures. This practice is also valuable for determining the effect of flexing on barrier properties such as gas and/or moisture transmission rates. This practice does not measure any abrasion component relating to flex failure.
Abrasion Usage R&D evaluation		No suitable standard test method currently exists for assessing abrasion resistance of flexible packaging materials.	
Tensile Usage R&D evaluation	ASTM D882	This test method covers the tensile properties of plastic films in the form of sheeting including film less than 1.0 mm (0.04 in.) in thickness. It defines a method of Static Weighing, Constant-Rate-of-Separation Testing. The modulus determination procedure is based on the use of grip separation as a measure of extension. This test method utilizes a precisely cut strip of film between 5 and 25.4 mm wide. Data available from this test include breaking factor (force per unit width at break), tensile strength, tensile strength at break, elongation at break, elongation at yield, elastic modulus, secant modulus, and tensile energy to break.	This is applicable to film less than 1.0 mm (0.04 in.) in thickness. For thicker materials, tensile properties shall be determined by Test Method D638. This test method may be used to evaluate changes in material properties from such factors as time, strength, storage conditions, etc. This test method may be used to compare and contrast materials, further steps would be needed to correlate these relative numbers to end use applications.

TABLE 1 *Continued*

Test	Test Method	Description	Applicability
Tensile Usage R&D evaluation	TAPPI T 494	This method determines four tensile breaking properties: tensile strength, stretch, tensile energy absorption, and tensile stiffness. Rate of elongation is 25.4 mm (1 in./min)	Due to paper's low elongation at break, alignment in the grips is much more critical than for plastic materials. Misalignment will produce stress on one side of the specimen and cause premature failure. This method may be used to evaluate changes in material properties from such factors as time, strength, storage conditions, etc. This method may be used to compare and contrast materials, further steps would be needed to correlate these relative numbers to end use applications.
Tensile Usage R&D evaluation	TAPPI T 404	This method utilizes pendulum type equipment for determining two tensile breaking properties: the force per unit width required to break a specimen (tensile strength) and the percentage elongation at break (elongation).	As it is a much higher speed test than TAPPI T 494. It may be more indicative of package performance in the packaging environment. This method may be used to evaluate changes in material properties from such factors as time, strength, storage conditions, etc. This test method may be used to compare and contrast materials, further steps would be needed to correlate these relative numbers to end use applications.
Bond strength Usage R&D evaluation Compliance testing	ASTM F904	This test method covers a procedure for comparing the bond strength or ply adhesion of similar laminates made from flexible materials such as cellulose, paper, plastic film, and foil. This includes laminates made by various processes: adhesive laminates, extrusion coatings, extrusion laminates, and coextrusions. Strip samples of the laminate are separated at their interface and the force required to propagate the separation is measured.	This value is not useful for engineering design or in comparing dissimilar materials because the value can change significantly depending upon the application. Exposure to heat, cold, and chemicals can all have significant impact on this property. This test method is routinely used as a test performed during the production of laminated or bonded structures to monitor the process.
Basis weight Usage R&D evaluation Compliance testing	ASTM D4321	This test method covers the determination of yield (area per unit mass) of plastic film. It also describes the means for calculating nominal yield from given values of nominal density and nominal thickness. In material specifications, limits for yield are normally stated in terms of the percent deviation of actual yield from nominal yield.	This test method is useful for incoming inspection, process control, and specification values. It does not identify gauge bands or variation in thickness across the width of the web.
Basis weight Usage R&D evaluation Compliance testing	ASTM D3776	This test method covers the measurement of fabric mass per unit area (weight). The four options defined are: Full Piece Roll, Bolt or Cut, Full Width Sample, Small Swatch of Fabric, and Narrow Fabrics	The small swatch method may be used in measuring the basis weight of non-woven materials.
Thickness Usage R&D evaluation Compliance evaluation	ASTM D1777	This test method applies to fabrics including woven fabrics, air bag fabrics, blankets, napped fabrics, knitted fabrics, layered fabrics and pile fabrics. The fabrics may be untreated, heavily sized, coated, resin treated or otherwise treated.	This test method measures the compressed thickness of the fabric. A16 mm diameter disk is loaded with a 500 g weight and the sample is allowed to equilibrate for 2 to 5 s before recording the thickness. Due to the mechanical nature of the test and the compressibility of the material, test results should be reported as the average value of multiple test points.
Thickness Usage R&D evaluation Compliance testing	ASTM D374	These test methods employ eight different methods for the measurement of thickness of solid electrical insulation materials. These test methods employ different micrometers that exert various pressures for varying times upon specimens of different geometries.	These test methods are designed for nonfibrous structures. Due to the mechanical nature of the test and the compressibility of the material, test results should be reported as the average value of multiple test points.
Thickness Usage R&D evaluation Compliance testing	ASTM D645/D645M	This test method employs a micrometer with a 16 mm diameter pressure foot.	This test method is frequently utilized for materials other than paper, such as film and composite flexible packaging materials. Due to the mechanical nature of the test and the compressibility of the material, test results should be reported as the average value of multiple test points.
Shelf life accelerated aging Usage R&D evaluation	ASTM F1980	This is a guide to the selection of time and temperature conditions for accelerated aging of medical packaging.	Accelerated aging is frequently used in the early development of medical packaging. Failures often occur due to the selection of aging conditions outside of the material's operational capability. This guide is an aid in selecting appropriate test conditions.
Thickness Usage R&D evaluation Compliance Testing	ASTM F2251	This test method covers the measurement of thickness of flexible packaging materials using contact micrometers.	Precision and Bias was developed using both handheld and benchtop micrometers with foot sizes ranging from 4.8 to 15.9 mm ($^3/_{16}$ to $^5/_8$ in.). Precision and Bias provides gage repeatability and reproducibility on wide range of materials.

TABLE 1 *Continued*

Test	Test Method	Description	Applicability
		Package Integrity & Seal Strength	
		Package Integrity	
Seal integrity Usage R&D evaluation	ASTM F1929	This test method defines materials and a procedure that will detect and locate a leak equal or greater than a channel formed by a 50 µm (0.002 in.) wire in package edge seals formed between a transparent film and a porous sheet material. A dye penetrant solution is applied locally to the seal edge to be tested for leaks. The method details different techniques for applying the dye penetrant solution. After contact with the dye penetrant for a specified time, the package is visually inspected for dye penetration.	This test method is intended for use on packages with edge seals formed between a transparent film and a porous sheet material. This test method is limited to porous materials which can retain the dye penetrant solution and prevent it from discoloring the entire seal area for a minimum of 20 s. Uncoated papers are especially susceptible to leakage and must be evaluated carefully for use with this test method. This test method specifies the dye penetrant for good contrast to the opaque packaging material and penetrating characteristics.
Seal Integrity Usage R&D evalution Compliance testing	ASTM F3004	This standard method describes the technology and testing procedures that can be used to detect seal defects in the size range of 1 mm and characterize seal quality in a variety of packaging styles using airborne ultrasound technology.	Seals can be tested in flexible, semi-rigid, and rigid packages. The test is a non-destructive and in-line, real time inspection is possible.
Seal integrity Usage R&D evaluation	ASTM F2391	This method describes how to measure package and seal integrity using helium as a tracer gas. Two procedures are detailed. In the first, the sniffer mode, the package is scanned externally for helium escaping into the atmosphere or fixture. For the second procedure, vacuum mode, the helium-containing package is placed in a closed fixture. After drawing a vacuum, helium escaping into the closed fixture (capture volume) is detected.	The sensitivity of the method is as low as 10^{-11} Pam^3/s. Unless helium can be incorporated into the headspace before sealing, the helium leak detection tests are destructive. This test method is not applicable to breathable or porous packaging.
Seal integrity Usage R&D evaluation Compliance testing	ASTM F1886	This test method covers the determination of channels in the package seal down to a width of 75 µm (0.003 in.) with a 60-100 % probability. This test method is applicable to flexible and rigid packages with at least one transparent side so that the seal area may be clearly viewed.	The ability to visually detect channel defects in package seals is highly dependent on the size of channel, the degree of contrast from sealed and unsealed areas, the amount and type of adhesive between the two package layers, reflecting light angle, types of material used, the use of magnification, and the inspector's level of training and experience.
Package integrity Usage R&D evaluation	ASTM D3078	This test method covers the determination of leaks in flexible packaging containing a headspace gas. Test sensitivity is limited to 1×10^{-5} atm cm^3/s (1×10^{-6} Pa m^3/s).	Small leaks may not be detected by this procedure. Viscoelastic effects on the products, or entrapped air, become significant and prevent passage through small openings. Positive pressure inside the pouch after the vacuum is drawn may force the product to plug small leaks. The size of the leak that can be detected is dependent upon the products contained, the nature of the packaging material, and the test parameters selected.
Package integrity Usage R&D evaluation	ASTM F2095	This test method includes several methods that cover the measurement of leaks in nonporous pouches or trays with nonporous sealed lids.	This test method is destructive because it requires entry into package to supply an internal pressure of a gas. The test methods detect leaks at a rate of 1104 secs (standard cubic centimetres per second) or greater. Limitation of leak rate is dependent on package volume. If product is enclosed, seals or surfaces cannot be in contact with water or another liquid.
Package integrity Usage R&D evaluation	ASTM F2096	This test method covers the detection of gross leaks in heat sealed flexible packages. Package is submerged under water, internal pressure is increased by inflating with air and operator observes package for bubbles.	Maybe used for porous and nonporous packages. When applying to porous packages, care must be taken not to exceed bubble point of material. Skill and accuracy in locating leaks is dependent on training and experience of operator.
Package integrity Usage R&D evaluation	ASTM F2228	This test method covers the detection of leaks in nonporous rigid trays, as well as channels in the seal between the porous lid and the tray. It does not detect leaks in the porous lids.	Test is used to evaluate sealed tray and lid packages. It is termed nondestructive and packages may be retested at different time intervals. Detects leaks as small as 100 µm (0.004 in.) in seal and 50 µm (0.002 in.) diameter pinholes. For testing trays without lids, use ASTM F2227. This test is not considered a whole package integrity test.
Package integrity Usage R&D evaluation	ASTM F2227	This test method covers the detection of leaks in rigid trays.	Trays may be retested at different time intervals. Detects pinholes as small as 50 µm (0.002 in.) diameter.

TABLE 1 *Continued*

Test	Test Method	Description	Applicability
Package integrity Usage R&D evaluation	ASTM F2338	This nondestructive test method for rigid and semi-rigid trays and cups with and without porous or nonporous lids and flexible nonporous packages can detect leaks by use of an absolute or differential pressure transducer leak detector.	At target vacuum levels, holes or cracks in non-lidded rigid trays or cups of 50 µm (0.0002 in.) in diameter can be detected. In trays or cups with porous or nonporous lids, channels in the seal area of 125 µm (0.0005 in.) and cracks or holes in the trays or cups of 100 µm (0.004 in.) can be detected. This test is not considered a whole package test for porous lidded packages.
Package Integrity Usage R&D evaluation Compliance testing	ASTM F3039	This test method provides two different methods for detecting leaks in nonporous packaging of flexible barrier materials. Method A defines a procedure that will detect and locate a leak equal to or greater than a channel formed by a 50 µm (0.002 in.) wire in the edge seals of a nonporous package. A dye penetrant solution is applied locally to the seal edge to be tested for leaks. After contact with the dye penetrant for a minimum specified time, the package is visually inspected for dye penetration or, preferably, the seal edge is placed against an absorbent surface and the surface inspected for staining from the dye. Method B for this test method defines a procedure that will detect and locate a leak equal to or greater than 10 µm [0.00039 in.] diameter in a nonporous flat sheet. The flat sheet is placed on an absorbent surface and then a dye penetrant is spread across the surface of the sheet, preferably using a small roller to apply pressure on the sheet to ensure adequate contact between the absorbent surface and the bottom surface of the sample being tested. The flat sheet is carefully removed and the absorbent surface is inspected for staining from the dye.	This test method can be used for both transparent and opaque nonporous surfaces. The method requires that the dye penetrant have good contrast to the materials being testing or the absorbent surface, or both. It is not intended to be used with porous packaging materials.
		Seal Strength	
Heatseals Usage R&D Evaluation Compliance Testing	ASTM F2029	This practice covers laboratory preparation of heatseals and the treatment and evaluation of heatseal strength data for the purpose of determining heatsealability of flexible barrier materials.	The practice of this standard is restricted to sealing with a machine employing hot-bar jaws. Impulse, high-frequency, and ultrasonic heating methods are not included.
Hot Tack Usage R&D Evaluation	ASTM F1921	This test method covers laboratory measurement of the strength of heat seals formed between thermoplastic surfaces of flexible webs, immediately after a seal has been made and before it cools to ambient temperature. There are two variations of the hot tack test differing primarily in two respects: (*1*) rate of grip separation during testing of the sealed specimen, and (*2*) whether the testing machine generates the cooling curve of the material under test, or instead makes a measurement of the maximum force observed following a set delay time.	This method is restricted to instrumented hot tack testing, requiring a testing machine that automatically heatseals a specimen and immediately determines strength of the hot seal at a precisely measured time after conclusion of the sealing cycle.
Seal strength (peel) Usage R&D evaluation Compliance testing	ASTM F88	This test method covers the measurement of the seal strength of flexible barrier materials. The techniques and equipment used to form these seals are not covered. This test method does not measure seal continuity or any other seal properties beyond the force required to tear apart a seal of standard width.	Test values show significant variation depending upon the test configuration. In order to be used as a specification, the test configuration and data interpretation must be agreed upon by all parties.
Seal strength (burst) Usage Compliance testing	ASTM F1140	These test methods explain the procedure for determining the ability of open or closed packages to withstand internal pressurization. The burst test internally and increasingly pressurizes the package until the package fails. The creep test maintains a specified pressure for a specified time.	For some combinations of materials data from this test may have a very high standard deviation. The actual values produced are highly dependent on package dimensions. In order to be used as a specification, the test configuration and data interpretation must be agreed upon by all parties. Where test variability has been shown to be acceptable, it may be used as an internal process or quality control test method. In case of interlaboratory disagreement, use of Test Method F88 with agreed upon test configuration, shall be used as the determinant factor.
Seal strength (restrained burst) Usage Compliance testing	ASTM F2054	Similar to Test Methods F1140. This test method is conducted between rigid restraining plates to restrict expansion of the package. This results in more uniform stress distribution.	This test method may be used in place of Test Methods F1140. Special consideration must be given to selection of the gap dimension for each package as a function of package materials, geometry, and bond mechanism. Extra safety consideration must be given to the design and operation of the apparatus as substantial stresses develop during use.

TABLE 1 *Continued*

Test	Test Method	Description	Applicability
Seal strength (peel) for lids on round cups and bowls Usage R&D evaluation	ASTM F2824	This test method describes a method for the measurement of mechanical seal strength while separating the entire lid (cover/membrane) from a rigid or semi-rigid round container. An angle of pull of 45° is used and the continuous and maximum forces required to separate the entire lid (cover/membrane) from the container is determined.	This method applies to round rigid or semi-rigid containers with a lid (cover/membrane). It differs from ASTM F88 in that F88 tests a portion of the seal whereas this test method tests the force required to separate the entire lid (cover/membrane) from the container.
		Visibility and Appearance	
Haze Usage R&D evaluation	ASTM D1003	This test method covers the evaluation of specific light-transmitting and wide-angle-light-scattering properties of planar sections of materials such as essentially transparent plastic. A procedure is provided for the measurement of luminous transmittance and haze. Material having a haze value greater than 30 % is considered diffusing and should be tested in accordance with Practice E167.	This test method derives a single value for total scattered light by comparing the sample with a known standard. No angular information and no back scatter information is available. Data from this test are suitable only for comparison of similar materials.
Gloss Usage R&D evaluation	ASTM D2457	This test method describes procedures for the measurement of gloss of plastic films and solid plastics, both opaque and transparent. It contains three separate gloss angles: 60°, recommended for intermediate-gloss films, 20°, recommended for high-gloss films, and 45°, recommended for intermediate and low-gloss films.	In packaging it is used as a measure of the aesthetic appearance of film, over lacquers or inks.
Opacity Usage R&D evaluation	ASTM D589	This test method covers the determination of the opacity of paper. Two different types of "white" backing are specified, leading to two different opacity values. This test method employs 15° diffuse geometry, Illuminant A/2° and 89 % reflectance backing or paper backing. For the measurement of opacity with d/0° geometry, Illuminant C/2° and paper backing (see TAPPI T 519). This test method follows closely the TAPPI T425 Opacity of Paper (15/d geometry, illuminant A/2°, 89 % reflectance backing and paper backing).	In addition to paper, this test method may be applied to other flexible packaging materials.
		Processing	
Coefficient of friction Usage R&D evaluation	ASTM D1894	This test method covers determination of the coefficients of starting and sliding friction of plastic film and sheeting when sliding over itself or other substances at specified test conditions. The procedure permits the use of a stationary sled with a moving plane, or a moving sled with a stationary plane. Both procedures yield the same coefficients of friction values for a given sample.	When determining the COF of film to metal, inconsistencies in the metal surface may increase variation in the results and make it more difficult to correlate. COF test values may change over time for packaging materials using migratory slip additives. Test method may be used to compare and contrast materials, further steps would be needed to correlate these relative numbers to end use applications
Coat weight Usage R&D evaluation Compliance testing	ASTM F2217	This practice outlines the steps for determining coat weight on a given ara. The sample is weighed, the coating or adhesive removed and the sample reweighed. The results are calculated from the difference in the weights.	The solvents needed for this practice vary depending on the material being removed and the substrate to which it is applied, therefore each test must be designed with guidance from coating/adhesive manufacturer.
Dimensional measurements Usage Compliance testing	ASTM F2203	This test method covers the measurement of linear dimensions of flexible packages and packing materials.	This method is suggested for use with an allowable tolerance range of 3 mm (⅛ in.) or greater. Precision and Bias section provides gage repeatability and reproducibility on wide range of dimensions and substrates.
Sealability Usage R&D evaluation	ASTM F2029	These practices cover laboratory preparation of heat seals and treatment of seal strength data for determining the heat sealability of flexible barrier films.	Used for determination of the heat sealability of a surface as a function of interface temperature in the development of improved sealant layers. The practices of this standard are restricted to sealing with a machine employing hot-bar jaw(s). Impulse, high-frequency, and ultrasonic heating methods are not included. These practices apply primarily to webs intended to be used on commercial machines employing reciprocating sealing jaws, such as most form-fill seal packaging machines, platen heatsealers, and so forth.
		Printed Ink	

TABLE 1 *Continued*

Test	Test Method	Description	Applicability
Rub testing Usage R&D evaluation	ASTM D5264	This test method covers a procedure for determining the abrasion resistance of printed materials using the Sutherland Rub Tester, or its equivalent, equipped with full-width rubber pads and using standardized receptors. This test method is applicable to labels, folding cartons, corrugated boxes, inserts, circulars, and other packaging materials having applied graphics on a flat substrate.	This method is used to evaluate changes in the aesthetic characteristics of packaging after subjection to standardized levels of abrasion.
Anchorage Usage R&D evaluation Compliance	ASTM F2252	This practice covers evaluating the adhesion of ink or coating using tape. Typically, a strip of tape is applied to the printed surface and removed. Tape and tested surface are inspected.	A widely used test to characterize the relative degree of adhesion of ink or coating to a substrate.
Chemical resistance Usage R&D evaluation	ASTM F2250	This practice describes the procedure for evaluating the ability of an ink, overprint, varnish, or coating to withstand chemical exposure.	The specific chemical and method of choice as well as determination of measurement outcome are left to users to agree upon in joint discussion. There are several methods detailed, choice depends on anticipated conditions of use.
		Package Performance	
General Usage R&D evaluation	All	All standards, practices, and procedures for package performance testing provide an evaluation of the packaging system using established test methods at levels representative of those occurring in actual distribution. They are designed to provide a laboratory simulation of the damage-producing motions, forces, conditions, and sequences of transport environments. Applicable across broad sets of circumstances, such as a variety of vehicle types and routes, or a varying number of handling exposures. Characteristics will include simple shaped random vibration, different drop heights applied to the sample package, and/or atmospheric conditioning.	Performance testing must be used to confirm product protection and sterile package integrity in design validation. Confirmation is via product testing and package integrity testing. It is also used to confirm the minimum seal strength requirement in process validation. At the very minimum, performance testing is performed with the product in the final package design produced at the worst case process conditions. Consideration should be given to evaluating the effects of environmental extremes.
General Simulation Usage R&D evaluation	ASTM D4169	This practice provides a test plan with identified test methods for a given distribution cycle representing a specific routing from production to consumption. Eighteen different distribution cycles are listed.	Users must first be able to identify the distribution cycle for their product. Tests in the provided test plan should be performed sequentially on the same containers in the order given. Distribution Cycle 13 is commonly applied to medical devices, however, other cycles may also apply. DC 13 also has an optional vibration/vacuum test that is normally not required for porous medical device packages because of pressure differential equilibration Establishing a level of test intensity, assurance level, may affect the desired outcome of performance testing. Consult the standard to understand the different assurance level rationales.
General Simulation Usage R&D evaluation	ISTA 3E	Test Procedure 3E is a general simulation test for unitized loads of the same retail or institutional packaged-products. A unitized load is defined as one or more products or packaged-products usually on a skid or pallet, but always secured together or restrained for distribution as a single load. Examples would be a stretch wrapped pallet load of individual containers, a single non-packaged machine banded to a pallet or a pallet with a corrugated tray, tube and a cap. Basic requirements include atmospheric conditioning, compression, random vibration and shock testing.	This procedure may be applicable for consumer goods going to retailers or retail distributors. Additionally, some distributors may unitize a mixed load when the number of packages is a consideration
Single Parcel Simulation Usage R&D evaluation	ASTM D7386	This practice provides a uniform basis of evaluating, in a laboratory, the ability of packaging systems, weighing up to but not exceeding 150 lb (68 kg), intended for the single parcel delivery system to withstand the hazards associated with the distribution environment.	This practice may be applied when using a distribution carrier that transports packages weighing up to 150 lb through ground and/or air transport systems, such as FedEx, UPS, DHL, etc. Overnight delivery of medical devices to the user is commonly employed. When employing a contract sterilizer and/or a distribution center prior to single parcel delivery, this practice, alone, may not be sufficient.

TABLE 1 *Continued*

Test	Test Method	Description	Applicability
Single Parcel Simulation Usage R&D evaluation	ISTA 3A	Test Procedure 3A is a general simulation test for individual packaged-products shipped through a parcel delivery system. The test is appropriate for four different package types commonly distributed as individual packages, either by air or ground. The types include standard, small, flat and elongated packages. 3A includes an optional test combining Random Vibration with Low Pressure (simulated high altitude). This tests the container's (whether primary package or transport package) ability to hold a seal or closure and the retention of contents (liquid, powder, or gas) without leaking. Basic requirements include atmospheric pre-conditioning, random vibration with and without top load, and shock testing.	This procedure may be applied when using a distribution carrier that transports packages weighing up to 150 lb through ground and/or air transport systems, Overnight delivery of medical devices to the user is commonly employed. When employing a contract sterilizer and/or a distribution center prior to single parcel delivery, this practice, alone, may not be sufficient. Vibration/vacuum testing is optional and normally not needed for porous medical device packages, because of pressure differential equilibration. UPS has recognized this test procedure.
Single Parcel Simulation Usage R&D evaluation	ISTA 6–FEDEX-A	A series of pre-shipment tests to simulate FedEx air and ground shipping environments.	FedEx package testing procedures are based on industry data, as well as international testing procedures and standards, to provide reliable packaging tests. It is a general simulation procedure for testing packaged products weighing up to 150 lbs. Drop, impact, compression and vibration tests are used to evaluate the integrity and protective performance of the packaging.
Enhanced Simulation Usage R&D evaluation	ISTA 4AB	A general simulation test with at least one element of focused simulation, such as test sequence or condition linked to actual known distribution. 4AB is a web-based application to generate customized test plans. It closely ties the tests and sequence to a user-defined pattern of distribution, and includes a broad range of current and quantitative information on distribution environment hazards. The focused simulation elements are test-tailoring to individual situations, and usage of up-to-date and specific hazard profiles and parameters	This procedure covers the testing of 11 different package types, 4 handling types, and 7 types of load-carrying materials or combinations; any hazard (test) element may be assigned one of three intensities. The user must be able to designate each of the aforementioned criteria. Program inputs and test plans may be in English or metric units. Test plans may require relatively sophisticated laboratory testing equipment. As a maximum, the required equipment may include several types of appropriate drop test apparatus, a random vibration test system, an inclined impact tester, compression test apparatus,
Conditioning Usage R&D evaluation	ASTM D4332	This practice provides for standard and special conditioning and testing atmospheres that may be used to simulate particular field conditions that a container, package, or packaging component may encounter during its life or testing cycle. Procedures for conditioning these containers, packages, or packaging components so that they may reach equilibrium with the atmosphere to which they may be exposed are detailed.	Many materials from which containers and packages are made, especially cellulosic materials, undergo changes in physical properties as the temperature and the relative humidity (RH) to which they are exposed are varied. The conditions described in this practice are either historically accepted standard conditions or special laboratory conditions chosen to represent particular phases of the distribution environment. These special conditions do not necessarily duplicate actual field conditions, but tend to simulate them and have effects on packages and materials which may be related to their field performance.
Conditioning Usage R&D evaluation	ASTM F2825	This practice provides a uniform basis for evaluating, in a laboratory, the ability of a packaging system to withstand a range of climatic stresses that a packaging system may be exposed to during distribution throughout the world and still provide the product protection from damage or alteration.	This practice is designed as conditioning prior to testing for overnight or two-day delivery systems of a single parcel packaging system or as a standalone test for climatic stressing of packaging systems. This practice does not cover refrigerated, frozen food storage, or cryogenic storage conditions. Only the climatic environments encountered in various regions of the world are covered by this practice.