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Standard Guide for Writing a Specification for Sterilizable Peel Pouches[1]

This standard is issued under the fixed designation F2559/F2559M; 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 defines the requirements and considerations for flexible peel pouches with one open, unsealed end that are intended to be sterilized containing medical devices. These are also known as preformed sterile barrier systems.

1.2 Pouch styles are categorized as chevron, header, and corner peel. These pouches are typically manufactured by heat sealing, or in some cases, by cohesive cold sealing. The sealing bond is intended to be peeled open to aseptically dispense the contents.

1.3 Pouch materials may be either porous, nonporous, or any combination of the two.

1.4 This guide addresses some critical printing requirements on the pouch.

1.5 The values stated in either SI units or inch-pound units are to be regarded separately as standard. The values stated in each system may not be exact equivalents; therefore, each system shall be used independently of the other. Combining values from the two systems may result in non-conformance with the standard.

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

2. Referenced Documents

2.1 *ASTM Standards:*[2]

E122 Practice for Calculating Sample Size to Estimate, With Specified Precision, the Average for a Characteristic of a Lot or Process

F17 Terminology Relating to Flexible Barrier Packaging

F88 Test Method for Seal Strength of Flexible Barrier Materials

F1140 Test Methods for Internal Pressurization Failure Resistance of Unrestrained Packages

F1886 Test Method for Determining Integrity of Seals for Medical Packaging by Visual Inspection

F2054 Test Method for Burst Testing of Flexible Package Seals Using Internal Air Pressurization Within Restraining Plates

F2097 Guide for Design and Evaluation of Primary Flexible Packaging for Medical Products

F2203 Test Method for Linear Measurement Using Precision Steel Rule

F2250 Practice for Evaluation of Chemical Resistance of Printed Inks and Coatings on Flexible Packaging Materials

F2475 Guide for Biocompatibility Evaluation of Medical Device Packaging Materials

2.2 *TAPPI Standards:*

T437 Dirt in Paper and Paperboard[3]

3. Terminology

3.1 *Definitions*—For definitions and terms used in this guide, see Terminology F17.

3.2 *Definitions of Terms Specific to This Standard:*

3.2.1 *pouch, n*—a flexible package constructed of one or more materials sealed together to form a preformed sterile barrier system. When purchased, one end or side is open to allow for product loading and final sealing.

3.2.2 *specification, n*—an explicit set of requirements to be satisfied by a material, product, system, or service. Examples of specifications include, but are not limited to, requirements for; physical, mechanical, or chemical properties, and safety, quality, or performance criteria. A specification identifies the test methods for determining whether each of the requirements is satisfied.[4]

4. Summary

4.1 This guide provides guidance for writing a peel pouch material specification. Materials, method of manufacture,

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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] Available from Technical Association of the Pulp and Paper Industry (TAPPI), 15 Technology Parkway South, Norcross, GA 30092, http://www.tappi.org.

[4] In accordance with ASTM International *Form and Style for ASTM Standards*.

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physical properties, performance requirements, dimensioning, appearance, and printing are all issues that need to be addressed in a peel pouch specification. Appropriate requirements and test methods are suggested for preparing a specification.

5. Significance and Use

5.1 Medical device peel pouches are universally used by the industry and produced by a myriad of suppliers. They may be constructed of many different materials including films, foils, paper, nonwovens such as Tyvek, and combinations thereof. However, even with the diversity of materials, there are still basic requirements that all pouches should exhibit. Above all, the pouches must contain and protect the device while maintaining sterility during all physical handling.

5.2 Pouch requirements may be divided into two categories, initial pouch and material qualification, and routine production and receipt requirements to ensure the purchaser receives exactly what is ordered. While all requirements should be included in the written specification, initial qualification tests may only be needed prior to the first order. Routine production and receipt requirements should be adhered to on every order. Initial qualification requirements are indicated within each clause, where applicable.

5.3 This guide provides an understanding of the requirements needed for the manufacture, purchase, and acceptance of a preformed peelable pouch. Appropriate test methods for compliance are also cited.

NOTE 1—All test methods for a particular requirement may not be cited due to specific or unique circumstances. For additional guidance on applicable methods, refer to Guide F2097.

5.4 The specification and its requirements should be mutually agreed to by the supplier and purchaser of pouches. This helps ensure that pouches will comply to specified requirements.

6. Specification

6.1 *Classification:*

6.1.1 *Style:*

6.1.1.1 Chevron pouch (see Fig. 1),

6.1.1.2 Corner peel pouch (see Fig. 2), and

6.1.1.3 Header bag (see Fig. 3).

6.2 *Materials and Manufacture:*

6.2.1 Materials used in the construction of medical device peel pouches should be specified as non-toxic, providing a microbial barrier and any other appropriate physical barrier (oxygen, water vapor, light, and so forth), and being compatible with the intended sterilization process. These requirements should be evaluated during the initial package qualification and are not typically performed on a routine production basis.

NOTE 2—There are numerous test methods associated with determining physical and chemical properties of flexible materials used in the fabrication of pouches. Care should be taken in selecting the most appropriate test for the user's particular application and use. For guidance in determining which methods to use, refer to Guide F2097.

6.2.2 The ability of the materials to demonstrate compliance with predetermined requirements may be addressed by either the certification from raw or component materials supplier or by actual testing performed by the pouch manufacturer in compliance with quality systems. These requirements are often evaluated during the initial package qualification and not typically performed on a routine production basis.

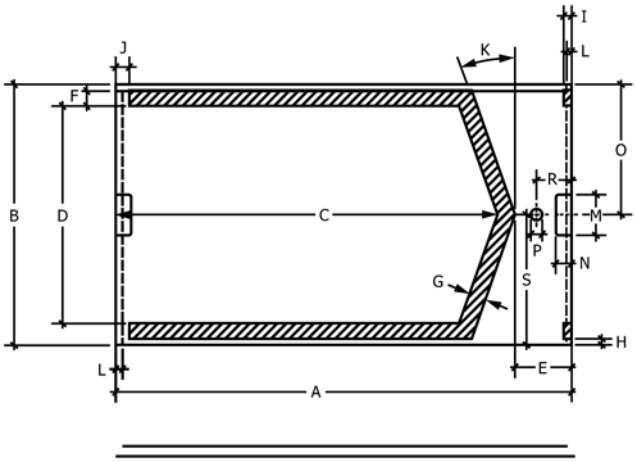
6.2.3 Pouches should be manufactured within a formal quality system.

6.2.4 The process of converting materials into pouches should be validated to demonstrate it is capable of consistently producing a product that complies with predetermined requirements such as dimensions, quality attributes, seal strength and seal integrity.

6.3 *Physical Properties:*

6.3.1 The critical physical property for a peel pouch is how well the seal is fabricated and how well it will stand up to the stresses of sterilization, distribution, storage, and handling environments.

6.3.2 A seal strength should be specified. This requirement may be a minimum or maximum value, or both, the user has qualified, or it may be an average or range value based on the sealing process capability.



NOTE 1—Dimension "I" or "J" but not both.

FIG. 1 Chevron Pouch

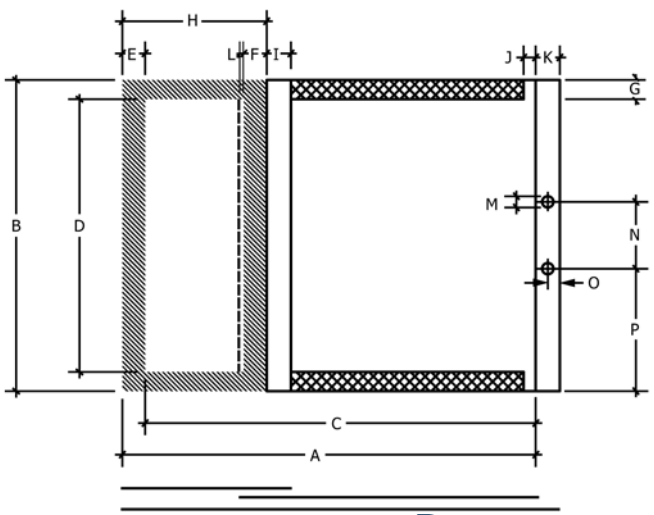


FIG. 2 Header Bag

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