Designation: F 1327 – 05

Standard Terminology Relating to Barrier Materials for Medical Packaging[1]

This standard is issued under the fixed designation F 1327; 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 terminology contains related definitions and descriptions of terms used or likely to be used in medical packaging standards that involve barrier materials. The purpose of terminology is to promote clear understanding and interpretation of the standards in which they are used.

2. Referenced Document

2.1 *ASTM Standards:* [2]

F 17 Terminology Relating to Flexible Barrier Materials

F 1980 Guide for Accelerated Aging of Sterile Medical Device Packages

3. Terminology Definitions

accelerated aging—a technique to simulate the effects of time on a package by subjecting the product/package system to elevated temperatures in a controlled environment representative of controlled environment storage conditions. The equivalent time is generally estimated by assuming the degradation of packaging materials follows the kinetics described by the Arrhenius reaction rate function, more discussion of which is available in Guide F 1980.

adhesive transfer—a condition occurring when an adhesive-coated material is peeled away from an opposing material to which it has been sealed and shows visible evidence of the adhesive being left on the opposing material. This evidence is in the form of an adhesive layer that remains with the opposing material, the adhesive having separated either adhesively from the coated web or cohesively within the adhesive itself.

aseptic packaging— See Terminology F 17.

barrier—See Terminology F 17.

barrier materials—specialized porous or nonporous packaging materials that provide environmental protection to the package contents as well as protection to the environment from the package contents: (*1*) gas, vapor, humidity, liquid, microbial, or light resistant materials that control or eliminate the amount of those environmental constituents that pass into or out of a package; (*2*) a porous material preventing the passage of microorganisms that might contaminate the contents of the package.

biological evaluation test (biotest)—See Terminology F 17.

burst strength—a measure of the internal pressure necessary to rupture a package or seal.

channel—any unimpaired pathway across the entire width of the intended seal.

coextrusion—See Terminology F 17.

delamination—See Terminology F 17.

dispersion coating— See Terminology F 17.

environmental challenging—the process of subjecting a package to extremes of temperature, or humidity, or both, with the goal of determining sensitivities of the package to environmental stresses. In contrast to accelerated aging, environmental challenging often includes conditions, or transitions, or both, of temperature and humidity that equal or exceed those that can be encountered in a package life cycle.

extrusion coating— See Terminology F 17.

flexible—See Terminology F 17.

fusion seal—See Terminology F 17.

heat seal—the result of bonding surfaces by controlled application of heat, pressure, and dwell time.

hermetically sealed aseptic container—See Terminology F 17.

laminate—See Terminology F 17.

lamination—See Terminology F 17.

leak—any opening in a flexible package that is contrary to intention and either lets contents escape or permits substances to enter.

major package defect— See Terminology F 17.

microbial contamination— See Terminology F 17.

minor package defect— See Terminology F 17.

multilayered structure— See Terminology F 17.

package integrity—the physical capability of a given package to protect its contents with the desired level of protection

[1] This terminology is under the jurisdiction of ASTM Committee F02 on Flexible Barrier Materials and is the direct responsibility of Subcommittee F02.50 on Package Design and Devlopment.

Current edition approved April 1, 2005. Published April 2005. Originally approved in 1991. Last previous edition approved in 1998 as F 1327 – 98.

[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.