Designation: F 1929 – 98

Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration[1]

This standard is issued under the fixed designation F 1929; 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 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. After contact with the dye penetrant for a specified time, the package is visually inspected for dye penetration.

1.2 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 fro use with this test method.

1.3 This test method requires that the dye penetrant have good contrast to the opaque packaging material.

1.4 The values stated in SI units are to be regarded as the standard. The values given in parentheses are for information only.

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

2. Referenced Documents

2.1 *ASTM Standards:*

E 165 Practice for Liquid Penetrant Examination[2]

2.2 *ANSI Standards:*

Z1.4 Sampling Procedures and Tables for Inspection by Attributes[3]

3. Terminology

3.1 *wicking*—The migration of a liquid into the body of a fibrous material. This is distinct from a leak as defined in Terminology F 1327.

3.2 *dye penetrant*—An aqueous solution of a dye and a surfactant designed to penetrate and indicate a defect location in the time prior to the onset of wicking which could mask its presence.

3.3 *channel*—A small continuous open passage across the width of a package seal through which microorganisms could pass. It is the objective of this test method to visually observe the presence of these defects by the leakage of dye through them.

4. Significance and Use

4.1 Harmful biological or particulate contaminants may enter the device through leaks. These leaks are frequently found at seals between package components of the same or dissimilar materials. Leaks may also result from a pinhole in the packaging material.

4.2 This dye penetrant procedure is applicable only to individual leaks in a package seal. The presence of a number of small leaks, as found in porous packaging material, which could be detected by other techniques, will not be indicated.

4.3 There is no general agreement concerning the level of leakage that is likely to be deleterious to a particular package. However, since these tests are designed to detect leakage, components that exhibit any indication of leakage are normally rejected.

4.4 Since leaks may change in size with different ambient conditions, comparisons between test stations are not conclusive. Therefore this method is usually employed as a go, no-go test.

4.5 The dye solution will wick through any porous material over time, but usually not within the maximum time suggested. If wicking does occur, it may be verified by observing the porous side of the subject seal area. The dye will have discolored the surface of the material.

4.6 When puncturing the packaging to allow injection of the dye penetrant solution, care should be taken not to puncture other package surfaces. Puncturing of the package is facilitated

[1] This test method is under the jurisdiction of ASTM Committee F–2 on Flexible Barrier Materials and is the direct responsibility of Subcommittee F02.60 on Medical Packaging.

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

[3] Available from the American National Standards Institute, 11 West 42nd Street 13th Floor, New York, NY 10036.