Designation: F1929 – 23

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

This standard is issued under the fixed designation F1929; 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 procedures that will detect and locate a leak equal to or greater than a channel formed by a 50 µm (0.002 in.) wire in package edge seals formed between a transparent material 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 Three dye application methods are covered in this test method: injection, edge dip, and eyedropper.

1.3 These test methods are intended for use on packages with edge seals formed between a transparent material and a porous sheet material. The test methods are limited to porous materials which can retain the dye penetrant solution and prevent it from discoloring the seal area for a minimum of 5 seconds. Uncoated papers are especially susceptible to leakage and must be evaluated carefully for use with each test method.

1.4 These test methods require that the dye penetrant solution have good contrast to the opaque packaging material.

1.5 The values are stated in International System of Units (SI units) and English units. Either is to be regarded as 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, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

1.7 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

2. Referenced Documents

2.1 *ASTM Standards:*[2]

F17 Terminology Relating to Primary Barrier Packaging

2.2 *ANSI Standards:*[3]

Z1.4 Sampling Procedures and Tables for Inspection by Attributes

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 F17.

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*—refer to definition in F17.

4. Significance and Use

4.1 Harmful biological or particulate contaminants may enter the medical package 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 It is the objective of this test method to visually observe the presence of channel defects by the leakage of dye through them.

4.3 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.

4.4 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 leaks, components that exhibit any indication of leakage are normally rejected.

[1] This test method is under the jurisdiction of ASTM Committee F02 on Primary Barrier Packagingand is the direct responsibility of Subcommittee F02.40 on Package Integrity.

Current edition approved Nov. 15, 2023. Published December 2023. Originally approved in 1998. Last previous edition approved in 2015 as F1929 – 15. DOI: 10.1520/F1929-23.

[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 American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036.

4.5 These procedures are suitable to verify and locate leakage sites. They are not quantitative. No indication of leak size can be inferred from these tests. The methods are usually employed as a pass/fail test.

4.6 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. Refer to Appendix X1 for details on wicking and guidance on the observance of false positives.

5. Apparatus

5.1 Means of breaching one of the packaging materials such as a small knife. (Method A)

5.2 *Dye Dispenser,* such as an eyedropper or syringe for injection of the dye penetrant solution. (Method A)

5.3 *Dye Solution Container.* (Method B)

5.4 *Scissors* or other cutting instrument. (Method B)

5.5 *Eyedropper* or 1 Mil. Pipette. (Method C)

5.6 *Microscope* or optical loop with magnification of 5× to 20× (optional for all methods).

5.7 Aqueous dye penetrant solution consisting of a carrier, a surfactant, and an indicator dye. The surfactant should be nonionic. The chemical properties of the surfactant should be as follows: surface tension between 30 mN⁄m to 33 mN⁄m, hydrophilic⁄lipophilic balance (HLB) greater than 10, and critical micelle concentration (cmc) less than 2000 ppm. The formula of the solution by weight:

Wetting agent/surfactant:		0.5 %
Indicator dye:	Toluidine blue[A]	0.05 %
Carrier:	Water	99.45 %

[A] The chemical name for Toluidine blue is 3-Amino-7-(dimethylamino)-2-methylphenothiazin-5-ium chloride.

NOTE 1—The solution must remain homogeneous. If precipitate is noted, the solution must be replaced.

5.7.1 If other colored or fluorescent dyes are substituted for toluidine blue, their precision and bias must be experimentally determined.

5.7.2 Because of the viscosity of many surfactants, the preparation of the solution is most easily accomplished by first taring a container with about 10 % of the required amount of water on a scale. The appropriate amount of surfactant is added to the water by weight and the mixture gently stirred. Vigorous stirring or shaking is not recommended, as it may cause foaming that may be difficult to dissipate. Once the surfactant is dissolved, the remaining water can then be added, followed by the toluidine blue dye.

6. Safety Precautions

6.1 Injecting dye penetrant into a package with a hypodermic needle and syringe is a common method for performing this test. This practice can result in puncture of the skin with a contaminated needle and is therefore not recommended. Because of this hazard, it is recommended that the dye penetrant is dispensed using a flexible tube attached to a syringe through an opening formed with an appropriate cutting instrument.

7. Test Specimen

7.1 The test specimen shall consist of a complete packaged device, empty packages, or edge seal samples. Blemished, rejected or dummy products may be used if they will not affect test results and are recorded prior to the test.

8. Calibration and Standardization

8.1 Since these procedures are not quantitative, no calibration is required.

9. Sampling

9.1 The number of samples tested should be adequate to be predictive of performance. Caution should be taken when eliminating samples with defects as this can bias the results. See ANSI ASQC Z1.4.

10. Conditioning

10.1 Packaging must be free of condensation or any other source of liquid water. Water already in the seal defects may render them undetectable with a dye penetrant. If there is any indication that the package has been exposed to any liquid, it must be thoroughly dried at its typical storage temperature before testing.

10.2 If conditioning is required standard conditioning atmosphere of 23 ± 2°C or 73.4 ± 3.6°F and 50 ± 2 % relative humidity is recommended, for a minimum of 24 hr. prior to testing.

11. Procedure

11.1 *Method A (Injection Method):*

11.1.1 Inject sufficient dye penetrant into the package to cover the longest edge to a depth of approximately 5 mm or 0.25 in. (see 6.1 for safety precautions).

11.1.1.1 When puncturing the packaging to allow injection of the dye penetrant solution, care should be taken not to puncture through or damage other package surfaces. Puncturing of the package is facilitated if it is done adjacent to a dummy device inside the package. The device will provide a tenting effect that will separate the two sides of the package, reducing the chance of accidental puncture of both sides.

11.1.2 Visually examine the seal area through the transparent side of the package. Observe the package seal area for penetration of the dye solution across the seal width. Channels in the seal will be readily detected. Use 5 seconds per side max as a guide for a 4 sided package. Total time should be less than or equal to 20 seconds. With prolonged exposure wicking of dye through the porous packaging will color the entire seal making defect detection difficult. An optical device with 5× to 20× magnification may be used for detailed examination.

11.1.3 Rotate the package as necessary to expose each seal edge to the dye penetrant solution. Inject additional dye as needed to insure complete edge exposure.

11.2 *Method B (Edge Dip Method):*

11.2.1 Select a container whose length is long enough to accommodate the longest sealed edge of the package.