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An American National Standard

Standard Practice for Extraction of Medical Plastics[1]

This standard is issued under the fixed designation F 619; 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.

ε[1] NOTE—Keywords were added editorially in May 1998.

1. Scope

1.1 This practice covers methods for extraction of medical plastics in liquids that simulate body fluids in their action on the plastics. This practice identifies two methods of extraction: one used for obtaining" extract liquid" to be analyzed by chemical and physical tests; and the other obtaining "extract liquid" for use in determining the biological response of animals. Further testing of the "extract liquid" is specified in other ASTM standards. The plastic after extraction may also be examined.

1.2 This practice may be used for, but is not limited to the following areas: partial evaluation of raw materials, auditing materials within the manufacturing process, and testing final products. This practice may also be used as a referee method for the measurement of extractables in plastics used in medical devices.

1.3 The values stated in SI units are to be regarded as the standard.

1.4 *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:*

D 543 Test Method for Resistance of Plastics to Chemical Reagents[2]

D 570 Test Method for Water Absorption of Plastics[2]

D 618 Practice for Conditioning Plastics and Electrical Insulating Materials for Testing[2]

D 1193 Specification for Reagent Water[3]

D 1239 Test Method for Resistance of Plastic Films to Extraction by Chemicals[2]

D 1898 Practice for Sampling of Plastics[4]

E 171 Specification for Standard Atmospheres for Conditioning and Testing Materials[5]

3. Terminology Definitions

3.1 *extraction vehicle*—a liquid specified for use in testing the plastic. Specific extraction vehicles are to be designated by the ASTM standard that references this practice (see Section 7 for a list of standard extraction vehicles).

3.2 *extract liquid*— that liquid which is tested for biological and chemical/physical response; the end result of this practice.

3.3 *specimen portion*— the unit or units of plastic placed into the extraction vehicle.

3.4 *blank*—the extraction vehicle not containing the specimen under test which is used for comparison with the extract liquid.

4. Summary of Practice

4.1 Standard-size specimens of the plastic, which may closely simulate the intended device depending upon the use, are immersed in definite volumes of selected liquids (extraction vehicles) for the time and temperature specified.

4.2 A choice is made, based on the end use, of the extraction vehicles (see Section 7) and one of the combinations of time and temperature for the test (see Section 12).

4.3 The resultant test liquids (extract liquids) are kept in glass containers until used for testing. Test liquids for biological testing are kept in sterile glass containers. The test liquids for biological testing should be used within 24 h.

5. Significance and Use

5.1 These extraction procedures are the initial part of several test procedures used in the biocompatibility screening of plastics used in medical devices.

5.2 The limitations of the results obtained from this practice should be recognized. The choice of extraction vehicle, duration of immersion, and temperature of the test is necessarily arbitrary. The specification of these conditions provides a basis for standardization and serves as a guide to investigators wishing to compare the relative resistance of various plastics to extraction vehicles.

5.3 Correlation of test results with the actual performance or serviceability of plastics is necessarily dependent upon the

[1] This practice is under the jurisdiction of ASTM Committee F-4 on Medical and Surgical Materials and Devicesand is the direct responsibility of Subcommittee F04.16 on Biocompatibility.

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[2] *Annual Book of ASTM Standards,* Vol 08.01.

[3] *Annual Book of ASTM Standards,* Vol 11.01.

[4] *Annual Book of ASTM Standards,* Vol 08.02.

[5] *Annual Book of ASTM Standards,* Vol 15.09.

similarity between the testing and end-use conditions (see 12.1.2 and Note 7).

5.4 Caution should be exercised in the understanding and intent of this practice as follows:

5.4.1 No allowance or distinction is made for variables such as end-use application, for example, short-term versus long-term application or implantation.

5.4.2 No allowance is made to distinguish between a non-porous versus a porous plastic. Although no definitions are given in this practice for the following terms, such items as extraction vehicle surface tension at the specified extraction condition and plastic specimen physical structure should be taken into account.

5.5 Test Methods D 543, D 570, and D 1239 may be useful in providing supplemental information.

6. Apparatus

6.1 *Autoclave*, capable of maintaining a temperature of 121 ± 2.0°C (249.8 ± 3.8°F), and equipped with a thermometer, pressure gage, vent cock, and a rack to hold the extraction containers above the water level.

6.1.1 The autoclave preferably should have a water cooling system that will allow for the cooling of the extraction containers to about, but not less than, 22°C (71.6°F) immediately following the heating cycle.

6.1.2 Autoclaves not equipped with a water cooling system may be used. However, sealed, unvented, extraction vessels should not be removed from such an autoclave until internal temperature and pressure have reached ambient conditions. Such vessels, when hot, represent an extreme explosion hazard capable of causing serious injury or even death.

6.2 *Balance*, accurate to ±0.1 mg.

6.2.1 Caution should be exercised when performing weighings in glassware. Depending upon the required accuracy, the relative humidity should be the same for weighings at different times.

6.3 *Extraction Containers*—Suitable glass containers that protect the extract liquid from biological and chemical contamination or evaporation. One suggested container is the screw-cap culture test tube of borosilicate glass, unless a larger container is required for the size and shape for the material to be extracted. Screw caps, if used, shall have a rubber liner, whose exposed surface shall be completely covered with polytetrafluorethylene film 0.05 to 0.075 mm (0.002 to 0.003 in.) in thickness.

6.4 *Heating Equipment*:

6.4.1 *Oven*, forced air-circulation type that will maintain temperatures of 50 to 70 ± 2°C (122 to 158 ± 3.6°F).

6.4.2 *Water Bath*, capable of maintaining temperatures of 50 to 70 ± 2°C (122 to 158 ± 3.6°F).

6.5 *Micrometers*, capable of measuring dimensions of test specimens to 0.025 mm (0.001 in.).

6.6 *Room*, or enclosed space capable of being maintained at the Standard Laboratory Atmosphere, as prescribed in Practice D 618 (see 11.3).

7. Reagents and Materials

7.1 *Purity of Reagents*—Reagent grade chemicals shall be used in all tests. Unless otherwise indicated, it is intended that all reagents shall conform to the specifications of the Committee on Analytical Reagents of the American Chemical Society, where such specifications are available.[6] Other grades may be used, provided it is first ascertained that the reagent is of sufficiently high purity to permit its use without lessening the accuracy of the determination.

7.2 *Purity of Water*— Unless otherwise indicated, references to water shall be understood to mean reagent water conforming to Specification D 1193, Type II.

7.3 *Extraction Vehicles*—The following list of standard extraction vehicles is intended to simulate the main constituents of human body fluids. Aqueous solutions shall be made with distilled water. The extraction vehicles shall be:

7.3.1 *Sodium Chloride Injection*, USP, containing by weight not less than 0.85 % and not more than 0.95 % sodium chloride.

7.3.2 *Vegetable Oil*:

7.3.2.1 *Sesame Oil*, USP.

7.3.2.2 *Cottonseed Oil*, USP.

NOTE 1—To preclude the use of vegetable oil of poor or deteriorated quality, the following additional negative reactivity test, beyond the respective description in the USP, may be performed.

Select three healthy, thin-skinned albino rabbits, not previously used for any test, whose fur can be clipped closely and whose skin is free of mechanical irritation or trauma. On the day of the test, clip the fur from the dorsal surface. Divide the test area into a grid of suitably identified individual injection sites. Inject 0.2 ml intracutaneously at each of ten sites on each animal. In handling the animals, avoid touching the injection sites during observation periods. Examine the injected sites 24, 48, and 72 h after the injection. No site should show an edema or erythema over an area greater than 5 mm (0.197 in.) in diameter. Qualify a vegetable oil batch and store under adequate conditions until use. Ideal storage conditions may be under a nitrogen blanket in complete darkness. The primary objective is to prevent oxidative type reactions.

7.3.3 *Water for Injection*, USP.

7.3.4 Other extraction vehicles, as required.

NOTE 2—Depending upon the medical plastic under test and the user's needs, extraction vehicles other than those in 7.3 may be used. An example is pseudoextracellular fluid (PECF).[7]

8. Sampling

8.1 The application of this practice may be in various areas. Therefore, although some well-known quality sampling methods may be used, a statistician should be consulted to ensure a statistically valid sampling plan.

8.2 Practice D 1898 may also be consulted.

9. Test Specimen

9.1 This practice is designed primarily for application to plastics in the condition in which they are used. The plastic should be exposed to all conditions and substances as during a production run, such as washing, packaging, and sterilization.

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[6] "Reagent Chemicals, American Chemical Society Specifications," Am. Chemical Soc., Washington, D.C. For suggestions on the testing of reagents not listed by the American Chemical Society, see "Reagent Chemicals and Standards," by Joseph Rosin, D. Van Nostrand Co., Inc., New York, N. Y., and the "United States Pharmacopeia."

[7] Homsy, C. A., "Bio-Compatibility in Selection of Materials for Implantation," *Journal of Biomedical Materials Research*, Vol. 4, 1970, pp. 341–356.