Designation: ~~F619 – 03 (Reapproved 2008)~~ F619 – 14

Standard Practice for Extraction of Medical Plastics[1]

This standard is issued under the fixed designation F619; 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 practice covers methods of extraction of medical plastics and may be applicable to other materials. This practice identifies a method for obtaining "extract liquid" for use in determining the biological response in preclinical testing. Further testing of the "extract liquid" is specified in other ASTM standards. The extract may undergo chemical analysis as part of the preclinical evaluation of the biological response, and the material 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 This practice was initially developed for extraction of medical plastics not intended to undergo degradation or absorption during normal medical device usage. When applied to the extraction of absorbable materials, additional considerations may be necessary in the selection of extraction procedures and fluids.

1.4 The values stated in inch-pound units are to be regarded as standard. The values given in parentheses are mathematical conversions to SI units that are provided for information only and are not considered standard.

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:*[2]

D543 Practices for Evaluating the Resistance of Plastics to Chemical Reagents
D570 Test Method for Water Absorption of Plastics
D1193 Specification for Reagent Water
D1239 Test Method for Resistance of Plastic Films to Extraction by Chemicals
D1898 Practice for Sampling of Plastics (Withdrawn 1998)[3]
F748 Practice for Selecting Generic Biological Test Methods for Materials and Devices

2.2 *Other Documents:*

USP NF 24 or current edition[4]

3. 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, after extraction of the specimen, is used in tests.

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.

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[1] This practice is under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.16 on Biocompatibility Test Methods.

Current edition approved ~~Aug. 1, 2008~~March 1, 2014. Published ~~August 2008~~April 2014. Originally approved in 1979. Last previous edition approved in ~~2003~~2008 as ~~F619 – 03.~~F619 – 03 (2008). DOI: ~~10.1520/F0619-03R08.~~10.1520/F0619-14.

[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] The last approved version of this historical standard is referenced on www.astm.org.

[4] Available from U.S. Pharmacopeia (USP), 12601 Twinbrook Pkwy., Rockville, MD 20852-1790, http://www.usp.org.

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 defined 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~~ suitable containers as described in 6.3 until used for testing. The test liquids shall be stored tightly stoppered at normal room temperature. Test liquids for biological testing are kept in sterile ~~glass~~ containers. Consideration should be given as to whether the extraction should be done under aseptic conditions. 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 materials is necessarily dependent upon the similarity between the testing and end-use conditions (see 12.1.2 and Note 4).

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 and duration of use. Decisions on selection of tests to be done should be made based on Practice F748.

5.4.2 This practice was originally designed for use with nonporous, solid materials. Its application for other materials, such as those that are porous, or absorptive, or resorptive, should be considered with caution. Consideration should be given to altering the specified material to liquid ratio to allow additional liquid to fully hydrate the material and additional liquid or other methods to fully submerge the test article. Additional procedures that fully remove the extract liquid from the test article, such as pressure or physically squeezing the material, should also be considered as appropriate. 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 D543, D570, and D1239 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) for at least 1 h and equipped with a display of temperature and pressure. A slow exhaust cycle is necessary. A rack to hold the extraction containers above the water level is also necessary. Loss of fluid volume should be recorded.

6.1.1 Sealed, unvented extraction vessels should not be removed until internal temperature and pressure have reached ambient conditions and the door can be opened. It is recommended that the extraction vessels be left undisturbed until any risk of boil over has passed. When the extraction vessels are cool to the touch, the lids should be sealed.

6.2 *Heating Equipment:*

6.2.1 Ovens or incubators that will maintain temperatures of 37, 50, 70 ± 2°C (98, 122, 158 ± 3°F).

6.2.2 Water baths capable of maintaining temperatures described in 6.2.1. Those with the ability to agitate the extraction vessels are preferred.

6.3 *Extraction Containers*—Suitable containers that protect the extract liquid from the biological and chemical contamination. They should allow expansion of the liquid, but then be sealed to prevent 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 of the material to be extracted. Screw caps, if used, shall have polytetrafluoroethylene liners.

6.4 *Balance,* accurate to ±0.1 mg.

6.4.1 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.

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