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Standard Specification for Polyethylene Plastics for Medical Applications[1]

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1. Scope

1.1 This specification covers polyethylene plastics (as defined in Terminology D883) intended for use in medical device applications involving human tissue contact devices, short-term indwellings of 30 days or less, and fluid transfer devices. The biocompatibility of these materials as a class has not been established. Biocompatibility tests must be conducted on the final product.

1.2 This specification is not applicable to ultra-high molecular weight polyethylenes (UHMWPE) plastics, such as those used in joint implants, and so forth.

1.3 The values stated in SI units are to be regarded as standard. No other units of measurement are included in this 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:*[2]

D638 Test Method for Tensile Properties of Plastics

D671 Test Method for Flexural Fatigue of Plastics by Constant-Amplitude-of-Force (Withdrawn 2002)[3]

D695 Test Method for Compressive Properties of Rigid Plastics

D747 Test Method for Apparent Bending Modulus of Plastics by Means of a Cantilever Beam

D790 Test Methods for Flexural Properties of Unreinforced and Reinforced Plastics and Electrical Insulating Materials

D883 Terminology Relating to Plastics

D1238 Test Method for Melt Flow Rates of Thermoplastics by Extrusion Plastometer

D1505 Test Method for Density of Plastics by the Density-Gradient Technique

D1898 Practice for Sampling of Plastics (Withdrawn 1998)[3]

D4976 Specification for Polyethylene Plastics Molding and Extrusion Materials

E117 Method for Spectrographic Analysis of Pig Lead by the Point-to-Plane Technique (Withdrawn 1995)[3]

F748 Practice for Selecting Generic Biological Test Methods for Materials and Devices

2.2 *ISO Standard:*

ISO 10993 Biological Evaluation of Medical Devices[4]

3. Significance

3.1 This specification describes polyethylene plastics used in the manufacture of medical devices or components of medical devices. The properties listed should be considered in selecting material according to the specific end-use requirements.

4. Classification

4.1 Types of polyethylene plastics molding and extrusion material are described in Specification D4976.

5. General Requirements

5.1 Polyethylene plastics consist of basic polymers made with ethylene as essentially the sole monomer (as defined in Terminology D883).

5.2 Polyethylene for use in medical applications shall have a maximum extractable fraction, expressed as weight percent in polymer, in *n*-hexane of 5.5 % at 50°C.[5]

5.3 The formulated compound may contain optional adjuvant substances required in the production of the polymer or in the fabrication or intended use of the end product. The biocompatibility of these adjuvant substances shall be established on the finished compound (see Section 9).

[1] This specification is under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.11 on Polymeric Materials.

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[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 American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, http://www.ansi.org.

[5] *Federal Register*, Vol 21, Part 177.1520.

5.4 The formulated compound shall yield a consistent infrared absorption spectrum characteristic of the established formulation.

5.5 Maximum levels and type of extractable metals shall be established in accordance with the intended use of the formulated resin[6] (see Appendix X1).

NOTE 1—Appendix X1 is a suggested method for determining extractable metals utilizing the current state-of-the-art methodology. Alternative methods with equal reliability may be used.

5.6 The physical properties of polyethylene plastics may be determined by the methods given in Section 7.

6. Sampling

6.1 The material should be sampled in accordance with standard sampling procedures such as those described in Practice D1898.

7. Physical Methods

7.1 The following physical test procedures are suggested where applicable to the intended application:

7.1.1 *Density*—Test Method D1505.
7.1.2 *Melt Flow*—Test Method D1238.
7.1.3 *Tensile Properties*—Test Method D638.
7.1.4 *Compressive Properties*—Test Method D695.
7.1.5 *Stiffness*—Test Method D747.
7.1.6 *Flexural Fatigue*—Test Method D671.
7.1.7 *Flexural Properties*—Test Method D790.

[6] *Accuracy in Trace Analysis*, NBS Special Publication No. 422, U.S. Government Printing Office, Washington, DC, Catalog No. C-13.10:422.

8. Packaging and Labeling

8.1 The product shall be packaged in a suitable container to prevent contamination of contents.

8.2 The material shall be identified, including lot or batch numbers and recommended method of storage.

9. Biocompatibility

9.1 The biological safety of each polyethylene plastic formulation shall be established. Specific biological tests shall be determined in accordance with the intended use. Formulated compounds used in these tests should include all colorants and other additives present in the final product.

9.2 Biological tests are appropriate to determine biological safety and tissue reaction, depending on the end use application. These tests should be conducted when indicated for specific applications. Additional tests may be necessary for certain cases; Practice F748 and ISO 10993 may be used as guidelines.

9.2.1 Biocompatibility testing should be performed on specimens that have been processed and sterilized using the methods intended for the final device. It should be noted that radiation sterilization of the polyethylene has been shown to cause adverse effects on the properties of the material, such as chain scission and the creation of free radicals that lead to oxidation and subsequent deterioration of mechanical properties.

10. Keywords

10.1 plastic surgical devices/applications; polyethylene (PE) plastics—surgical implant applications; polymers—surgical applications

APPENDIXES

(Nonmandatory Information)

X1. SUGGESTED PRACTICE FOR EXTRACTABLE METALS ANALYSIS OF PLASTIC BY ATOMIC ABSORPTION SPECTROSCOPY

X1.1. Scope

X1.1.1 This practice covers the analysis of extractable metals from plastics intended for use in medical device application.

X1.1.2 Formulated raw materials or finished products may be used.

X1.2. Significance

X1.2.1 Concentrations of trace metals are measured as extracts in simulated body fluids. The metal's concentration in extracts is based on the surface area of the plastic extracted from which the total amount of metal deliverable to the patient may be estimated.

X1.3 Preparation of Specimens

X1.3.1 Use suitable molded test strips of the formulated compound. The total surface area of the specimen to be exposed should be equivalent to 120 cm^2 when the specimen thickness is 0.5 mm or less or 60 cm^2 when the thickness is greater than 0.5 mm. Specimens may be separated from each other by suitable inert spacers to ensure contact with the extraction solvent.

X1.3.2 After the plastic sample has been prepared, extract the specimens using 20 ml of the desired solvent for 72 h at 50°C or 24 h at 70°C, as appropriate for the particular plastic. Then remove the plastic strips and analyze the extract for metals as described in Section X1.4.

X1.4 Preparation of Extract Solution

X1.4.1 Pipet 5.0 ml of the cottonseed oil (CSO) extract into a 10-ml volumetric flask and dilute to volume with hexane. Dilute the CSO atomic absorption standards and controls in the same manner.

X1.4.2 Run the saline eluate directly without dilution.

X1.5 Preparation of Atomic Absorption Standards

X1.5.1 Prepare certified aqueous standard solutions by diluting 1000 ppm of aqueous stock solutions with the 0.9 % saline solution used for extractions. Use the saline solution alone as the blank.

X1.5.2 Prepare the CSO standards by dissolving the appropriate organometallic compound in CSO to give intermediate solutions which are then diluted by volume 1 + 1 with hexane, giving final standard solutions of metal in the same matrix as the samples. Use a 1 + 1 dilution of CSO with hexane as the blank. Obtain the concentration analysis on organometallic standards from the manufacturer.

X1.6. Procedure

X1.6.1 Place the hollow cathode lamp for the element being tested in the instrument and set the instrument conditions for that element in accordance with the manufacturer's recommended procedure.

X1.6.2 When the lamp has warmed up, light the flame, adjust to the proper mixture, and allow to burn for 1 min to equilibrate the instrument. For the CSO-hexane mixtures, adjust the flame while aspirating the blank solution.

X1.6.3 Zero the instrument while aspirating the blank solution corresponding to the matrix to be analyzed.

X1.6.4 Aspirate a high standard and adjust the burner position and flame for the optimum signal and optimum signal-to-noise ratio.

X1.6.5 Rezero the instrument while aspirating blank solutions.

X1.6.6 Starting with the lowest, aspirate the standard solutions and record the absorbance corresponding to each. Between standards, aspirate the blank solution and check the zero.

X1.6.7 Aspirate the sample solutions and record the corresponding absorbance readings. Aspirate the blank solution and check the zero between samples.

X1.6.8 If there are many samples to be run, recheck the standards periodically during the analysis. In any case, reanalyze the standards after all the samples have been run.

X1.7. Calculation

X1.7.1 Prepare a calibration chart by plotting absorbance versus concentration.

X1.7.2 Calculate the concentrations of metal in the sample extracts by reference to the standard curve.

X1.7.3 Calculate the total amount of metal extracted as follows:

$$\frac{\mu g \text{ metal}}{\text{ml extract}} \times \text{ml of extracts} = \text{total metal extracted, } \mu g \quad (X1.1)$$

X1.7.4 Calculate the amount of metal extracted per square centimetre of sample, $\mu g/cm^2$:

$$\frac{\text{total metal extracted, } \mu g}{\text{surface area of film, } cm^2} \quad (X1.2)$$

X1.8. Precision and Accuracy

X1.8.1 The precision and accuracy of this practice has not yet been determined. It is dependent upon several factors, including sample matrix, ionization interferences, sophistication of instrumentation, and so forth.

X1.8.2 Determine the precision for each test system in accordance with Method E117.

NOTE X1.1—Pertinent data and other information regarding this specification may be reported to Committee F04 Staff Manager, ASTM International Headquarters, 100 Barr Harbor Drive, W. Conshohocken, PA 19428. Comments and suggestions will be considered in future standards development activities.

X2. BIOCOMPATIBILITY

X2.1 The suitability of these materials from a human implant perspective is dependent on the specific application. The biological tests appropriate for the specific site, such as recommended in Practice F748 or ISO 10993, should be used as a guideline.

X2.2 No known implant material has ever been shown to be completely free of adverse reactions in the human body. However, long-term clinical experience of use of specific formulations of this material class referred to in this standard has shown that an acceptable level of biological response can be expected, if the material is used in appropriate applications.