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Standard Specification for Ultra-High Molecular Weight Polyethylene Powder Blended With Alpha-Tocopherol (Vitamin E) and Fabricated Forms for Surgical Implant Applications[1]

This standard is issued under the fixed designation F2695; 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 specification covers ultra-high molecular weight polyethylene (UHMWPE) powder blended with alpha-tocopherol (vitamin E) intended for use in surgical implants.

1.2 The requirements of this specification apply to alpha-tocopherol-containing UHMWPE in two forms. One is virgin polymer powder blended with alpha-tocopherol prior to consolidation (Section 4). The second is any form fabricated from this blended, alpha-tocopherol-containing powder from which a finished product is subsequently produced (Section 5). This specification does not apply to finished or semi-finished products that are doped with vitamin E after consolidation.

1.3 Aside from blending with alpha-tocopherol, the provisions of Specifications F648 and D4020 apply. Special requirements detailed in this specification are added to describe powders containing alpha-tocopherol that will be used in surgical implants. This specification addresses material characteristics and does not apply to the packaged and sterilized finished implant. This specification also does not apply to UHMWPE materials extensively crosslinked by gamma and electron beam sources of ionizing radiation.

1.4 The following precautionary caveat pertains only to the fabricated forms portion, Section 5, of this specification. *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]

D648 Test Method for Deflection Temperature of Plastics Under Flexural Load in the Edgewise Position

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

D1898 Practice for Sampling of Plastics[3]

D4020 Specification for Ultra-High-Molecular-Weight Polyethylene Molding and Extrusion Materials

F619 Practice for Extraction of Medical Plastics

F648 Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants

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

F749 Practice for Evaluating Material Extracts by Intracutaneous Injection in the Rabbit

F756 Practice for Assessment of Hemolytic Properties of Materials

F763 Practice for Short-Term Screening of Implant Materials

F813 Practice for Direct Contact Cell Culture Evaluation of Materials for Medical Devices

F895 Test Method for Agar Diffusion Cell Culture Screening for Cytotoxicity

F981 Practice for Assessment of Compatibility of Biomaterials for Surgical Implants with Respect to Effect of Materials on Muscle and Bone

2.2 *ISO Standards:*

ISO 3451-1 Plastics—Determination of Ash, Part 1: General Methods[4]

ISO 10993 Biological Evaluation of Medical Devices, Parts 1–12[4]

3. Terminology

3.1 *Definitions of Terms Specific to This Standard:*

3.1.1 *crosslinking*—the process by which ionizing irradiation produces chemical bonds between two UHMWPE molecules.

3.1.2 *extensively crosslinked UHMWPE*—UHMWPE material that has been subjected to total doses of gamma and/or electron beam ionizing irradiation greater than 40 kGy.

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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] Withdrawn.

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

3.1.3 *fabricated form*—any bulk shape of UHMWPE, fabricated from the virgin polymer powder, used during the process of fabricating surgical implants prior to crosslinking, packaging, and sterilization. A fabricated form includes a semi-finished rod or sheet as well as a direct compression molded component.

3.1.4 *generic property*—that property which is determined solely by the chemical composition and structure of the virgin polymer.

3.1.5 *ionizing irradiation*—gamma ray or high energy electron irradiation sources.

3.1.6 *virgin polymer powder*—the form of UHMWPE as obtained from the powder manufacturer and prior to fabrication into a bulk shape.

4. Alpha-Tocopherol-Blended UHMWPE Powder Requirements

4.1 *Generic Properties*:

4.1.1 The virgin polymer shall be a homopolymer of ethylene in accordance with Specification D4020.

4.1.2 The resin type and solution viscosity number requirements are listed in Table 1 of Specification F648.

4.2 *Nongeneric Properties*:

4.2.1 When a 300 g sample is prepared and viewed in accordance with section 7.1.2 of Specification F648, there shall be no more particles of extraneous matter than that specified in Table 1 of Specification F648.

4.2.2 To promote uniformity between different lots of polymer powder, concentration limits for trace elements have been established and are listed in Table 1 of Specification F648.

4.2.3 When determined as described in ISO 3451-1, the mean ash of duplicate samples shall not exceed the limits established in Table 1 of Specification F648.

4.3 *Compositional Requirements*:

4.3.1 Only alpha-tocopherol (certified pharmaceutical grade) is to be blended with the virgin polymer powder.

4.3.1.1 The alpha-tocopherol content in the blended powder may be based on agreement between the vendor and purchaser.

4.3.1.2 When measured based on agreement between the vendor and purchaser, the alpha-tocopherol content added to the powder shall be reported in units of ppm and percent mass.

4.3.1.3 Uniformity of the alpha-tocopherol in the blended powder will be measured based on agreement between the vendor and the purchaser.

4.3.1.4 No other stabilizers or processing aids are to be added to the virgin polymer powder.

5. Alpha-Tocopherol-Blended UHMWPE Fabricated Form Requirements

5.1 *Compositional Requirements*:

5.1.1 Only alpha-tocopherol-blended powder, specified in Section 4, is to be used to produce the fabricated form.

5.1.1.1 The alpha-tocopherol content in the fabricated form may be based on agreement between the vendor and purchaser.

5.1.1.2 When measured based on agreement between the vendor and purchaser, the alpha-tocopherol content used to produce the fabricated form shall be reported in units of ppm and percent mass.

5.1.2 Uniformity of the alpha-tocopherol in the fabricated form shall be measured based on agreement between the vendor and the purchaser.

5.1.3 No other stabilizers or processing aids are to be added to the alpha-tocopherol-blended polymer powder during manufacture of the fabricated form.

5.2 *Physical Requirements*:

5.2.1 *Foreign Matter Requirements*:

5.2.1.1 When 3200 cm^2 is evaluated according to section 7.2.2 of Specification F648, there shall be no more than 10 particles of extraneous matter visible on the surface when visually inspected by normal or corrected vision.

5.2.2 *Morphology Requirements*:

5.2.2.1 When evaluated according to Annex 2 of Specification F648, the calculated Morphology Index (MI) shall be reported.

5.3 *Mechanical Requirements*:

5.3.1 UHMWPE in fabricated form from which implants shall be made shall meet the requirements listed in Table 2 of Specification F648.

5.3.2 The following mechanical tests may be conducted based on agreement between the vendor and purchaser: *(1)* Deflection temperature; Test Method D648 (1.8 MPa); *(2)* Flexural modulus; Test Methods D790 (secant, 2 % offset).

6. Sampling

6.1 Where applicable, the requirements of this specification shall be determined for each lot of powder and fabricated form by sampling sizes and procedures according to Practice D1898, or as agreed upon between the purchaser and seller.

7. Biocompatibility

7.1 No known surgical implant material has ever been shown to be completely free of adverse reactions in the human body. However, published studies **(1-5)**[5] of specific formulations of alpha-tocopherol doped UHMWPE have shown that an acceptable level of biological response can be expected. Virgin (undoped) UHMWPE has been shown to produce a well-characterized level of biological response following long term clinical use. The clinical history for virgin UHMWPE indicates an acceptable level of biological response in the applications in which the undoped material has been utilized. When new applications of the material, or modification to the material or physical forms of the materials are being contemplated (such as, blending with alpha-tocopherol), the recommendations of ISO 10993, Parts 1–12 and Practice F748 should be considered and testing considered as described in Practices F619, F749, F756, F763, F813, and F981 as well as Test Method F895.

8. Keywords

8.1 alpha-tocopherol; fabricated forms; powdered form; ultra-high molecular weight polyethylene; vitamin E

[5] The boldface numbers in parentheses refer to the list of references at the end of this standard.