Designation: F1925 – 22

Standard Specification for Semi-Crystalline Poly(lactide) Polymer and Copolymer Resins for Surgical Implants[1]

This standard is issued under the fixed designation F1925; 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 virgin semi-crystalline poly(L-lactide) or poly(D-lactide) homopolymer resins intended for use in surgical implants. This specification also covers semi-crystalline resins of L-lactide copolymerized with other bioabsorbable monomers including, but not limited to, glycolide, D-lactide, and DL-lactide. The poly(L-lactide) or poly(D-lactide) based homopolymers and copolymers covered by this specification possess lactide segments of sufficient length to allow potential for their crystallization upon annealing.

1.2 Since poly(glycolide) is commonly abbreviated as PGA for poly(glycolic acid) and poly(lactide) is commonly abbreviated as PLA for poly(lactic acid), these polymers are commonly referred to as PGA, PLA, and PLA:PGA resins for the hydrolytic byproducts to which they respectively degrade. PLA is a term that carries no stereoisomeric specificity and therefore encompasses both the amorphous atactic/syndiotactic DL-lactide based polymers and copolymers as well as the isotactic D-PLA and L-PLA moieties, each of which carries potential for crystallization. Inclusion of stereoisomeric specificity within the lactic acid based acronyms results in the following: poly(L-lactide) as PLLA for poly(L-lactic acid), poly(D-lactide) as PDLA for poly(D-lactic acid), and poly(DL-lactide) as PDLLA for poly(DL-lactic acid).

1.3 This specification is applicable to lactide-based polymers or copolymers that possess isotactic polymeric segments sufficient in size to carry potential for lactide-based crystallization. Such polymers typically possess nominal mole fractions that equal or exceed 50 % L-lactide. This specification is particularly applicable to isotactic-lactide based block copolymers or to polymers or copolymers synthesized from combinations of D-lactide and L-lactide that differ by more than 1.5 total mole percent (1.5 % of total moles). This specification is not applicable to lactide-co-glycolide copolymers with glycolide mole fractions greater than or equal to 70 % (65.3 % in mass fraction), which are covered by Specification F2313. This specification is not applicable to amorphous polymers or copolymers synthesized from combinations of D-lactide and L-lactide that differ by less than 1.5 total mole percent (1.5 % of total moles) as covered by Specification F2579.

1.4 This specification covers virgin semi-crystalline poly(lactide)-based resins able to be fully solvated at 30 °C by either methylene chloride (dichloromethane) or chloroform (trichloromethane). This specification is not applicable to lactide:glycolide copolymers that possess glycolide segments sufficient in size to deliver potential for glycolide-based crystallization, thereby requiring fluorinated solvents for complete dissolution under room temperature conditions (see Specification F2313).

1.5 Within this specification, semi-crystallinity within the resin is defined by the presence of a DSC (differential scanning calorimetry) crystalline endotherm after annealing above the glass transition temperature. While other copolymeric segments may also crystallize upon annealing (for example, glycolide), specific characterization of crystalline structures other than those formed by lactide are outside the scope of this specification.

1.6 This specification addresses material characteristics of the virgin semi-crystalline poly(lactide)-based resins intended for use in surgical implants and does not apply to packaged and sterilized finished implants fabricated from these materials.

1.7 As with any material, some characteristics may be altered by processing techniques (such as molding, extrusion, machining, assembly, sterilization, and so forth) required for the production of a specific part or device. Therefore, properties of fabricated forms of this resin should be evaluated independently using appropriate test methods to ensure safety and efficacy.

1.8 Biocompatibility testing is not a requirement since this specification is not intended to cover fabricated devices.

1.9 The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.

1.10 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the*

[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.

Current edition approved Feb. 1, 2022. Published February 2022. Originally approved in 1998. Last previous edition approved in 2017 as F1925 – 17. DOI: 10.1520/F1925-22.

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.

1.11 *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]

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

D2857 Practice for Dilute Solution Viscosity of Polymers

D3417 Test Method for Enthalpies of Fusion and Crystallization of Polymers by Differential Scanning Calorimetry (DSC) (Withdrawn 2004)[3]

D3418 Test Method for Transition Temperatures and Enthalpies of Fusion and Crystallization of Polymers by Differential Scanning Calorimetry

D4603 Test Method for Determining Inherent Viscosity of Poly(Ethylene Terephthalate) (PET) by Glass Capillary Viscometer

D5296 Test Method for Molecular Weight Averages and Molecular Weight Distribution of Polystyrene by High Performance Size-Exclusion Chromatography

E473 Terminology Relating to Thermal Analysis and Rheology

E793 Test Method for Enthalpies of Fusion and Crystallization by Differential Scanning Calorimetry

E794 Test Method for Melting And Crystallization Temperatures By Thermal Analysis

E967 Test Method for Temperature Calibration of Differential Scanning Calorimeters and Differential Thermal Analyzers

E968 Practice for Heat Flow Calibration of Differential Scanning Calorimeters

E1142 Terminology Relating to Thermophysical Properties

E1252 Practice for General Techniques for Obtaining Infrared Spectra for Qualitative Analysis

E1356 Test Method for Assignment of the Glass Transition Temperatures by Differential Scanning Calorimetry

E1994 Practice for Use of Process Oriented AOQL and LTPD Sampling Plans

E2977 Practice for Measuring and Reporting Performance of Fourier-Transform Nuclear Magnetic Resonance (FT-NMR) Spectrometers for Liquid Samples

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

F2313 Specification for Poly(glycolide) and Poly(glycolide-co-lactide) Resins for Surgical Implants with Mole Fractions Greater Than or Equal to 70 % Glycolide

F2579 Specification for Amorphous Poly(lactide) and Poly(lactide-co-glycolide) Resins for Surgical Implants

F2902 Guide for Assessment of Absorbable Polymeric Implants

2.2 *ANSI Standards:*[4]

ANSI/ISO/ASQ Q9000-2000 Quality Management Systems—Fundamentals and Vocabulary

ANSI/ISO/ASQ Q9001-2000 Quality Management Systems—Requirements

ANSI/ISO/ASQ 13485 Medical Devices—Quality Management Systems—Requirements for Regulatory Purposes

2.3 *ISO Standards:*[5]

ISO 80000-9 Quantities and Units—Part 9: Physical chemistry and molecular physics

ISO 10993 Biological Evaluation of Medical Devices[4]

ISO 11357 Plastics—Differential Scanning Calorimetry (DSC)[4]

2.4 *Code of Federal Regulations:*[6]

21 CFR 820 United States Code of Federal Regulations, Title 21—Food and Drugs Services, Part 820—Quality System Regulation

2.5 *United States Pharmacopeia:*[7]

USP, 26th Edition United States Pharmacopeia

USP <232> Elemental Impurities—Limits

USP <233> Elemental Impurities—Procedure

USP <781> Physical Tests—Optical Rotation

USP <788> Particulate Matter in Injections

2.6 *NIST Publication:*[8]

NIST Special Publication SP811 Guide for the Use of the International System of Units (SI)

2.7 *Other Documents:*[9]

ICH Q3C(R5) International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, Quality Guideline: Impurities: Residual Solvents

ICH Q3D(R4) International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use: Guideline for Elemental Impurities

3. Terminology

3.1 *Definitions:*

[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] Available from International Organization for Standardization (ISO), ISO Central Secretariat, BIBC II, Chemin de Blandonnet 8, CP 401, 1214 Vernier, Geneva, Switzerland, http://www.iso.org.

[6] Available from U.S. Government Printing Office Superintendent of Documents, 732 N. Capitol St., NW, Mail Stop: SDE, Washington, DC 20401, http://www.access.gpo.gov.

[7] Available from U.S. Pharmacopeia, 12601 Twinbrook Pkwy., Rockville, MD 20852 or through http://www.usp.org/products/USPNF/. The standards will be listed by appropriate USP citation number. Succeeding USP editions alternately may be referenced.

[8] Available from National Institute of Standards and Technology (NIST), 100 Bureau Dr., Stop 1070, Gaithersburg, MD 20899-1070, at http://physics.nist.gov/cuu/Units/bibliography.html.

[9] Available from ICH Secretariat, c/o IFPMA, 30 rue de St-Jean, P.O. Box 758, 1211 Geneva 13, Switzerland. Available online at http://www.ich.org/LOB/media/MEDIA423.pdf.