



Standard Specification for Virgin Poly(glycolide) and Poly(glycolide-co-lactide) Resins for Surgical Implants with Mole Fractions Greater Than or Equal to 70 % Glycolide¹

This standard is issued under the fixed designation F 2313; 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 both virgin poly(glycolide) resin and poly(glycolide-co-lactide) resin with mole fractions greater than or equal to 70 % glycolide. This specification is not applicable to glycolide:lactide copolymers with mole fractions exceeding 30 % lactide.

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 and PGA:PLA resins for the hydrolytic byproducts to which they respectively degrade.

1.3 This specification addresses material characteristics of both virgin poly(glycolide) and poly(≥ 70 % glycolide-co-lactide) resins intended for use in surgical implants and does not apply to packaged and sterilized finished implants fabricated from this material.

1.4 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.

1.5 *This standard may suggest use of hazardous materials, operations, and equipment. This standard does not purport to address safety concerns associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and to determine the applicability of regulatory limitations prior to use.*

2. Referenced Documents

2.1 ASTM Standards:²

D 1505 Test Method for Density of Plastics by the Density-Gradient Technique

¹ This specification is under the jurisdiction of ASTM Committee F04 on Medical 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.

D 1898 Practice for Sampling of Plastics

D 2857 Practice for Dilute Solution Viscosity of Polymers

D 3536 Test Method for Molecular Weight Averages and Molecular Weight Distribution by Liquid Exclusion Chromatography (Gel Permeation Chromatography—GPC)³

D 3593 Test Method for Molecular Weight Averages and Molecular Weight Distribution of Certain Polymers by Liquid Size-Exclusion Chromatography (Gel Permeation Chromatography—GPC) Using Universal Calibration³

D 4603 Test Method for Determining Inherent Viscosity of Poly(Ethylene Terephthalate) (PET) by Glass Capillary Viscometer

E 386 Practice for Data Presentation Relating to High-Resolution Nuclear Magnetic Resonance (NMR) Spectroscopy

E 1252 Practice for General Techniques for Obtaining Infrared Spectra for Qualitative Analysis

F 748 Practice for Selecting Generic Biological Test Methods for Materials and Devices

2.2 Other Standards:

United States Pharmacopeia (USP) Edition 26⁴

ISO 10993-9 Biological Evaluation of Medical Devices, Part 9: Framework for Identification and Quantification of Potential Degradation Products, Annex A⁵

21 CFR 820, United States Code of Federal Regulations, Title 21—Food and Drugs Services, Part 820—Quality System Regulation⁶

ANSI/ISO/ASQ Q9000-2000, Quality Management Systems; Fundamentals and Vocabulary⁵

ANSI/ISO/ASQ Q9001-2000, Quality Management Systems; Requirements⁵

3. Terminology

3.1 Definitions:

³ Withdrawn.

⁴ Available from U.S. Pharmacopeia (USP), 12601 Twinbrook Pkwy., Rockville, MD 20852.

⁵ Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036.

⁶ Available from U.S. Government Printing Office Superintendent of Documents, 732 N. Capitol St., NW, Mail Stop: SDE, Washington, DC 20401.