



Standard Test Method for Determining the Chemical Composition and Sequence in Alginate by Proton Nuclear Magnetic Resonance (¹H NMR) Spectroscopy¹

This standard is issued under the fixed designation F2259; 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.

ε¹ NOTE—Editorial changes were made to subsections 2.2 and 4.2 in November 2012.

1. Scope

1.1 This test method covers the determination of the composition and monomer sequence of alginate intended for use in biomedical and pharmaceutical applications as well as in Tissue Engineered Medical Products (TEMPs) by high-resolution proton NMR (¹H NMR). A guide for the characterization of alginate has been published as Guide F2064.

1.2 Alginate, a linear polymer composed of β-D-mannuronate (M) and its C-5 epimer α-L-guluronate (G) linked by β-(1→4) glycosidic bonds, is characterized by calculating parameters such as mannuronate/guluronate (M/G) ratio, guluronic acid content (G-content), and average length of blocks of consecutive G monomers (that is, N_{G>1}). Knowledge of these parameters is important for an understanding of the functionality of alginate in TEMP formulations and applications. This test method will assist end users in choosing the correct alginate for their particular application. Alginate may have utility as a scaffold or matrix material for TEMPs, in cell and tissue encapsulation applications, and in drug delivery formulations.

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

E386 Practice for Data Presentation Relating to High-Resolution Nuclear Magnetic Resonance (NMR) Spectroscopy

F2064 Guide for Characterization and Testing of Alginates as Starting Materials Intended for Use in Biomedical and Tissue Engineered Medical Product Applications

2.2 *United States Pharmacopeia Document*:

USP 35-NF30 <761> Nuclear Magnetic Resonance³

3. Terminology

3.1 *Definitions*:

3.1.1 *alginate, n*—polysaccharide obtained from some of the more common species of marine algae, consisting of an insoluble mix of calcium, magnesium, sodium, and potassium salts.

3.1.1.1 *Discussion*—Alginate exists in brown algae as its most abundant polysaccharide, mainly occurring in the cell walls and intercellular spaces of brown seaweed and kelp. Alginate's main function is to contribute to the strength and flexibility of the seaweed plant. Alginate is classified as a hydrocolloid. The most commonly used alginate is sodium alginate. Sodium alginate and, in particular, calcium cross-linked alginate gels are used in Tissue Engineered Medical Products (TEMps) as biomedical matrices, controlled drug delivery systems, and for immobilizing living cells.

3.1.2 *degradation, n*—change in the chemical structure, physical properties, or appearance of a material. Degradation

¹ This test method is under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.42 on Biomaterials and Biomolecules for TEMPs.

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