



Standard Test Method for Determining the Molar Mass of Sodium Alginate by Size Exclusion Chromatography with Multi-angle Light Scattering Detection (SEC-MALS)¹

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1. Scope

1.1 This test method covers the determination of the molar mass (typically expressed as grams/mole) of sodium alginate intended for use in biomedical and pharmaceutical applications as well as in tissue-engineered medical products (TEMPs) by size exclusion chromatography with multi-angle laser light scattering detection (SEC-MALS). A guide for the characterization of alginate has been published as Guide [F2064](#).

1.2 Alginate used in TEMPs should be well characterized, including the molar mass and polydispersity (molar mass distribution) in order to ensure uniformity and correct functionality in the final product. 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

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

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.

[F2315](#) Guide for Immobilization or Encapsulation of Living Cells or Tissue in Alginate Gels

2.2 *United States Pharmacopeia/National Formulary*:³
[<621> Chromatography](#)

2.3 *National Institute of Standards and Technology*:⁴
[NIST SP811 Special Publication: Guide for the Use of the International System of Units](#)

2.4 *ISO Standards*:⁵
[ISO 31-8 Quantities and units- Part 8: Physical chemistry and molecular physics](#)

3. Terminology

3.1 *Definitions*:

3.1.1 *alginate, n*—a polysaccharide substance extracted from brown algae, mainly occurring in the cell walls and intercellular spaces of brown seaweed and kelp. Its main function is to contribute to the strength and flexibility of the seaweed plant. Sodium alginate, and in particular calcium cross-linked alginate gels are used in tissue-engineered medical products (TEMPs) as biomedical scaffolds and matrices, for immobilizing living cells (see Guide [F2315](#)), and in drug delivery systems.

3.1.2 *molar mass average, n*—the given molar mass (M_w) of an alginate will always represent an average of all of the molecules in the population. The most common ways to express the molar mass are as the *number average* ($\bar{M}_n$) and the *mass average* ($\bar{M}_w$). The two averages are defined by the following equations:

$$\bar{M}_n = \frac{\sum_i N_i M_i}{\sum_i N_i} \quad \text{and} \quad \bar{M}_w = \frac{\sum_i w_i M_i}{\sum_i w_i} = \frac{\sum_i N_i M_i^2}{\sum_i N_i M_i} \quad (1)$$

³ Available from United States Pharmacopeia and National Formulary, U.S. Pharmaceutical Convention, Inc. (USPC), Rockville, MD.

⁴ Available from National Institute of Standards and Technology (NIST), 100 Bureau Dr., Stop 1070, Gaithersburg, MD 20899-1070, <http://physics.nist.gov/cuu/Units/bibliography.html>.

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>.