



Standard Guide for Immobilization or Encapsulation of Living Cells or Tissue in Alginate Gels¹

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INTRODUCTION

Encapsulation in insoluble alginate gel is recognized as a rapid, non-toxic, and versatile method for immobilization of macromolecules and cells. Microencapsulated cells or tissue as artificial organs are under study for treatment of a variety of diseases such as Parkinson's disease, chronic pain, liver failure, hypocalcemia, and, perhaps the most well-known example, immobilization of islets of Langerhans utilized as an artificial pancreas in the treatment of diabetes. Since alginates are a heterogeneous group of polymers with a wide range of functional properties, the success of an immobilization or encapsulation procedure will rely on an appropriate choice of materials and methodology. This must be based on knowledge of the chemical composition of alginate and the correlation between the structure, composition, and functional properties of the polymer, as well as differences in gelation technologies. It is also important to recognize the need for working with highly purified and well-characterized alginates in order to obtain gels with reproducible properties. The aim of this guide is to provide information relevant to the immobilization or encapsulation of living cells and tissue in alginate gels.

1. Scope

1.1 This guide discusses information relevant to the immobilization or encapsulation of living cells or tissue in alginate gels. Immobilized or encapsulated cells are suitable for use in biomedical and pharmaceutical applications, or both, including, but not limited to, Tissue Engineered Medical Products (TEMPs).

1.2 This guide addresses key parameters relevant for successful immobilization and encapsulation in alginate gels.

1.3 *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 requirements prior to use.*

2. Referenced Documents

2.1 ASTM Standards:

F 748 Practice for Selecting Generic Biological Test Methods for Materials and Devices²

F 1251 Terminology Relating to Polymeric Biomaterials in Medical and Surgical Devices²

F 1903 Practice for Testing for Biological Responses to Particles *In Vitro*²

F 1904 Practice for Testing the Biological Responses to Particles *In Vivo*²

F 1905 Practice for Selecting Tests for Determining the Propensity of Materials to Cause Immunotoxicity²

F 1906 Practice for Evaluation of Immune Responses in Biocompatibility Testing Using ELISA Tests, Lymphocyte Proliferation, and Cell Migration²

F 2064 Guide for Characterization and Testing of Alginates as Starting Materials Intended for Use in Biomedical and Tissue-Engineered Medical Products Application²

2.2 USP Document:

USP Monograph USP 24/NF19 Sodium Alginate³

2.3 Other Referenced Documents:

EN-ISO 10993 Biological Evaluation of Medical Devices⁴
International Conference on Harmonization (ICH) S2B

¹ This guide is under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.43 on Cells and Tissue Engineered Constructs for TEMPs.

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² *Annual Book of ASTM Standards*, Vol 13.01.

³ Available from U.S. Pharmacopeia (USP), 12601 Twinbrook Pkwy., Rockville, MD 20852.

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