

**CBER Standards Recognition Program for Regenerative Medicine Therapies
Standards Recognition Summary (SRS)**

Recognition Number: 020

Date of Recognition: 08/05/2025

SDO Name/Designation: ASTM F2315

Year of Publication: 2018

Title:

Standard guide for immobilization or encapsulation of living cells or tissue in alginate gels

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 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, health, and environmental practices and determine the applicability of regulatory limitations prior to use.

Extent of Recognition: Complete Recognition

Rational for Recognition:

This standard is relevant to regenerative medicine therapies and is recognized because it is scientifically and technically valid and does not conflict with existing regulations and policies.

Standards Development Organization: <https://www.ASTM.org>

Please note that this standard may also be recognized under the Center for Devices and Radiological Health's (CDRH) Recognized Consensus Standards Database for Medical Device, found here: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm> .