

CBER Standards Recognition Program for Regenerative Medicine Therapies

Standard Recognition Summary (SRS)

Recognition Number: 037

Date of Recognition: 9/11/2024

SDO Name/Designation: ASTM F2027

Year of Publication: 2016

Title: Standard Guide for Characterization and Testing of Raw or Starting Materials for Tissue-Engineered Medical Products

Scope: 1.1 This document provides guidance on writing a materials specification for raw or starting materials intended for use in tissue engineering scaffolds for growth, support, or delivery of cells and/or biomolecules. This guide does not apply to materials that are already in a scaffold form or are finished tissue-engineered medical products. 1.2 The purpose of this guide is to provide a compendium of relevant existing standards and test methods for materials already commonly used within medical products and to provide characterization guidance for interim use of raw materials for which a standard does not exist. 1.3 This guide covers specifications and characterizations of all the major classes of materials including polymers, ceramics, metals, composites, and natural tissues of human, animal, or plant origin. This guide does not apply to pharmaceuticals. 1.4 This guide is focused on specification of chemical, physical, and mechanical properties of the raw or starting material. It does not include safety and biocompatibility requirements since safety and biocompatibility testing is typically done on materials fabricated into a final form to include all possible effects of fabrication and sterilization techniques. 1.5 Compliance with materials specifications developed in accordance with this standard may not necessarily result in a material suitable for its intended purpose. Additional testing specific to the intended use may be required.

Extent of Recognition: Complete recognition

Rational for Recognition: The standard is scientifically sound and is relevant to cellular therapies. The standard does not conflict with regulations or FDA guidances.

Standard 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>