CBER Standards Recognition Program for Regenerative Medicine Therapies

Standard Recognition Summary (SRS)

Recognition Number: 032 **Date of Recognition:** 09/29/2023

SDO Name/Designation: ASTM F3504 **Year of Publication:** 2021

Title: Standard Practice for Quantifying Cell Proliferation in 3D Scaffolds by a Nondestructive Method

Scope:
1.1 This practice describes how to conduct a nondestructive proliferation test for mammalian cells based on metabolic activity that can be used to assess the number of viable cells within three-dimensional (3D) scaffolds for regenerative medicine and in tissue-engineered medical products (TEMPs).
1.2 This practice provides a detailed explanation of the resazurin cell metabolic activity method in terms of reagent concentrations, incubation times, cell culture media composition, calibration curve, controls, assay linearity, and limitations of the assay.
1.3 This practice describes factors that can interfere with accurate cell proliferation assessment.
1.4 Since the assay has washing steps, it is limited to assessing cells that are immobilized, such as by adhesion to a culture dish, adhesion to a scaffold, or encapsulation in a hydrogel.
1.5 The assay is limited to cell types that can metabolize resazurin to provide a signal in the assay.
1.6 This document does not propose acceptance criteria for a cell-based product based on the application of a cell proliferation test method.
1.7 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.
1.8 This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.

Extent of Recognition: Complete Recognition

Rational for Recognition: The standard is applicable to tissue engineered products.

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