



TBS/AFDC 11 (2271) DTZS/ISO 24190:2023

DRAFT TANZANIA STANDARD

Biotechnology - Analytical methods - Risk-based approach for method selection and validation for rapid microbial detection in bioprocesses

TANZANIA BUREAU OF STANDARDS

NATIONAL FOREWORD

The Tanzania Bureau of Standards is a statutory national standards body for Tanzania established under the Act.No.3 of 1975, amended by Act.No.2 of 2009.

This draft Tanzania Standard is being prepared by the Biotechnology Technical Committee, under supervision of Agriculture and Food Standards Divisional Committee (AFDC)

This draft Tanzania standard provides guidance, a framework and a risk-based approach for the selection and validation of methods for rapid microbial detection in cellular therapeutic product manufacturing. It provides a flexible risk-based framework for the detection of microbial contamination in cellular therapeutic products and cellular intermediates.

This document provides general requirements and risks associated with cellular therapeutic product manufacturing, with flexibility to address differences in specific manufacturing processes of each unique cellular therapeutic product.

This draft Tanzania standard is applicable to other cell-derived therapeutic product manufacturing. This document focuses on rapid microbial test methods (RMTMs) used for both in-process and final product testing. The viral testing in cellular therapeutic product manufacturing is not included in this document.

This draft Tanzania standard is identical to the ISO 24190:2023 Biotechnology - Analytical methods - Risk-based approach for method selection and validation for rapid microbial detection in bioprocesses, published by International Organization for Standardization.

TERMINOLOGY AND CONVENTIONS

This text of the international standards if found suitable, may be approved for application as a Tanzania Standard without deviations.

Some terminology and certain conventions are not identical with those used in Tanzania standards; attention is drawn especially to the following.

- 1) The comma has been used as a decimal marker for metric dimensions. In Tanzania standards, it is current practice to use a full point on the base line as the decimal marker.
- 2) Wherever the words “International Standard” appear, referring to this Standard they should read as “Tanzania Standard”.