SLS ISO 20391 PART 1: 2022
(ISO 20391-1:2018)
UDC 602

BIOTECHNOLOGY – CELL COUNTING - PART 1: GENERAL GUIDANCE ON CELL COUNTING METHODS

SRI LANKA STANDARDS INSTITUTION

Sri Lanka Standard
BIOTECHNOLOGY - CELL COUNTING - PART 1: GENERAL GUIDANCE ON CELL COUNTING METHODS

SLS ISO 20391 PART 1: 2022
(ISO 20391-1:2018)

Gr. H

SRI LANKA STANDARDS INSTITUTION
17, Victoria Place
Elvitigala Mawatha
Colombo 08
Sri Lanka

Sri Lanka Standard
BIOTECHNOLOGY - CELL COUNTING - PART 1: GENERAL GUIDANCE ON CELL COUNTING METHODS

NATIONAL FOREWORD

This Sri Lanka Standard was approved by the Sectoral Committee on Food Products and was authorized for adoption and publication as a Sri Lanka Standard by the Council of the Sri Lanka Standards Institution on 2022-07-07

Cell counting (or cell enumeration) is a fundamental measurement that broadly impacts many aspects of biotechnology, from biomanufacturing to advanced therapy. The cell count (or discrete number of cells) is often expressed as cell concentration (i.e. cell count per volume) when in suspension and area density of cells (i.e. cell count per unit area) when adhered to a surface. Cell count is critical in evaluating potency and efficacy for cell-based therapy. The cell concentration within a bioreactor can serve as a quality assurance metric in cell-based manufacturing processes. Many cell-based bioassays need to be normalized to the respective cell count to allow data inter-comparability. This document (which is Part 1 of a multi-part standard on cell counting) defines terms and provides general guidance for the cell counting measurement process, including method selection, sample preparation, measurement, qualification and validation, and data analysis and reporting.

This Sri Lanka Standard is identical with **ISO 20391-1:2018** Biotechnology - Cell counting Part 1: General guidance on cell counting methods published by the International Organization for Standardization (ISO).

Terminology and conventions:

The text of the International Standard has been accepted as suitable for publication, without deviation, as a Sri Lanka Standard. However, certain terminology and conventions are not identical with those used in Sri Lanka Standards. Attention is therefore drawn to the following:

a) Wherever the words “International Standard” appear referring to this Standard, it should be interpreted as “Sri Lanka Standard”.

b) The comma has been used throughout as a decimal marker. In Sri Lanka Standards it is the current practice to use the full point on the base line as the decimal marker.

c) Wherever page numbers are quoted, they are ISO page numbers.

……..

INTERNATIONAL STANDARD

ISO 20391-1

First edition
2018-01

Biotechnology — Cell counting —

Part 1: General guidance on cell counting methods

Biotechnologie — Dénombrement des cellules —

Partie 1: Lignes directrices générales relatives aux méthodes de dénombrement des cellules

Reference number
ISO 20391-1:2018(E)

Contents

Page

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2. www.iso.org/directives

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received. www.iso.org/patents

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

This document was prepared by ISO/TC 276, *Biotechnology*.

A list of all the parts of ISO 20391 can be found on the ISO website.