

මහජන අදහස් සඳහා ප්‍රමිති කෙටුම්පත
பொதுசனக் கருத்துரைக்கான கட்டளை வரைவு
DRAFT STANDARD FOR PUBLIC COMMENT

(වෙනස්වීමට ඉඩ ඇත. திருத்தத்திற்குட்படக்கூடியது. Liable to alteration)

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අදහස් එවිය යුතු අවසාන දිනය
அபிப்பிராயங்களை தெரிப்பதற்கான இறுதித்திகதி
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Draft Sri Lanka standard

BIOTECHNOLOGY – BIOBANKING – REQUIREMENTS FOR HUMAN MESENCHYMAL STROMAL
CELLS DERIVED FROM UMBILICAL CORD TISSUE
(DSLS ISO/TS..... :)(ISO/TS 22859 : 2006)

ජෛවනාස්‍යණවේදය - ජෛව බැංකු - පෙකණි වැල පටක මගින් ලබාගත් මානව මෙසෙන්කයිමල් සෛල සඳහා වන අවශ්‍යතා
ඇතුළත් ශ්‍රී ලංකා ප්‍රමිති කෙටුම්පත
(ශ්‍රී ලංකා කෙටුම්පත :)(ISO/TS 22859 : 2006)

මෙම කෙටුම්පත ශ්‍රී ලංකා ප්‍රමිතියක් ලෙස නොසැලකිය යුතු මෙන් ම භාවිතා නොකළ යුතු ද වේ.
இவ்வரைவு இலங்கைக் கட்டளையெனக் கருதப்படவோ அன்றிப் பிரயோகிக்கப்படவோ கூடாது
This draft should not be regarded or used as a Sri Lanka Standard.

අදහස් එවිය යුත්තේ : ශ්‍රී ලංකා ප්‍රමිති ආයතනය, 17, වික්ටෝරියා පෙදෙස, ඇල්විටිගල මාවත, කොළඹ 08.

Comments to be sent to: SRI LANKA STANDARDS INSTITUTION, 17, VICTORIA PLACE,
ELVITIGALA MAWATHA, COLOMBO 08.

නැඳින්වීම

මෙම ශ්‍රී ලංකා ප්‍රමිති කෙටුම්පත , ශ්‍රී ලංකා ප්‍රමිති ආයතනය විසින් සකසන ලදුව, සියලුම උදෙසාගේ අංශ වලට තාක්ෂණික විවේචනය සඳහා යටත් ලැබේ.

අදාළ අංශ හැර කමිටු මාර්ගයෙන් ආයතනයේ මහා මණ්ඩල වෙත ඉදිරිපත් කිරීමට පෙර , ලැබෙන සියලුම විවේචන ශ්‍රී ලංකා ප්‍රමිති ආයතනය විසින් සලකා බලා අවශ්‍ය වෙනස්කම් කෙටුම්පත සංශෝධනය කරනු ලැබේ.

මෙම කෙටුම්පතට අදාළ යෝජනා හා විවේචන නියමිත දිනට පෙර ලැබෙන්නට සැලැස්වුවහොත් අභ්‍යන්තර සලකුණු, තවද, මෙම කෙටුම්පත පිළිගත හැකි බැව් හැඟෙන අය ඒ බව දන්වන්නේ නම් එය ආයතනයට උපකාරී වනු ඇත.

මේ පිළිබඳව එවන සියලුම ලිපි පහත සඳහන් ලිපිනයට එවිය යුතුය.

අධ්‍යක්ෂ ජනරාල්
ශ්‍රී ලංකා ප්‍රමිති ආයතනය,
17, වික්ටෝරියා පෙදෙස,
ඇල්විටිගල මාවත,
කොළඹ 08.

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Introduction

This Draft Sri Lanka Standard has been prepared by the Sri Lanka Standards Institution and is now being circulated for technical comments to all interested parties.

All comments received will be considered by the SLSI and the draft if necessary, before submission to the Council of the Institution through the relevant Divisional Committee for final approval.

The Institution would appreciate any views on this draft which should be sent before the specified date. It would also be helpful if those who find the draft generally acceptable could kindly notify us accordingly.

All Communications should be addressed to:

The Director General
Sri Lanka Standards Institution,
17, Victoria Place,
Elvitigala Mawatha,
Colombo 08.

Draft Sri Lanka Standard
BIOTECHNOLOGY – BIOBANKING – REQUIREMENTS FOR HUMAN
MESENCHYMAL STROMAL CELLS DERIVED FROM
UMBILICAL CORD TISSUE

DSLS ISO/TS 22859:
(ISO/TS 22859: 2022)

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Sri Lanka

Draft Sri Lanka Standard
BIOTECHNOLOGY – BIOBANKING – REQUIREMENTS FOR HUMAN
MESENCHYMAL STROMAL CELLS DERIVED FROM
UMBILICAL CORD TISSUE

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

This Standard is identical with **ISO/TS 20388: 2021** Biotechnology – Biobanking – Requirements for human mesenchymal stromal cells derived from umbilical cord tissue which is published by the International Organization for Standardization (ISO).

This Standard specifies requirements for the biobanking of human mesenchymal stromal cells derived from umbilical cord tissue (i.e. Wharton’s jelly), further referred to as hUC-MSCs, including the collection of umbilical cord tissue and associated data, isolation, culture characterization, quality control, cryopreservation, storage, thawing, disposal, distribution and transport.

This Standard is applicable to all organizations performing biobanking of hUC-MSCs used for research and development. This document does not apply to hUC-MSCs for the purpose of in vivo application in humans, clinical applications or therapeutic use.

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.

CROSS REFERENCES

International Standard

Corresponding Sri Lanka Standard

ISO 8601-1, Date and time — Representations for information interchange — Part 1: Basic rules

No corresponding Sri Lanka Standard

ISO 20387: 2018, Biotechnology — Biobanking — General requirements for biobanking

SLS ISO 20387: 2023, Biotechnology — Biobanking — General requirements for biobanking

ISO 21709: 2020, Biotechnology — Biobanking — Process and quality requirements for establishment, maintenance and characterization of mammalian cell lines

SLS ISO 21709: 2022, Biotechnology — Biobanking — Process and quality requirements for establishment, maintenance and characterization of mammalian cell lines

PUBLIC COMMENT