



BSI Standards Publication

Biotechnology — Bioprocessing — General requirements for the design of packaging to contain cells for therapeutic use

National foreword

This British Standard is the UK implementation of ISO 20404:2023.

The UK participation in its preparation was entrusted to Technical Committee BTI/1, Biotechnologies.

A list of organizations represented on this committee can be obtained on request to its committee manager.

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Published by BSI Standards Limited 2023

ISBN 978 0 539 15765 9

ICS 07.080

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This British Standard was published under the authority of the Standards Policy and Strategy Committee on 30 April 2023.

Amendments/corrigenda issued since publication

Date	Text affected
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INTERNATIONAL STANDARD

ISO
20404

First edition
2023-04-13

Biotechnology — Bioprocessing — General requirements for the design of packaging to contain cells for therapeutic use

*Biotechnologie — Bioprocédés — Exigences générales pour la
conception d'emballages destinés à contenir des cellules à usage
thérapeutique*



Reference number
ISO 20404:2023(E)
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ISO copyright office
Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
www.iso.org

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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 (see 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 (see www.iso.org/patents).

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For an explanation of 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 World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

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

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

Medicinal products containing cells as active substances, which are employed in cell therapy or gene therapy, are expected to deliver novel therapeutic value to patients who are currently untreated or under-treated. These products have potential capabilities to repair, replace or regenerate tissues affected by disease or injury. Development of such products is at the forefront of scientific innovation. Therefore, manufacturers of cells for therapeutic use are expected to maintain product quality throughout the product life cycle by continuously improving their ability to process cells with advanced technology.

Cells for therapeutic use are complex products, as compared with conventional pharmaceuticals. They are produced in a variety of culture systems, such as a system in which cells are suspended in a medium, or a system in which tissue formed by cells is immersed in a medium. At the point of their administration, various methods such as surgery or infusion are applied. In addition, special attention is taken in their storage and transportation, which is not always considered in conventional pharmaceuticals. This includes the need to store products in a precisely controlled, closed environment to prevent contamination by foreign substances (viruses, bacteria, mycoplasmas, etc.) at a certain temperature, such as culture environment or at a cryogenic temperature. Even with these complexities, it is indispensable to maintain the quality of cells for therapeutic use from manufacturing to usage.

Packaging is important for cells for therapeutic use to keep their quality. Therefore, a standard for packaging to contain cells for therapeutic use is necessary. Existing standards, such as ISO 3826-1, however, do not provide information for handling cells for therapeutic use.

This document provides general requirements to design packaging intended to contain cells for therapeutic use. It provides useful information for packaging suppliers to manufacture packaging with consideration given to the specific configurations needed for cells for therapeutic use. It is also useful for packaging users when they need to consult with packaging suppliers for custom-made packaging.

This document is intended to help packaging suppliers to design and manufacture packaging in consideration of enclosing, storage, transportation, and utilization processes of cells for therapeutic use. This document is also intended to help packaging users to design and employ packaging in consideration of the above-mentioned processes.

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Biotechnology — Bioprocessing — General requirements for the design of packaging to contain cells for therapeutic use

1 Scope

This document specifies general requirements and considerations for the design of packaging used to contain cells for therapeutic use.

This document is applicable to packaging intended to contain the final products of cells for therapeutic use, as well as their starting and intermediate materials.

This document does not apply to:

- a) receptacles used for processing cells in manufacturing processes, e.g. cell culture flask or bag;
- b) shipping containers containing packages for transportation;
- c) services that utilize packages, e.g. storage services.

NOTE 1 Examples of packaging, packages and shipping containers are illustrated in [Annex A](#).

NOTE 2 The design of packaging includes processes to ensure that the designed packaging is manufactured to a required specification through trial manufacturing, testing and implementation of quality management.

NOTE 3 International, national or regional regulations or requirements can also apply to specific topics covered in this document.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <https://www.electropedia.org/>

3.1

cells for therapeutic use

product containing cells as the active substance

EXAMPLE Cell therapy medicinal product, tissue engineered product.

Note 1 to entry: The term “cells” refers to cells and *tissues* ([3.12](#)) for autologous, allogeneic and xenogeneic use.

Note 2 to entry: This term includes cells as starting materials and those cultured as intermediate materials of the product.

Note 3 to entry: The term “therapeutic use” includes clinical research, hospital exemption and testing use.