

ICS 07.080
CCS A 40



**NATIONAL STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

GB/T 47527-2026

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

生物技术 生物过程 治疗用细胞包装设计通用要求

(English Translation)

Issued on: April 30, 2026

Implemented on: November 1, 2026

Issued by: State Administration for Market Regulation

Table of Contents

Preface
Introduction
1 Scope
2 Normative References
3 Terms and Definitions
4 General Strategies for Packaging Design
5 Packaging Design
6 Implementation of Packaging Design
7 Quality Management
8 Example of test method 9.
Appendix A (Informative) Illustrated Examples of Packaging, Packaging Materials and Transport Containers
Reference

Foreword

This document complies with the provisions of GB/T 1.1-2020 "Standardization Work Guidelines Part 1: Structure and Drafting Rules of Standardization Documents".

Drafting.

This document adopts ISO 20404:2023 "General requirements for the design of cell packaging for biotechnology and bioprocesses".

Please note that some content in this document may involve patents. The issuing organization of this document assumes no responsibility for identifying patents.

This document was proposed and is under the jurisdiction of the National Working Group on Standardization of Bioprocesses (SAC/SWG36).

Introduction

Cell therapy or gene therapy pharmaceutical products containing cellularly active substances hold promise for addressing areas where there are currently no effective treatments or where treatment methods are insufficient.

These products bring entirely new therapeutic value to patients. They possess the potential to repair, replace, or regenerate tissue damaged by disease or injury, and their research

and development...

This is at the forefront of scientific innovation. Therefore, manufacturers of therapeutic cells need to continuously improve their ability to apply advanced technologies in cell products.

Ensure quality stability throughout the entire lifecycle.

Compared to traditional drugs, therapeutic cell products have a more complex structure. Their production requires multiple culture systems, such as cell suspensions.

Systems that float on the culture medium, or systems where cells are immersed in the culture medium; drug delivery methods also include surgical implantation, infusion, and other methods.

Furthermore, its storage and transportation require special management, which is usually not a major consideration for traditional drugs. Specifically, this includes the need to...

The product is placed in a precisely controlled, closed environment to prevent it from being contaminated by viruses and bacteria under specific temperature conditions (such as culture temperature or low temperature).

Contamination by foreign substances such as bacteria and mycoplasma. Despite these complexities, maintaining the quality of therapeutic cells throughout the entire process from production to use is crucial.

Quantity remains crucial.

Packaging plays a crucial role in maintaining the quality of therapeutic cells; therefore, it is necessary to establish packaging standards for therapeutic cells. However...

However, existing standards (such as ISO 3826-1) do not cover the relevant content of therapeutic cell treatment.

This document outlines general requirements for the design of therapeutic cell packaging, providing packaging suppliers with a framework for considering the specific characteristics of therapeutic cells during the production process.

This document provides a reference for special configuration requirements. It also applies when packaging users need to communicate with suppliers to customize packaging. This document aims to assist...

Packaging suppliers fully consider the needs of the entire process of encapsulation, storage, transportation, and use of therapeutic cells during the design and production stages; they also provide packaging...

The system provides guidance to users on designing and selecting packaging in the above-mentioned stages.

Biotechnology, bioprocesses, therapeutic cells General requirements for packaging design

1 Scope

This document specifies the general requirements and precautions for the design of therapeutic cell packaging.

This document applies to the packaging of therapeutic cell end products and their starting and intermediate materials.

This document does not apply to.

- a) Containers used for cell processing during the production process, such as cell culture flasks and culture bags;
- b) Transport containers used for transport and containing packaged goods;
- c) Services provided based on packaging materials, such as storage services.

Note 1: Examples of packaging, packing materials and transport containers are given in Appendix A.

Note 2: Packaging design includes the process of ensuring that the designed packaging is manufactured according to the specified specifications through trial production, testing and implementation of quality management.

Note 3: International, national, or regional regulations or requirements may also apply to the specific matters covered in this document.

2 Normative references

This document has no normative references.

3 Terms and Definitions

The following terms and definitions apply to this document.

The URLs for the terminology databases maintained by ISO and IEC for standardization are as follows.

Products containing cells as active ingredients.

Examples. Cell therapy pharmaceutical products, tissue engineering products.

Note 1: Cells refer to cells and tissues derived from the body, allogeneic, and xenogeneic sources (3.12).

Note 2: This includes cells used as starting materials for the product and cultured cells used as intermediate materials for the product.

Note 3: Therapeutic use includes clinical research, hospital exemptions, and testing purposes.

Note 4: Therapeutic cells often need to be used in conjunction with other excipients. Furthermore, these cell products are sometimes shipped with pretreatment drugs and other concomitant medications.

Medications or symptomatic treatments.

[Source. ISO 21973:2020, 3.1, with modifications] 3.2 packaging Packaging containing contents (3.3).

Note 1: The contents include the following.

- a) Cells and/or cell suspensions (3.11);
- b) Impregnate the buffer or culture medium used in item a);