

ICS 07.080
CCS A 40



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

GB/T 47528-2026

**Biotechnology - Ancillary materials present during the
production of cellular therapeutic products and gene therapy
products**

生物技术 细胞治疗产品和基因治疗产品生产过程中存在的辅助材料

(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 Abbreviations	3.
5 Strategy	
5.1 Core Concepts of Auxiliary Materials	
5.2 Responsibilities Related to Auxiliary Materials	
5.3 Conformity assessment of auxiliary materials	
5.4 Animal-derived components of auxiliary materials	
5.4.1 General Rules	
5.4.2 Key Considerations When Using Animal-Derived Ingredients	
5.4.3 Virus inactivation	
6 Evaluation criteria and risk mitigation measures for auxiliary materials containing biomaterials.	7.
6.1 Evaluation Criteria for the Selection of Auxiliary Materials	
6.2 Risk Mitigation	
6.2.1 Scientific Method	
6.2.2 Supplier Audit and Questionnaire Survey	
6.2.3 Risk Assessment	
7 Auxiliary material properties and quality attributes	9.
7.1 Composition, properties, and purity of auxiliary materials	
7.1.1 General Rules	
7.1.2 Identification and content of components	
7.1.3 Purity and Impurities	
7.1.4 Batch-to-batch consistency of auxiliary materials containing proprietary ingredients	
7.2 Storage and stability of auxiliary materials	
7.2.1 General Rule	
7.2.2 Stability and Storage Conditions of Auxiliary Materials	
8 Auxiliary material production and biosafety	
8.1 Quality Management System	

- 8.2 Production Process
- 8.3 Containers and Sealing Systems
- 8.4 Animal and human-derived components
- 8.5 Safety to cells and humans
- 9 Performance of Auxiliary Materials
 - 9.1 General Rules
 - 9.2 Quality and Testing
 - 9.3 Qualification Confirmation Activity
 - 9.4 Performance Testing
 - 9.5 Performance Test Results
- 10 Supplementary Materials Documents
 - 10.1 General Rules
 - 10.2 Reporting Requirements
 - 10.3 Analysis Certificate
 - 10.4 Other Certificates
 - 10.4.1 Certificate of Origin
 - 10.4.2 Compliance Certificate
 - 10.4.3 Irradiation Certificate
- 11 Changes in Management Elements
 - 11.1 Impact of Element Changes
 - 11.2 Measures for Changes in Management Elements
- Appendix A (Informative) Decision Chart for Supporting Materials
- Appendix B (Informative) Example 20 of the workflow from auxiliary material supplier to auxiliary material user
- Appendix C (Informative) Information on auxiliary materials and their raw materials
- Appendix D (Informative) Characterization Considerations for Auxiliary Materials
- Appendix E (Informative) Biomaterials Quality Declaration for the Production of Cell Therapy Products
- References

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 is equivalent to ISO 20399:2022 "Auxiliary substances present in the manufacturing process of biotechnology cell therapy products and gene therapy products".

Auxiliary Materials".

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

Auxiliary materials refer to materials that come into contact with cell therapy products during cell processing but are not components of the final product.

See Appendix A for the decision diagram.

Auxiliary materials can be complex mixtures of multiple components. These include salts, buffer solutions, culture media, and supplements (such as biological agents).

Examples include growth factors, enzymes, and antibodies used for immunopurification. For substances composed of multiple materials (such as culture media), all components are auxiliary materials.

Batch-to-batch variations in ingredients can affect the ability to produce cell and gene therapy products with specific quality attributes and consistent quality.

Therefore, excipient materials may affect the safety and efficacy of cell and gene therapy products. Proper control of excipient materials is necessary.

It is determined based on risk assessment methods.

This document clarifies the definition of auxiliary materials.

This document provides recommendations and requirements to auxiliary material suppliers and users, aiming to ensure the consistency of auxiliary material production and its performance.

Reliability. This document also details the information available and made available to users to demonstrate the reliability of auxiliary materials in terms of identification, purity, storage and stability.

Batch-to-batch consistency in terms of traceability, biosafety, and performance.

Furthermore, this document provides recommendations and requirements to ensure the quality of auxiliary materials.

Quality enables the production of safe and effective final products.

Currently, many standards and guidelines specify the correct handling procedures for cell

and gene therapy products to ensure their safety and efficacy.

Sexuality. However, these standards are only indirectly related to auxiliary materials. This document is independent of the standards governing cell processing requirements and is specifically for auxiliary materials.

The issues related to materials were addressed, and the expectations of auxiliary material suppliers and users were clarified.

Biotechnology cell therapy products and gene therapy products Auxiliary materials present in the production process

1 Scope

This document specifies the requirements for suppliers and users of auxiliary materials and provides relevant guidance to improve the production of human cell therapy materials.

Consistency and quality of biological (human and animal) and chemically derived auxiliary materials for products and gene therapy products.

This document applies to materials that come into contact with active substances during cell processing but are not used as components in final cell and gene therapy products.

Example 1. Reagents, anticoagulants, cytokines, growth factors, enzymes, antibodies, serum (human serum or bovine serum), buffer solutions, culture media, petri dishes (coated with biological agents).

Materials), microbeads (coated with biological materials), cryoprotectants (reagents used for cryopreservation), activators/reagents, non-mammalian cells (such as insect cells, bacterial cells) Cells, plasmids, and viral vectors.

This document does not apply to materials not intended for cell treatment, materials not in contact with active substances, or materials intended as final cell and gene therapy products.

The ingredients of the product.

Example 2. Cells, feeder cells, additives used after bioprocessing, scaffolds, and non-cell therapy products as starting materials, intermediates, or final forms of cell therapy products.

Biological consumables (such as microbeads, culture dishes, tissue culture flasks, bags, tubes, pipettes, needles), plastic containers, devices, and instruments that come into contact with cells or tissues.

See Appendix A for the decision diagram.