

ICS 07.080
CCS A 40



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

GB/T 46490-2025

**Biotechnology - Analytical methods - General requirements and
considerations for the testing and characterization of cellular
therapeutic products**

生物技术 分析方法 细胞治疗产品的试验和表征的一般要求和考虑
(English Translation)

Issued on: October 31, 2025

Implemented on: May 1, 2026

Issued by: State Administration for Market Regulation

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Appendix A (Informative) Establishment of Trial and Characterization Strategies for Cell Therapy Products

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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 adopts ISO 23033:2021 "Analytical methods for biotechnology - General requirements for testing and characterization of cell therapy products".

And considerations.

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 Technical Committee on Standardization of Biochemical Testing (SAC/TC387).

Introduction

The emergence of cell therapy products has increased the demand for high-quality, stable, reliable, and validated measurement methods to characterize and test products containing...

Products containing cells as active substances. These products are regulated by health authorities and undergo appropriate biological, physical, and chemical assays.

(Analytical Methods) Evaluate the quality attributes (QA) of the product.

Analytical methods are used for cell starting materials, process testing, and product consistency testing, comparability studies, and stability testing. These methods...

Analytical methods are used to assess attributes related to product quality characteristics and manufacturing controls (process controls), and are applied at all stages of clinical research and commercialization.

These parameters are used to determine identity, purity, cell count, viability, potency, and stability. Quality attributes are used to ensure that only products meeting specified

specifications are released.

Product batch. Quality attributes are also used for stability testing, trend analysis, and process metrics.

Analytical methods support the development of new cell therapy products by providing insights into biological mechanisms of action and facilitating research and development in the manufacturing industry.

Furthermore, the analytical methods are also used to evaluate and compare different batches of cell therapy products, for example, on different dates, at different locations, or through modified methods.

Products manufactured using changing manufacturing processes.

Due to the complexity and high dynamism of cell samples, the different cell types and the fragility of processing steps, and the lack of basic cell biology knowledge...

Understanding and quantifying cell therapy products, along with the numerous parameters associated with bioprocessing and measurement, presents a challenge. Biological variability further contributes to this challenge.

This step complicates the measurement process. Furthermore, different donor samples may have varying sensitivities to processing steps, making it necessary to perform unnecessary steps during the measurement.

The need for process control has become more critical.

Therefore, analytical methods are crucial for evaluating cell therapy products, as well as cell starting materials and intermediates, although specific performance standards may differ.

The performance standards for the final cell therapy products differ.

This document provides guidelines for designing appropriate analytical methods to measure and evaluate the quality attributes of cell therapy products.

Sex. The contents of this document also apply to the testing and characterization of cells used in the production of viruses, exosomes, and antibodies. Selection and design of suitable...

The general procedure for the analytical methods used can be applied to cell starting materials, intermediates, final cell products, control cells, feeder cells, and for...

The cells being measured (e.g., target cells). It also provides a general method for understanding, minimizing, and monitoring sources of variation. Acceptable accuracy and precision.

Density levels are determined by the biological implications of the measurement results and the practical limitations of the measurement process.

This document provides general considerations for developing specifications for the final cell therapy product testing. It also provides key quality attributes for common categories.

CQA (Cell Quality Assurance) (i.e., used to determine identity, cell count, purity or impurities, potency or related biological activity, viability, sterility, stability and maturation) General considerations for establishing analytical methods and strategies (including an analytical method matrix) based on the attributes of the degree of overview.

This document aims to provide additional technical guidance for cell characterization and specifically outlines the characterization and testing methods for cell therapy products.

Strategic development requirements (see Appendix A for a diagram illustrating the concepts presented in this document).

Biotechnology analysis methods for cell therapy products General requirements and considerations for testing and characterization

1 Scope

This document provides general requirements for the testing and characterization of cell therapy products intended for use in humans.

This document provides methodological recommendations for characterizing cell therapy products, including the selection and design of suitable analytical methods to determine cell therapy efficacy.

Key quality attributes of a product.

This document applies to cell starting materials (including starting materials for tissue engineering products) and intermediate products for cell therapy products.

This document does not apply to transplanted tissues.

2 Normative references

This document has no normative references.

3 Terms and Definitions

The following terms and definitions apply to this document.

Acceptance criteria

Numerical limits, ranges, or other appropriate criteria used to determine whether analytical results are acceptable. (This applies to products or other stages of manufacturing.) the requirements that the materials need to meet.

exogenous factor adventitious agent Microorganisms introduced during the manufacturing