

ICS 07.080
CCS A 40



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

GB/T 45138-2024

**Technical specification for evaluation of antiviral activity of
interferon**

干扰素抗病毒活性评价技术规范

Issued on: December 31, 2024

Implemented on: December 31, 2024

**Issued by: State Administration for Market Regulation;
Standardization Administration of the PRC**

Table of Contents

Foreword

1 Scope

2 Normative references

3 Terms and definitions

3.1 Interferon interferon; IFN

3.2 Activity

3.3 dose-effect curve

3.4 four-parameter equation

4 Basic requirements for evaluation

Foreword

This document is in accordance with the provisions of GB/T 1.1-2020 "Guidelines for standardization work Part 1: Structure and drafting rules for standardization documents" Drafting is required.

Please note that some of the contents of this document may involve patents. The issuing organization of this document does not assume the responsibility for identifying patents.

This document is proposed and coordinated by the China National Institute of Standardization.

This document was drafted by: China National Institute of Standardization, China Food and Drug Inspection Institute, Shanxi Jinbo Biopharmaceutical Co., Ltd.

Department of Medicine, Beijing Tongren Hospital, Capital Medical University.

The main drafters of this document are: Zhao Lin, Shi Xinchang, Pei Dening, Yun Zhenyu, Wang Jian, Wu Qi, Wu Xi, Sun Dandan, Li Ling, Li Wenjun and Zhang Mengyan.

Technical Specifications for Evaluation of Interferon Antiviral Activity

1 Scope

This document specifies the basic requirements for the evaluation of interferon antiviral activity, the requirements for cells and viruses, and the requirements for personnel training.

Selection of measurement methods, evaluation models, result recording and effectiveness determination.

This document is applicable to the evaluation of the antiviral activity of interferon samples other than pharmaceuticals.

2 Normative references

GB 19489

GB 41918-2022

3 Terms and definitions

The following terms and definitions apply to this document.

3.1 Interferon; IFN

A class of broad-spectrum antiviral proteins that inhibit the spread of viruses by interacting with cell surface receptors to induce cells to produce antiviral proteins. proliferation.

3.2 Activity

Biological activity The nature of the antiviral effects of interferon-activated cells.

3.3 dose-effect curve

A curve used to represent the relationship between the concentration/content of the test article and its biological effect.

Note. The horizontal axis is the test sample concentration/content or dilution, and the vertical axis is the biological effect intensity.

3.4 four-parameter equation

A mathematical model with four parameters (A, B, C, and D) that describes the relationship between the dependent variable (y) and the independent variable (x) and is used to present An expression for the relationship between each test concentration of the test article and its corresponding biological effect.

4 Basic requirements for evaluation

4.1 The laboratory's biosafety management should comply with the relevant requirements in GB 19489.

4.2 The evaluators should have corresponding test operation capabilities, skill certificates or work experience.