

ICS 13.040.30

CCS C30



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

GB/T 16294-2025

Replacing GB/T 16294-2010

**Test method for settling microbe in clean room (zone) of the
pharmaceutical industry**

医药工业洁净室（区）沉降菌的测试方法

Issued on: October 5, 2025

Implemented on: November 1, 2026

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

Table of Contents

Foreword

1 Scope

About this edition

Classification and status

How a Chinese national standard is set out

Foreword

This document was issued on 5 October 2025 by the State Administration for Market Regulation and the Standardization Administration of the People's Republic of China, and takes effect on 1 November 2026.

It replaces GB/T 16294-2010, which remains in force until that date.

Classification: ICS 13.040.30, CCS C30.

1 Scope

GB/T 16294-2025 is the Chinese national standard on test method for settling microbe in clean room (zone) of the pharmaceutical industry, in the field of environment and health protection, safety. The /T suffix marks it as a recommended standard: it is not compulsory by itself, but it becomes binding as soon as a contract, a tender or a customer specification calls it up - which in practice is how most foreign buyers meet it. It was issued on 5 October 2025 by the State Administration for Market Regulation; Standardization Administration of China, and takes effect on 1 November 2026. Classification: ICS 13.040.30, CCS C30. This page is published from the official record of the standard held by the Chinese standards administration: the identification, the dates, the classification and the issuing body are taken from there. The clause text, the tables and the numeric limits are in the document itself, which is delivered complete in English translation.

About this edition

GB/T 16294-2025 is the current edition. It was issued on 5 October 2025 and takes effect on 1 November 2026, replacing GB/T 16294-2010.

Until 1 November 2026 the previous edition, GB/T 16294-2010, remains the one in force: a contract, a specification or an inspection report that cites the standard without a year is met by GB/T 16294-2010 today and by GB/T 16294-2025 from that date. Anyone writing a new specification now has to decide which of the two to name, and anyone holding a certificate

issued against GB/T 16294-2010 should check what the transition requires of it.

The interval between issue and effect is the transition period. It exists so that producers, laboratories and buyers can requalify products, revise procedures and use up documentation before the new text becomes the one that applies. The date on this page is the official one from the record of the Standardization Administration.

Classification and status

GB/T 16294-2025 is classified under ICS 13.040.30, in the field of environment and health protection, safety. ICS is the International Classification for Standards, the same scheme used by ISO and by the national bodies of most countries, which is what allows a Chinese standard to be placed beside its foreign counterparts on subject rather than on number.

Its Chinese Standard Classification code is CCS C30. CCS is the domestic scheme, a letter for the sector and two digits for the subject within it, and it is the code by which the standard is filed and searched in China.

The GB/T prefix marks a recommended national standard. It is not, in itself, law: it becomes binding when a contract names it, when a regulation or a mandatory standard refers to it, or when a producer declares conformity with it. In practice that covers most of the cases in which it will be read - a purchase specification, an inspection agreement or a certification scheme.

How a Chinese national standard is set out

Chinese national standards are drafted to the rules of GB/T 1.1, which fixes the order in which a standard is set out. The document opens with a foreword recording the issuing bodies, the relationship to any previous edition and the technical committee responsible for it. Clause 1 is the scope. Clause 2 lists the normative references - the other standards that have to be applied together with this one, and without which its requirements cannot be met. Clause 3 gives the terms and definitions. The technical clauses follow: the requirements themselves, the test or measurement methods by which conformity is established, the inspection rules that say how a lot is sampled and judged, and, for a product standard, the provisions on marking, packaging, transport and storage. Annexes, normative or informative, come last.

GB/T 16294-2025 runs to 11 pages in the English translation. What is delivered is the complete document in that order: every clause, every table, every figure and every annex of the Chinese original, with the same numbering, so that a reference to a clause number in a contract or a test report points to the same place in both languages.