NATIONAL STANDARD OF THE

PEOPLE'S REPUBLIC OF CHINA

GB/T 51466-2025

Standard for construction and acceptance of pharmaceutical industry cleanroom

医药工业洁净厂房施工与验收标准

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Issued by: Ministry of Housing and Urban-Rural Development of the PRC and the State Administration for Market Regulation

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Foreword

This document was issued on 21 April 2025 by the Ministry of Housing and Urban-Rural Development of the PRC and the State Administration for Market Regulation and takes effect on 1 September 2025.

It is a GB/T standard: recommended rather than compulsory, but it is the text a Chinese reviewer applies.

The document runs to 82 pages. The identification, the dates, the classification and the table of contents on this page are taken from the cover and the printed contents of the standard itself.

This standard was approved by the Ministry of Housing and Urban-Rural Development of the PRC under Announcement No. 68 of 2025 and takes effect on 1 September 2025.

Its editing organisation is the China Pharmaceutical Engineering Design Association.

Its stated purpose is to strengthen the management of the construction and acceptance of pharmaceutical cleanrooms and to provide the basis for installation qualification, operational qualification and performance qualification of pharmaceutical engineering works.

1 Scope

GB/T 51466-2025 is the Chinese national standard for the construction and acceptance of pharmaceutical industry cleanrooms, and it is written to serve a specific regulatory purpose: to provide the basis for the installation, operational and performance qualification that GMP requires. That is what distinguishes it from a general cleanroom construction code, and what makes it directly relevant to any company building or validating

pharmaceutical manufacturing in China. It covers the building finishing, floors, sandwich panel ceilings and interior walls, doors and windows; the clean air-conditioning systems, their ducts and components, installation and testing; the process piping, with six pages on the installation of hygienic piping and fittings, which is where product contact cleanliness is won or lost; the plumbing system; the equipment installation in the pharmaceutical clean area and its hook-up; the fire fighting and safety facilities; the electrical facilities including cleanroom lighting and the lightning protection and grounding; the instrumentation and communication systems; and finally the acceptance, covering cleanroom testing and the classification of air cleanliness, the microbial contamination level testing and the construction acceptance itself. It applies to new build, rebuilt and extended pharmaceutical industry cleanrooms.

3 Building finishing

Clause 3 is organised as follows: 3.1 General requirements; 3.2 Floors; 3.3 Sandwich panel ceilings; 3.4 Sandwich panel interior walls; 3.5 Doors and windows.

4 Clean air-conditioning systems

Clause 4 is organised as follows: 4.1 General requirements; 4.2 Ducts and components; 4.3 Installation of duct systems; 4.4 Testing.

5 Process piping

Clause 5 is organised as follows: 5.1 General requirements; 5.2 Installation of hygienic piping and fittings.

7 Equipment

Clause 7 is organised as follows: 7.1 General requirements; 7.2 Equipment installation in the pharmaceutical cleanroom; 7.3 Hook-up.

8 Fire fighting and safety facilities

Clause 8 is organised as follows: 8.1 General requirements; 8.2 Installation of pipes and conduits; 8.3 Installation of fire fighting and safety equipment.

9 Electrical facilities

Clause 9 is organised as follows: 9.1 General requirements; 9.2 Installation of electrical lines; 9.3 Installation of electrical equipment and devices; 9.4 Lighting in the pharmaceutical cleanroom; 9.5 Installation of lightning protection and grounding devices.

10 Instrumentation and communication

Clause 10 is organised as follows: 10.1 Instrumentation; 10.2 Communication; 10.3 Installation of lines.

11 Acceptance

Clause 11 is organised as follows: 11.1 General requirements; 11.2 Cleanroom testing and classification of air cleanliness; 11.3 Cleanroom microbial contamination level testing; 11.4 Construction acceptance.