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

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Code for design of pharmaceutical industry clean room

医药工业洁净厂房设计标准

(English Translation)

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1 General

1.0.1

This standard is formulated in order to implement the relevant national guidelines and policies in the design of clean workshops in the pharmaceutical industry, to achieve advanced technology, safety and reliability, quality assurance, energy conservation and environmental protection.

1.0.2

This standard applies to the design of new, expanded and reconstructed pharmaceutical industry clean workshops. The production and quality inspection facilities of biological products, toxic drugs, psychotropic drugs, narcotic drugs and radioactive drugs should not only implement this standard, but also comply with the relevant national regulatory regulations.

1.0.3

The design of clean workshops in the pharmaceutical industry should create necessary conditions for construction and installation, verification of system facilities, maintenance management, inspection and testing, and safe operation.

1.0.4

The design of clean workshops in the pharmaceutical industry shall not only comply with this standard, but also comply with the current relevant national standards and regulations.

2.0.1 Pharmaceutical clean room

Airborne particle and microbial concentrations, as well as controlled pharmaceutical production rooms or limited spaces with parameters such as temperature, humidity, and pressure.

2.0.2 Pharmaceutical industry clean room

A building used for pharmaceutical production and quality control that includes pharmaceutical clean rooms.

2.0.3 Room for cleaning personnel

A room where personnel are purified according to certain procedures before entering the medical clean room.

2.0.4 Room for cleaning material

A room where materials are purified according to certain procedures before entering the pharmaceutical clean room.

2.0.5 Controlled environment controlled environment

A specific area where pollution sources are controlled by prescribed methods.

2.0.6 Suspended particles airborne particles

Solid and liquid particles in the air suspension particle size range of 0.1 μm to 1000 μm for air cleanliness classification.

2.0.7 Microorganisms

A bacterial or non-bacterial microscopic biological entity capable of replicating or transmitting genetic material.

2.0.8 Particle concentration

The number of suspended particles per unit volume of air.

2.0.9 Bacteria concentration microorganisms concentration

The number of microorganisms in a unit volume of air.

2.0.10 Air cleanliness

The air cleanliness is distinguished by the number of particles of a certain particle size and the number of microorganisms in a unit volume of air.

2.0.11 Air flow type air pattern

Air flow form and distribution state.

2.0.12 Unidirectional airflow

Through the entire section of the clean area, the wind speed is stable, and the controlled airflow is roughly parallel.

2.0.13 Non-unidirectional airflow

An airflow distribution in which the air introduced into the clean area is inductively mixed with the air in the area.

2.0.14 Mixed airflow

Combination of unidirectional and non-unidirectional airflows.

2.0.15 Airlock

At the entrance and exit of a medical clean room, it is a room set up to block the airflow from the outside or adjacent rooms and control the pressure difference.

2.0.16 Pass cabinet (window) pass box

On the partition wall of the medical clean room, the window for transferring materials and tools is equipped with windows on both sides that cannot be opened at the same time.

2.0.17 Clean working clothing clean working garment

Special work clothes used in medical clean rooms.

2.0.18 Empty as-built

The facility has been built, all power is connected and running, but there are no production equipment, materials and personnel.

2.0.19 Static at-rest

All production equipment has been installed in place, but there is no production activity and no operators are on site.

2.0.20 Dynamic in-operation

The facility is operating in the specified state, with the specified personnel present and working in the agreed state.

2.0.21 High efficiency particulate air filter high efficiency particulate air filter

Under the rated air volume, the air filter has a collection efficiency of more than 99.95% according to the most penetrable particle size (MPPS).

2.0.22 Process water for pharmaceutical process

Water used in the pharmaceutical production process, including drinking water, purified water, and water for injection.

2.0.23 Purified water purified water

The quality of the water used for medicinal purposes, which is produced by distillation, ion exchange, reverse osmosis or other appropriate methods, does not contain any additives, and its quality conforms to the current regulations on purified water in the Pharmacopoeia of the People's Republic of China.

2.0.24 Water for injection

The quality of purified water obtained by distillation is in line with the current regulations on water for injection in the Pharmacopoeia of the People's Republic of China.

2.0.25 Self-cleaning time cleanliness recovery characteristic

After the medical clean room is polluted, the purification air conditioning system starts to operate under the specified number of air changes until it returns to the inherent static standard.

2.0.26 Recovery time recovery time

The time required for the production and operation of the medical clean room to be completed, the operators to withdraw from the site, and the suspended particles in the air to reach the static standard.

2.0.27 Sterile

No living microorganisms are present.