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Test method for airborne particles in cleanroom (zone) of the pharmaceutical industry

医药工业洁净室(区)悬浮粒子的测试方法

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Test method for airborne particles in cleanroom (zone) of the pharmaceutical industry

1 Scope

This Standard specifies the test method for airborne particle contamination.

This Standard is applicable to the verification of airborne particle testing and environment in cleanroom and clean areas in the pharmaceutical industry, sterile rooms or local air purification areas (including clean bench).

This Standard cannot be used to characterize physical, chemical, or reflective, or reproducible properties of airborne particles.

NOTE: Within the sampling particle size range, the actual particle concentration is unpredictable and significantly changes with time as the sampling amount increases.

2 Normative references

The following standards contain the provisions which, through reference in this Standard, constitute the provisions of this Standard. For dated references, subsequent amendments (excluding corrections) or revisions do not apply to this Standard. However, the parties who enter into agreement based on this Standard are encouraged to investigate whether the latest versions of these documents are applicable. For undated reference documents, the latest versions apply to this Standard.

YY 0033-2000, *Good manufacture practice for sterile medical devices*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1 cleanroom (zone)

A room or area that requires environmental control for dust and microbial contamination. Its building structure, equipment and its use have the function of reducing the involvement, generation and retention of pollution sources in the area. Other relevant parameters such as temperature, humidity, and pressure are also necessary to control.

process equipment has been installed, and there are no production personnel in the cleanroom (zone).

At-rest b: after the production operation is completed, the production operator evacuates the site and after 20 minutes of self-purification of the cleanroom (zone).

3.10 operational

The cleanroom (zone) is in normal production state, the equipment is carried out in the specified mode, and the designated personnel are operating according to the specifications.

3.11 clean bench

A workbench or a closed enclosure work area similar to it. It is characterized by its ability to supply filtered air or gas, and is divided into a vertical one-way flow table, a horizontal one-way flow table, etc. according to the air flow form.

4 Test methods

4.1 Method summary

The method adopts the counting concentration method, that is, the level of airborne particles cleanness in the cleanroom (zone) is assessed by testing the number of airborne particles that have a particle size greater than or equal to a certain particle, in unit-volume in a clean environment.

4.2 Staff duties and training

Testers in cleanroom (zone) shall be trained in the profession and qualified to perform their duties in cleanroom (zone) testing, including the health knowledge and basic microbiological knowledge involved.

Testers in cleanroom (zone) shall choose the wear method that suits the air cleanliness level requirements of the production operation. Outer clothes cannot be brought into the area of level above 100000.

4.3 Instrument

The instrument shall use any of the following:

a) light scattering particle counter (for airborne particle counts with particle sizes greater than or equal to 0.5μm);

b) laser particle counter (for airborne particle counts with a particle size greater than or equal to 0.1μm).

5 Test rules

5.1 Test conditions

Pre-test the relevant parameters of the cleanroom (zone) before testing. Such tests shall provide environmental conditions for testing airborne particles, such as: such pre-tests may include:

a) Temperature and relative humidity testing. The temperature and relative humidity of the cleanroom (zone) shall be compatible with its production and process requirements (when no special requirements are required, the temperature is between 18°C and 26°C, and the relative humidity is between 45% and 65%), and the test equipment shall meet the use scope of testing instrument.

b) Indoor air supply or wind speed test, or differential pressure test.

c) High efficiency filter leak test.

5.2 Test state

Three states of as-bulit, at-rest and operational-state can be tested.

In as-bulit or at-rest test, there must be no more than 2 testers in the room.

The test report shall indicate the state of the test and the number of testers in the room.

5.3 Test time

5.3.1 In the case of as-bulit or at-rest a test, for a unidirectional flow cleanroom (zone), the test shall begin after the normal operation time of the purified air conditioning system is not less than 10min. For non-unidirectional flow cleanroom (zone), the test shall start after the normal operation time of the purified air conditioning system is not less than 30min. In the at-rest b test, for the unidirectional airflow cleanroom (zone), the test shall be started after the production operator evacuates the site and after 10min of self-cleaning. For non-unidirectional flow cleanroom (zone), the test shall be started after the production operator evacuates the site and after 20min of self-cleaning.

5.3.2 In operational-state testing, it must record the start of production and test time.

5.4 Airborne particle count

5.4.1 Number of sampling points and their layouts

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