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

医药工业洁净室(区)浮游菌的测试方法

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

1 Scope

This Standard specifies the test conditions, test methods for airborne microbe in cleanroom (zone) of the pharmaceutical industry.

This Standard is applicable to the verifications of test and environment for airborne microbe in cleanroom and clean zone in the pharmaceutical industry, sterile room or partial air purification area (including clean bench).

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.

GB/T 16292-2010, *Test method for airborne particles in clean room(zone) of the pharmaceutical industry*

JGJ 71-1990, *Code for Construction and Acceptance of Cleanroom*

3 Terms and definitions

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

3.1 colony forming units

Microbial colonies formed by one or several microorganisms after microbial culture, referred to as CFU; usually expressed in numbers.

3.2 airborne microbe

Number of colonies that it collects live microbial particles suspended in air by the methods mentioned in this Standard, through specialized medium, breeding to visible under suitable growth conditions.

a) airborne microbe sampler;

b) petri dish;

c) medium (see Annex B of this Standard);

d) constant temperature incubator;

e) high pressure steam sterilizer.

4.4 Principle of airborne microbe sampler

The airborne microbe sampler generally uses the impact mechanism. It can be divided into slit sampler, centrifugal or pinhole sampler. The slit sampler draws in the airflow from the internal fan and sprays the collected air through the slit plate of the sampler onto the surface of the slowly rotating plate medium; attached live microbial particles are cultured to form colonies. For centrifugal sampler, due to the high-speed rotation of the internal fan, the airflow is sucked from the front of the sampler and flows out from the rear. Under the action of centrifugal force, the living microbe particles in the air have enough time to hit the special solid-shaped culture strip, and the attached live microbial particles are cultured to form colonies. The pinhole sampler is a gas stream that is drawn through a metal cover. The cover is densely machined and specially made through a small hole. The collected small air flow directly hits the surface of the plate medium by the fan, and the attached living microbes are attached. Colony is formed after culture.

4.5 Test points

4.5.1 The instrument must be periodically verified according to the test cycle of the test instrument. Use instrument that passes the verification and is in use.

4.5.2 When the test instrument does not enter the tested area, if necessary, clean the surface first, or prepare and store in the corresponding clean room (protect the instrument with a protective cover or other appropriate cover).

4.5.3 When using paper in level 100 cleanroom, it shall be covered with a transparent, dust-free cover. It cannot use pencil and eraser in level 100 cleanroom.

4.5.4 When using the test instrument, strictly follow the instructions of the instrument.

4.5.4.1 The instrument is turned on and preheated until it is stable before the instrument can be calibrated according to the specifications of the instrument. Check the sampling flow at the same time and set the sampling time according to the sampling amount.

4.9.1.6 The sampling instrument is not put into the culture dish after being disinfected. Open the airborne microbe sampler to evaporate the residual disinfectant in the instrument for no less than 5min. And check the flow and adjust the sampling time according to the sampling amount.

4.9.1.7 Close the airborne microbe sampler, place it in the Petri dish, and close the lid.

4.9.1.8 After the sampling port is set at the sampling point, the airborne microbe sampler is turned on for sampling.

4.10 Cultivation

4.10.1 After all sampling is completed, the culture dish is placed in a constant temperature incubator for cultivation.

4.10.2 The culture dish prepared by Trypticase soy agar medium (TSA) is sampled and cultured in an incubator at 30°C ~ 35°C for at least 2d; the culture dish prepared in Sabouraud dextrose agar medium (SDA) is sampled and cultured in an incubator at 20°C ~ 25°C for at least 5d.

4.10.3 Each batch of mediums shall have a control test to check whether the medium itself is contaminated. 3 culture dishes can be selected for each batch for control culture.

4.11 Count of colony forming units

4.11.1 Directly count, label or count all colonies on the culture dish with the naked eye. Then use a 5 to 10 times magnifying glass to check if there is any omission.

4.11.2 If there are 2 or more colonies on the plate that overlap, 2 or more colonies are still counted when they are distinguishable.

4.12 Precautions

4.12.1 The quality of each culture dish shall be carefully checked before use. If culture medium and culture dish may be deteriorated, damaged or contaminated, they cannot be used.

4.12.2 Make detailed recording of media, culture conditions and other parameters.

4.12.3 Due to the wide variety of bacteria, the difference is very large. When counting, generally use the transmitted light to observe carefully on the back or front of the dish. Do not miss the colonies growing on the edge of the dish. And pay attention to the difference between bacterial colonies or medium sediments. Use microscopic identification if necessary.

Average concentration of airborne microbe=3/2=1.5/m^3

5.7 Result evaluation

5.7.1 The average concentration of airborne microbe at each measurement point must be below the limit in the selected assessment criteria.

5.7.2 In the at-rest test, if the average concentration of airborne microbe at a certain measuring point exceeds the evaluation standard, it shall be re-sampled twice, and the two test results are all qualified before they can be determined as conforming.

5.8 Daily monitoring

For the monitoring of airborne microbe, it is advisable to set the airflow with a uniform wind speed in the cross section of the cross-flow line in the single direction and the direction of the airflow to ensure the microbial concentration of the cleanroom (zone) is controlled. It shall be regularly tested to check the microbial load and the effectiveness of the disinfectant, and to analyze the propensity. Both at-rest and operational monitoring can be used.

For the sampling frequency of airborne microbe, if the following conditions shall be considered, the frequency of detection of other items shall also be determined after the following conditions are evaluated.

- Continuously exceeds the action levels and the alert levels.
- Downtime is longer than expected.
- Pollution is found in key areas.
- The air purification system performs any major repairs during production.
- Daily operational records reflect propensity data.
- Changes in disinfection procedures.
- Accidents causing biological pollution, etc.
- When the production equipment has major repairs or when adding equipment.
- When there is a major change in the structure or area distribution of the cleanroom (zone).

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