ICS 13.040.30
CCS C30

NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

GB/T 16293-2010

Replacing GB/T 16293-1996

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

医药工业洁净室(区)浮游菌的测试方法

Issued on: September 2, 2010 **Implemented on: February 1, 2011**

Issued by: General Administration of Quality Supervision, Inspection and Quarantine of the People's Republic of China;
Standardization Administration of China

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1 Scope

GB/T 16293-2010 is the Chinese national standard on test method for airborne 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 2 September 2010 by the General Administration of Quality Supervision, Inspection and Quarantine of the People's Republic of China; Standardization Administration of China, and has been in force since 1 February 2011. 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.

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.

3.3 airborne microbe concentration The number of colonies containing airborne microbe per unit volume of air, expressed in terms of counting concentration, the unit is number/m3 or /L.

3.4 action levels For controlled cleanroom (zone), the user sets the microbial content level by the user. When the test result exceeds this level, the monitoring program shall be initiated to immediately track the microbial contamination of the area.

3.5 alert levels For a controlled clean room (zone), the user sets a microbiological content level, giving a bias value that is the earliest alert compared to the normal state. When the deviation value of the earliest warning is exceeded, procedures and related measures to ensure that the process or environment are not affected shall be initiated.

4 Test methods

4.1 Method summary The method used in this Standard is the counting concentration method, that is, by collecting biological particles suspended in the air in a special medium (selecting a medium that can confirm the growth of the microorganisms).

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.

4.3 Instrument, auxiliary equipment and medium Choose a suitable airborne microbe sampler, including an oil-free pump, lower airflow rate and larger sample flow rate so as to ensure that the moisture on the surface of the medium is not dried.

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.

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.

4.6 Petri dish

4.6.1 Generally use a petri dish of phi90mmx15mm size. Select the appropriate dish according to the selected sampler.

4.6.2 Centrifugal sampler uses dedicated solid culture strip.

4.7 Medium Trypticase soy agar medium (TSA) or Sabouraud dextrose agar medium (SDA) or other user-approved and validated medium. See Annex B for preparation method.

4.8 Constant temperature incubator The constant temperature incubator must be checked regularly.

4.9 Test procedures

4.9.1 The surface of the instrument and the culture dish must be strictly disinfected before the test.

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.

4.12 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.

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.

5.2 Test state Both at-rest and operational-state can be tested. No more than 2 indoor testers during at-rest testing. Before the airborne microbe test, the cleanroom (zone) to be tested is determined by the user, whether it needs to be pre-sterilized. The test report shall indicate the state of the test and the number of indoor testers.

5.3 Test time

5.3.1 In the case of as-built 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 flow 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 test, it must record the start of production and test time.

5.4.1 Number of sampling points and their layouts

5.4.1.1 Number of minimum sampling points The number of minimum sampling points for the airborne microbe test can refer to GB/T 16292-2010.