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GB/T 16294-2010

Replacing GB/T 16294-1996

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

医药工业洁净室（区）沉降菌的测试方法

Issued on: September 02, 2010 **Implemented on: February 01, 2011**

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Foreword

This Standard refers to ISO 14698-1 “Cleanrooms and associated controlled environments - Biocontamination control - Part 1: General principles and methods”, ISO/TS 11133-1:2000 (English version) “Microbiology of food and animal feeding stuffs - Guidelines on preparation and production of culture media - Part 1: General guidelines on quality assurance for the preparation of culture media in the laboratory”.

This Standard replaces GB/T 16294-1996 “Test method for settling microbe in clean room (area) of the pharmaceutical industry”.

The main differences between this Standard and GB/T 16294-1996 are:

- ADD the method for determining the minimum number of sampling points;

- MODIFY the original standard 4.8.3.2 to “4.10.2 [Translator’s note: this should be 4.4.5 in this Standard] The petri dish prepared by soybean casein agar medium (TSA) are sampled and cultured in the incubator at 30 °C to 35 °C for no less than 2 d. The petri dish prepared by sabouraud medium (SDA) are sampled and cultured in the incubator at 20 °C ~ 25 °C for no less than 5 d.”;

- ADD the content of 5.8 “Daily monitoring”, ADD the establishment of correcting limits and warning limits for the control of microbial concentration in the air of clean room (zone) and the content of how to determine the sampling frequency in this Standard.

Annex A and Annex B of this Standard are normative annexes.

Annex C of this Standard is an informative annex.

This Standard was proposed and shall be under the jurisdiction of China Food and Drug Administration.

Drafting organizations of this Standard: Shanghai Food and Drug Packaging Material Control Center, China Food and Drug Testing Institute Medical Device Testing Center.

Main drafters of this Standard: Lu Weiyi, Xu Minfeng, Feng Xiaoming, Wang Zhimin.

The historical edition of the standard replaced by this Standard is: GB/T 16294-1996.

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

1 Scope

This Standard specifies the test conditions and test method for setting microbe in clean room and clean zone of the pharmaceutical industry.

This Standard is applicable to the test of setting microbe in clean room and clean zone of the pharmaceutical industry, and in sterile room or local air purification area (including the clean bench), and the verification of the environment.

2 Normative references

The following documents contain the provisions which, through reference in this Standard, become the provisions of this Standard. For dated references, their subsequent amendments (excluding corrigendum) 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

3 Terms and definitions

For the purpose of this Standard, the following terms and definitions apply.

3.1

settling microbe

Visible number of colonies that are colonized using living microbial particles in the air collected by the method mentioned in this Standard, in special culture medium, under suitable growth conditions.

3.2

settling microbe plate count

Number of setting microbe in the air that are collected in each plate petri dish in the specified period of time, expressed in cells/dish.

4 Test method

4.1 Method summary

This test method adopts the sedimentation method, that is, collect biological particles in the air on the culture medium plate through natural sedimentation principle, after some time, let it grow to visible colonies under appropriate conditions and count, determine the number of living microorganisms in a clean environment by counting the number of colonies in the plate petri dish, so as to assess the cleanliness of the clean room (zone).

4.2 Personnel responsibility and training

The test personnel of the clean room (zone) shall be trained in this specialty and obtain relevant qualifications before they can perform their duties in the clean room (zone) test, which includes hygienic knowledge and basic knowledge of the microorganisms involved.

The test personnel of the clean room (zone) shall select the wear that suits the air cleanliness grade requirements of the production operation, and the outer clothes cannot be brought into the area of 100 000 grade or more.

4.3 Instruments

The instrument shall include:

a) petri dish;

b) culture medium (see Annex B of this Standard);

c) constant temperature incubator;

d) high pressure steam sterilizer.

4.3.1 Petri dish

It generally uses φ90 mm × 15 mm petri dishes.

4.3.2 Culture medium

Soybean casein agar medium (TSA) or sabouraud medium (SDA) or user-approved and validated medium. The preparation method is shown in Annex B.

5.4.4.1 For unidirectional-flow clean rooms (zones) or air supply ports, the sampling port of the sampler shall face the airflow direction; for non-unidirectional-flow clean rooms (zones), the sampling port shall be upward.

5.4.4.2 When arranging the sampling points, it shall at least avoid the return air outlets with relatively concentrated dust particles as far as possible.

5.4.4.3 When sampling, the testing personnel shall stand on the downwind side of the sampling port and move as little as possible.

5.4.4.4 It shall take all measures to prevent contamination during the sampling process and other possible contamination of the sample.

5.4.4.5 When the petri dish is used for testing, in order to avoid the influence of the process of transporting or moving the petri dish, it should carry out a control test at the same time. TAKE a control dish each time or at each area, OPERATE in the same way as the sampling dish without exposing the sampling, and then PLACE it in the incubator along with the sampled petri dish (TSA or SDA). The result shall be there is no colonies.

5.5 Records

The test report shall contain the following:

a) name and address of the tester, test date;

b) test basis;

c) plane position of the clean room (zone) to be tested (mark the plane position of the adjacent area if necessary);

d) description of the test instrument and the test method: including test environmental conditions, number of sampling points and layout diagram, number of tests, or possible changes in the test method, test instrument certification certificates, etc.; if it is a dynamic state test, it shall record the number and location of on-site operators and the number and location of on-site instruments.

e) test result; including all statistical calculation data.

5.6 Result calculation

5.6.1 Count the number of colonies in each petri dish.

5.6.2 For the calculation of the average colony count of setting microbe at each test point, see equation (1).

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