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JAPANESE INDUSTRIAL STANDARD

Testing methods for collection efficiency of airborne microbe samplers

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Testing methods for collection efficiency
of airborne microbe samplers

K 3836-1995

1. Scope This Japanese Industrial Standard specifies the methods for testing the collection efficiency of the airborne microbe samplers used for measuring the concentration of the airborne microbes in bioprocess.

Remarks: The following standards are cited in this Standard:

- JIS B 8330 Testing methods for turbo-fans and blowers
- JIS B 9920 Measuring methods for airborne particles in clean room and evaluating methods for air cleanliness of clean room
- JIS B 9921 Light scattering automatic particle counter
- JIS B 9927 Cleanroom – Air filters – Test methods
- JIS K 0557 Water used for chemical analysis
- JIS T 8202 Portable type thermal anemometer
- JIS Z 8122 Contamination control – Vocabulary
- JIS Z 8901 Dusts and aerosols for industrial testing

2. Definitions For the purpose of this Standard, in addition to those specified in JIS Z 8122, the following definition applies.

airborne microbe sampler The device to collect the microbes floating in the air on to a suitable culture medium and, after cultivating for the specific time, obtain the number of collected microbes from the number of colonies of microbes appearing on the surface of culture medium.

3. Outline of testing method The method specified herein is that the biotic particles for testing (hereafter referred to as "biotic particles") or the abiotic particles for testing (hereafter referred to as "abiotic particles") are generated and then these particles are collected by means of the airborne microbe sampler in order to compare the measured values of the concentration (number of particles per unit volume) of the generated particles and the concentration of the particles collected by the airborne microbe sampler by this comparison, to test the collection efficiency of the airborne microbe sampler.

4. Test condition

4.1 Biotic particles The living beings used for the biotic particles shall be strong against the physical condition such as dry, hardly perished during the test, capable of being generated stably for a specific time as single substance by using a generator and not hazardous to human body (1).

These particles are sprayed by an aerosol constant generator. The particle size distribution is measured by the light scattering automatic particle counter specified in 5.2.

Note (1) The spores of *Bacillus subtilis* (*Bacillus globigii*) ATCC 9372, IFO 13721 and the like are used.

4.2 Abiotic particles The DOP particles specified in Class 14 of JIS Z 8901 or the PSL particles specified in Annex 1 to JIS B 9921 shall be used.

For the DOP particles, the particle size distribution is measured by the light scattering automatic particle counter specified in 5.2.

The range of particle size to be selected shall be the particle size divisions of 0.5 μm to 1.0 μm and 1.0 μm to 2.0 μm .

Remarks: Because it is impossible for the time being to find the biotic particles of relatively large particle size which are strong against physical condition, the confirmation of particle size of biotic particles and the compatibility of dispersion of measured values are measured by the abiotic particles and this measurement is substituted for the biotic particles.

4.3 Biotic particle suspension The biotic particle suspension shall be prepared by using the sterilized water of quality similar or superior to that of Class A2 specified in JIS K 0557.

4.4 Culture medium for measurement of airborne microbes It shall be suitable for the culture of biotic particles to be used.

Informative reference: If the biotic particles to be used are the spores of *Bacillus subtilis*, trypticase agar plate is used.

4.5 Temperature within measuring chamber It shall be the room temperature.

4.6 Humidity within measuring chamber It shall be the room humidity.

4.7 Cleanliness within measuring chamber It shall be cleaner than Class 3 (2) specified in JIS B 9920.

Note (2) Class 3 specified in JIS B 9920 is equivalent to the Class 1 in Federal Standard 209 D.

4.8 Wind speed within measuring chamber The wind speed within measuring chamber shall be that not hampering the collection of airborne microbes (3). The wind speed distribution shall be measured in accordance with Annex 1.

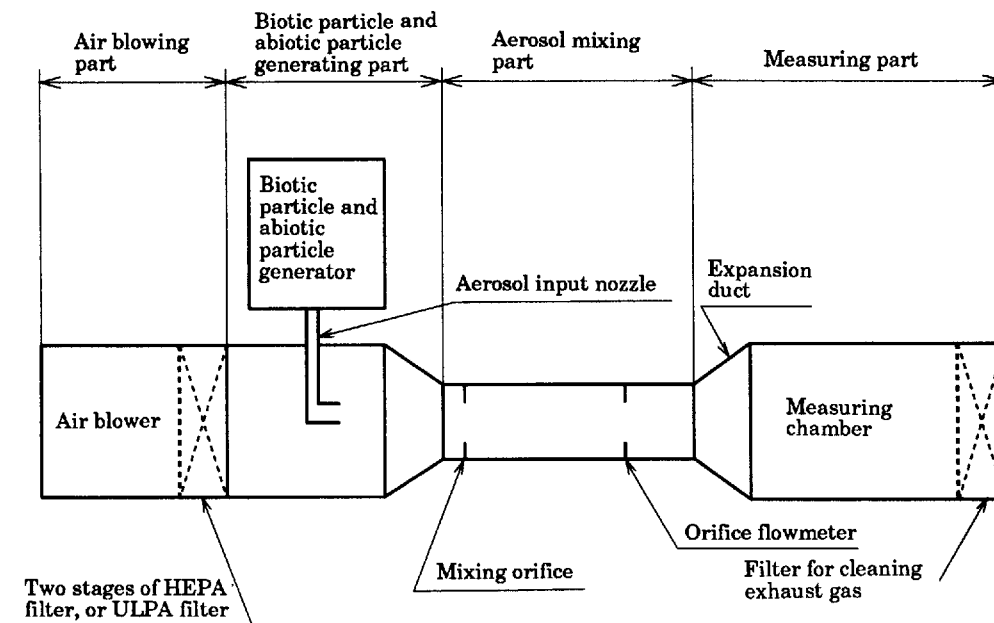
Note (3) For example, approximately 0.15 m/s.

5. Apparatus

5.1 Testing apparatus The testing apparatus shall consist of air blowing part, biotic particle and abiotic particle generating part, aerosol mixing part and measuring part. An example of the construction of testing apparatus is shown in Fig. 1.

Each part shall be as follows:

Fig. 1. An example of construction of testing apparatus



- (1) **Air blowing part** The air blowing part shall consist of two stages of HEPA filter or ULPA filter, air blower, etc. as described below:

- (a) **HEPA filter** It shall be of the performance capable of satisfying the requirement of 4.7 Cleanliness within measuring chamber of the test condition.

Remarks: A method for testing the performance of HEPA filter is specified in JIS B 9927.

- (b) **Air blower** It shall be of the performance capable of satisfying the test condition.

Remarks: A method for testing the performance of air blower is specified in JIS B 8330.

- (2) **Biotic particle and abiotic particle generating part** The biotic particle and abiotic particle generating part (hereafter referred to as "generating part") shall consist of biotic particle and abiotic particle generator (hereafter referred to as "generator") and aerosol input nozzle, and the generator shall be capable of obtaining the biotic and abiotic particles of uniform particle size and making the particles dried and unelectrified.
- (3) **Aerosol mixing part** The aerosol mixing part shall be of such shape, dimension and construction that the air sent from the air blowing part and the biotic particles and abiotic particles sent from the generating part are mixed sufficiently.
- (4) **Measuring part** The measuring part shall consist of expansion duct, measuring chamber equipped with airborne microbe sampler and filter for cleaning exhaust gas, as described below: