Pharmaceutical Industry Standard of the People's Republic of China

YY 0469-2011

Surgical Mask

This standard is drafted in accordance with the rules given in GB/T 1.1-2009.

Please note that certain elements of this document may relate to patents, and the publisher of this document assumes no responsibility for identifying such patents.

1. Scope

This specification covers the technical requirements of medical and surgical masks, test methods, marking and instructions for use and packaging, transportation and storage.

This standard applies to disposable masks worn by clinical medical personnel during invasive operations, etc.

2. Referenced Documents

The following documents are essential for the application of this document. Where a date-cited file is marked, only the date-cited version applies to this file. The latest version of any undated citation (including all change orders) applies to this document.

GB/T 14233.1-2008 Test methods for medical infusions, blood transfusions, syringes Part I: Chemical analysis methods

GB/T 14233.2-2005 Test methods for medical infusions, blood transfusions, syringes Part II: Biological test methods

GB/T 15979-2002 Standard for Disposable Sanitary Products

GB/T 16886.5-2003 Biological evaluation of medical devices Part 5: In vitro cytotoxicity testing

GB/T 16886.10-2005 Biological Evaluation of Medical Devices Part 10: Stimulus and Delayed Hairstyle Hypersensitivity Test

3. Terminology

The following terms and definitions apply to this document.

3.1 Medical-surgical masks are used to cover the user's mouth, nose and jaw to provide a physical barrier against direct transmission of pathogenic microorganisms, body fluids, particles, etc.

3.2 Synthetic blood Synthetic blood is a mixture of red dyes, surfactants, thickeners, and distilled water whose surface tension and viscosity can be representative of blood and other body fluids and have a similar color to blood. NOTE: Synthetic false nights used in this standard test do not have all the characteristics of blood or body fluids, such as polarity (wet), coagulability, and cellular material. [ASTM F1862-00a, Definition 3.1.9]

3.3 Particle Particle solid, liquid or solid and liquid granular matter suspended in air, such as dust, smoke, fog and microorganisms. [GB/T 12903-2008, definition 5.1.16]

3.4 Filtration Efficiency The percentage of particulate matter removed by the filter element under the specified test conditions. [GB 2626-2006, definition 3.16]

3.5 Bacterial Filtration Efficiency; BFE The percentage of mask material that is filtered out of

bacterial-containing suspended particles at a specified flow rate. [ASTM F2101-07, Definition 3.1.4]
3.6 Flame Retardation Properties prevents itself from being ignited and has the ability to burn with and without flames. [GB/T 12903-2008, definition 3.12]
3.7 Sterilization Sterilization is the physical or chemical killing of all microorganisms on the vector to render it sterile. [GB 15980-1995, definition 3.1]
3.8 Delayed-type hypersensitization Individuals exposed to a mutant produces specific T-cell-mediated immunological memory sensing, which causes a delayed-type hypersensitivity response upon re-exposure to the mutant. [GB/T 16886.10-2005, definition 3.5]
3.9 Stimulate a localized non-specific inflammatory response to Irritation caused by one, multiple or sustained contact with a substance material. [GB/T 16886.10-2005, definition 3.11]

4. Technical requirements

4.1 The appearance of the mask should be neat and in good shape, and the surface should not have any damage or stains.
4.2 Construction and size When worn, the mask should be able to cover the wearer's nose, mouth to jaw. Shall conform to the design dimensions and allowable errors of the sign.
4.3 Nose Clips 4.3.1 The mask shall be equipped with a nose clip made of a plastic material. 4.3.2 The length of the nasal clip should not be less than 8.0 cm.
4.4 Mask straps 4.4.1 The mask straps shall be easily accessible. 4.4.2 Each mask strap shall have a breaking force of not less than 10 N at the point of connection with the mask body.
4.5 Synthetic blood penetrates 2 ml of synthetic blood after spraying the outside side of the mask with 16.kPa (120 mmHg) pressure, there should be no penetration of the inside side of the mask.
4.6 Filtration Efficiency 4.6.1 Bacterial Filtration Efficiency (BFE) The bacterial filtration efficiency of the mask shall be not less than 95%. 4.6.2 Particle Filtration Efficiency (PFE) masks shall have a filtration efficiency of not less than 30% for non-oily particles.
4.7 Differential pressure ($\triangle$ p) The differential pressure ($\triangle$ p) between the two sides of the mask for gas conversion should be no greater than 49 Pa.
4.8 Flame retardant performance The mask material should be non-flammable; the mask should not burn for more than 5 s after leaving the flame.
4.9 Microbial indicators
4.9.1 Non-sterile masks shall meet the requirements of Table 1.

Total bacterial colonies CFU/g	Coliforms	Pseudomonas aeruginosa	Staphylococcus aureus	hemolytic streptococcus	fungus
$\leqslant$100	must not be detected	must not be detected	must not be detected	must not be detected	must not be detected

Table 1 Microbiological indicators of masks

4.9.2 Masks marked or illustrated with the words "sterile" or "sterile" on the package shall be sterile.
4.10 Ethylene oxide residue The ethylene oxide residue of a mask that has been sterilized with ethylene oxide shall not exceed 10 ug/g.

4.11 Skin irritation The primary irritation index of the mask material shall not exceed 0.4.
4.12 Cytotoxicity The cytotoxicity of the mask should be no greater than grade 2.
4.13 Delayed hairstyle hypersensitivity The mask material should be non-allergenic.

5. Test methods

5.1 Appearance A test with 3 samples, visually inspected, shall meet the requirements of 4.1.

5.2 Construction and Dimensions Testing with 3 samples, actually worn, and measured by pass-through or special gauges, shall meet the requirements of 4.2.

5.3 Nose clamp

5.3.1 The test with 3 samples, visually inspected and physically worn, shall meet the requirements of 4.3.1.

5.3.2 Tests with 3 samples, measured by pass-through or specialized gauges, shall meet the requirements of 4.3.2.

5.4 Masking tape

5.4.1 A test with three samples, whose adjustment is checked by wearing, shall meet the requirements of 4.4.1.

5.4.2 The results of the test with 3 samples, measured at a static pull of 10 N for 5 s, shall meet the requirements of 4.4.2.

5.5 Synthetic blood penetration test Sample size: 3 samples are used for the test. Sample pretreatment: the samples were pretreated at temperature (21 ± 5) °C and relative humidity (85 ± 5) % for at least 4 h and removed for 1 min. Test Procedure: The sample was fixed on the sample jig on the instrument (see Figure 1), 2 ml of synthetic blood with a surface tension of (0.042 ± 0.002) N/m (see Appendix A for configuration) was sprayed horizontally from a syringe with an inner diameter of 0.84 mm at a pressure of 16.0 kPa (120 mmHg) towards the target area of the sample under test at 30.5 cm from the center of the sample, and visually examined within 10 s after removal.

Results processing: check the inside of the sample for permeation on the sides. If the visual inspection is suspicious, the inside of the target area can be swabbed with an absorbent cotton swab or similar and then judged for synthetic blood penetration. The results should all meet the requirements of 4.5.

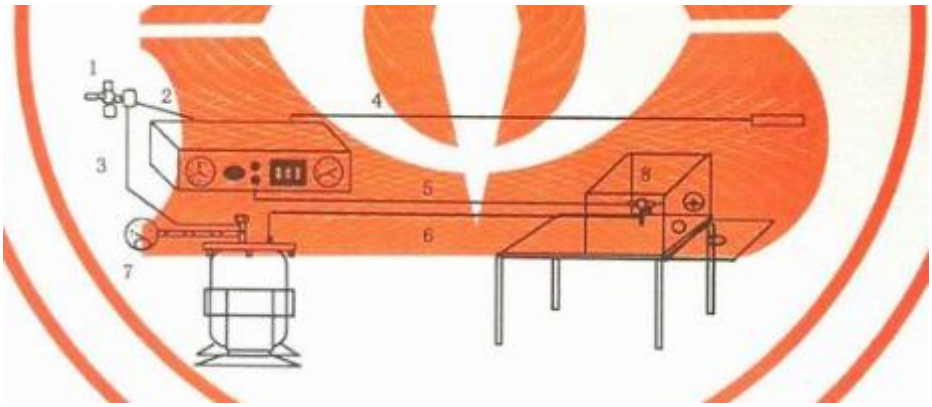

Figure 1 Schematic of synthetic blood test apparatus

1 - Filter/regulator - provides air supply.

2- Air line (outside diameter) to controller 12.7 mm, inside diameter 6.35 mm, pressure 1030 x 10^3Pa, length 193 cm.

3-Air lines (6.35 mm diameter, 300 cm length, plastic material).

4 - Wires from the controller to the valve switch.

5 - Air lines to valves (diameter 6.35 mm, length 150 cm, plastic material).

6 - Supply tube to the pneumatic valve (diameter 6.35 mm, length 94 cm, plastic material).

7 - Vessel pressure gauge.

8 - Valve screwed to a ring frame with a 42 cm long syringe.

5.6 Filtration efficiency

5.6.1 Bacterial Filtration Efficiency (BFE) shall be tested with three samples, tested in accordance with the methods in Appendix B, all of which shall meet the requirements of 4.6.1.

5.6.2 Number of Particulate Filtration Efficiency (PFE) samples: test with 3 samples. Sample pre-treatment: Prior to the test, samples were removed from the package and placed in an environment with (85 ± 5) % relative humidity and (25 ± 1) h at (38 ± 2.5) °C. The sample should then be sealed in an impermeable container and the test should be completed within 10 h of the end of the sample pretreatment. Test procedure: A sodium chloride aerosol or similar solid aerosol [median particle size diameter (CMD): (0.075 ± 0.020)um; geometric standard deviation of particle distribution: ≤ 1.86; concentration: ≤ 200 mg/m³] should be used in an environment with relative humidity (30 ± 10)% and temperature (25 ± 5)°C. The air flow rate is set to (30 ± 2) L / min and the area through which the air flow passes is 100 cm². Note: The median particle size diameter (CMD) corresponds to the median aerodynamic mass (MMAD) (0.24 ± 0.06) um.

5.7 Pressure differential

Sample size: 5 samples were used for the test.

Test procedure: The gas flow rate should be adjusted to 8 L/min, the diameter of the sample area should be 25 mm and the test area should be 4.9 cm2. Calculate the pressure difference (Δp) according to formula (1) and the result is reported as pressure difference value per square centimeter of area, which should comply with the provisions of 4.7.

$$\Delta p = \frac{P_M}{4.9} \quad \text{----------Formula（1）}$$

P_M : The mean value of the pressure difference of the test sample in Pa.

5.8 Flame retardant properties

Sample size: 3 samples were used for the test.

Test Procedure: Set the distance between the burner tip and the lowest part of the sample to (20 ± 2) mm, set the flame height to (40 ± 4) mm, and set the flame temperature to (800 ± 50) °C at (20 ± 2) mm above the burner tip.

The sample was worn on the head mold, the line of motion velocity of the head mold at the tip of the nose was set to (60 ± 5) mm/s, and the effect of the sample after one pass through the flame was recorded, recording the sum of the sustained and flame free burning time.

5.9 Microbiological indicators

Based on the condition of the sample, the following tests are performed.

a. Perform the test in accordance with the methods specified in appendix B to GB 15979-2002 and the results shall meet the requirements of 4.9.1.

b. Conduct sterility tests in accordance with the methods specified in Chapter 2 of GB/T 14233.2-2005, the results of which shall meet the requirements of 4.9.2.

5.10 Ethylene oxide residues

The test shall be carried out in accordance with the gas chromatography method specified in GB/T 14233.1-2008 and the results shall meet the requirements of 4.10.

5.11 Skin irritation

The test shall be performed in accordance with the methods specified in 6.3 of GB/T 16886.10-2005 and the results shall meet the requirements of 4.11.

5.12 Cytotoxicity

The test shall be performed in accordance with the methods specified in 8.2 of GB/T 16886.5-2003 and the results shall meet the requirements of 4.12.

5.13 Delayed hairstyle hypersensitivity reaction

The test shall be performed in accordance with the methods specified in 7.5 of GB/T 16886.10-2005 and the results shall meet the requirements of 4.13.

6. Signs

The minimum package of the mask should have a clear Chinese logo, if the package is transparent, the logo should be visible through the package. The logo should include, at a minimum.

a. Product name.

b. Date of production and/or lot number.

c. Name and contact details of the manufacturer.

d. Implementation standard number.

e. Product registration certificate number.

f. Instructions for use.

g. Storage conditions.

h. The word or symbol "single use".

i. In the case of sterilized products, the appropriate sterilization markings, indicating the sterilization method used and the expiration date.

j. Specifications and allowable errors.

k. Product use.

7. Packaging, transport and storage

7.1 Packaging

7.1.1 The packaging of the mask shall be such as to prevent mechanical damage and pre-use contamination.

7.1.2 Masks are boxed according to quantity.

7.2 Transport

Under the terms of the contract.

7.3 Storage

As required by the instructions for use.

Appendix A

A.1 Reagents

(Normative appendix)

Formulated composition of synthetic blood.

Sodium carboxymethyl cellulose (CMC, medium viscosity)	2 g
Twain 20	0.06 g
Sodium chloride (analytically pure)	4.5 g
Methylisothiazolinone (MIT)	0.5 g
Amaranth red fuel	1.0 g
Distilled water	Add to 1 L

A.2 Configuration methodology

Dissolve sodium carboxymethyl cellulose in 0.5 L water and mix on a magnetic stirrer for 60 min. Weigh spit 20 in a small beaker and add water to mix.

The Twain 20 solution was added to the sodium carboxymethyl cellulose solution described above and the beaker was washed several times with distilled water and added to the former solution.

Dissolve the sodium chloride in the solution. Add MIT and Amaranth Red Fuel. Dilute to 1 000 g with water.

The pH of the synthetic blood was adjusted to 7.3 ± 0.1 with 2.5 mol/L of sodium hydroxide solution.

The surface tension of synthetic blood should be (0.042 ± 0.002) N/m when measured with a surface tension meter. if this range is exceeded, it cannot be used.

Appendix B (Normative Appendix)

Bacterial Filtration Efficiency (BFE) Test Method

B.1 Test instruments and materials

B.1.1 Test instruments

A diagram of the test apparatus is shown in Figure B.1.

Autoclave (constant temperature 121 °C ~ 123 °C); incubator (constant temperature 37 °C + 2 °C); analytical balance (0.001 g); vortex mixer (16 mm x 150 mm tubes); orbital oscillator (100 r/min ~ 250 r/min); refrigerator (2 °C ~ 8 °C); six-layer live cell particle sampler; vacuum pump (57 L/m); air/pressure pump (at least 103 kPa); peristaltic pump (flow rate 0.01 mL/min); nebulizer; glass aerosol chamber (60 cm x 80 cm diameter glass tube); colony counter (400 colonies/plate possible); stopwatch (0.1 s accuracy); pipette (1.0 mL ± 0.05 mL); flow meter; aerosol condenser; pressure gauge (35 kPa ± 1 kPa accuracy); air conditioner.

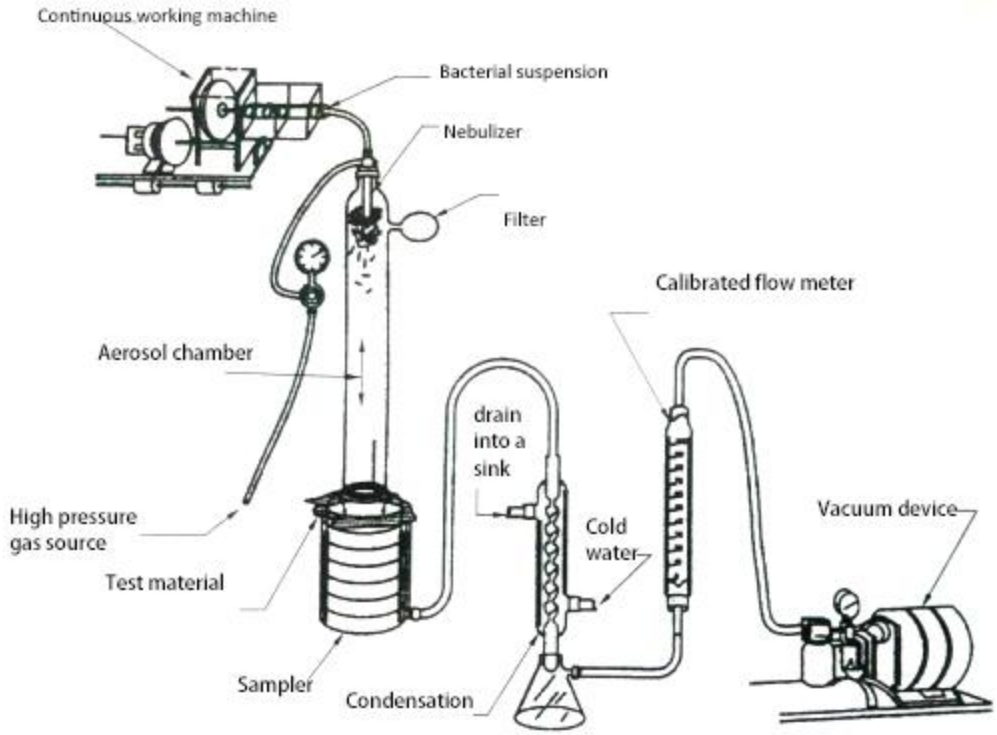

Figure B.1 Diagram of the Bacterial Filtration Efficiency Test Instrument

B.1.2 Materials

Conical flask (250 mL ~ 500 mL); Flat Petri dish; Pipette (1 mL, 5 mL, 10 mL); Stainless steel tube holder; Sterile glass flask (100 mL ~ 500 mL); Inoculation ring; Bottle stopper; Test tube (16 mm x 150 mm).

B.1.3 Reagents

Trypsin soy agar (TSA); trypsin soy broth (TSB); peptone water; Staphylococcus aureus ATCC 6538.

B.2 Sample Pretreatment

The samples were pretreated at a temperature of (21 ± 5) °C and relative humidity of (85 ± 5) % for at least 4 h before the test.

B.3 Preparation of bacterial suspensions for testing

Staphylococcus aureus ATCC 6538 was inoculated in an appropriate amount of trypsin soy broth and cultured at (37±2) °C for 24±2 h. The above cultures were then diluted with 1.5% peptone to a concentration of approximately 5 x 102 CFU/mL.

B.4 Test procedure

The gas flow rate through the sampler was controlled at 28.3 L/min, the time for delivery of bacterial suspension to the nebulizer was set to 1 min, and the air pressure and sampler running time were set to 2 min. The bacterial aerosol was collected on the trypsin soy dome as a positive

QC value, and the aerosol flow rate was calculated as (2 200 ± 500) CFU, otherwise the concentration of the culture had to be adjusted. and calculated the mean particle diameter (MPS) of the bacterial aerosol, which should be (3.0 ± 0.3) um; the pooled standard deviation of the bacterial aerosol distribution should not exceed 1.5.

After the positive QC test is completed, the agar plate is removed and labeled with the layer number. A new agar plate was then placed and the test sample was clamped to the top end of the sampler and was tested facing up. Sampling was carried out in accordance with the above procedures.

After a batch of test samples has been tested, the positive QC is tested again. Air samples from the 2 min aerosol chamber were then collected as negative QC, during which no bacterial suspension could be delivered to the nebulizer.

The test system (Figure B.2) can be used for both positive quality control and sample collection.

Agar plates were incubated at (37 ± 2) °C for (48 ± 4) h, and the colony-forming units (positive holes) of bacterial particle aerosol formation were counted and converted to the possible number of impacted particles using the conversion table (Table B.1). The converted values are used to determine the average level of bacterial particle aerosols delivered to the test sample.

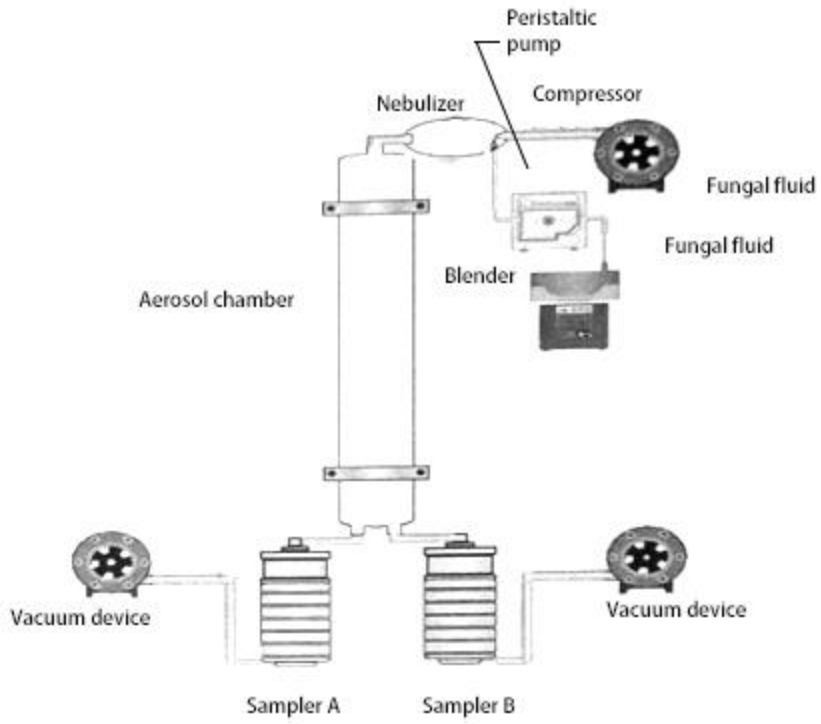

Figure B.2 Bacterial filtration efficiency two-way acquisition test instrumentation diagram

B.5 Calculation of results

Calculate the test results according to formula (B.1)

$$\mathrm{BFE} = \frac{c - T}{c} \times 100\% \text{ ---------- (B.1)}$$

c: Positive quality control average.

T: Sum of test sample counts.

r	P	r	P	r	P	r	P	r	P	r	P	r	P	r	P	r	P	r	P
1	1	11	11	21	22	31	32	41	43	51	55	61	66	71	78	81	91	91	103
2	2	12	12	22	23	32	33	42	44	52	56	62	67	72	79	82	92	92	105
3	3	13	13	23	24	33	34	43	45	53	57	63	69	73	81	83	93	93	106
4	4	14	14	24	25	34	36	44	47	54	58	64	70	74	82	84	94	94	107
5	5	15	15	25	26	35	37	45	48	55	59	65	71	75	83	85	96	95	108
6	6	16	16	26	27	36	38	46	49	56	60	66	72	76	84	86	97	96	110
7	7	17	17	27	28	37	39	47	50	57	61	67	73	77	86	87	98	97	111
8	8	18	18	28	29	38	40	48	51	58	63	68	75	78	87	88	99	98	112
9	9	19	19	29	30	39	41	49	52	59	64	69	76	79	88	89	101	99	114
10	10	20	21	30	31	40	42	50	53	60	65	70	77	80	89	90	102	100	115

Table B.1 Positive hole conversion table, Young surname hole calculation values (r) and corresponding corrected granular count values(P)

参 考 文 献

[1] Ahdersen, AA. 1958. New sampler for the collection, sizing, and enumeration of viable particles. J. B acteriol. 7 6;471-484

[2] ASTM F1670-98 Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Synthetic Blood.

[3] ASTM F1862-00a: Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity).

[4] EN 149-2001: Respiratory protective devices—Filtering half masks to protect against particles—Requirements, testing, marking.

[5] ASTM F2100-01 Standard Specification for Performance of Materials Used in Medical Face Masks.

[6] ASTM F2101-07 Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcusaureus.

[7] Guidance on the Content and Format of Premarket Notification [510 (k)] Submission for Surgical Mask. DRAFT. 1998.

[8] Greene VW, and Vesley D. 1962. Method for evaluation of effectiveness of surgical masks. J Bacterial 83:663-667.

[9] NIOSH 42 CFR 84: Regulation Tests and Requirements for Certification and Approval of Respiratory Protective Devices.

[10] EN 14683:2005 Surgical Masks-Requirements and test methods.

[11] AS 4381—2002 Single-use face masks for use in health care.

References

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