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INDUSTRY STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA

ICS 61.060

Y 28

File number: 43565-2013

QB/T 2881-2013

Replacing QB/T 2881-2007

Footwear and footwear components - Antibacterial performance specifications

鞋类和鞋类部件 抗菌性能技术条件

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Issued on: December 31, 2013

Implemented on: July 01, 2014

**Issued by: Ministry of Industry and Information Technology of the
People's Republic of China**

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Foreword

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

This standard is the revision of QB/T 2881-2007 “Antibacterial Technical Requirements for Footwear Linings & Insoles”. Compared with QB/T 2881-2007, the main technical changes are as follows:

- Change the standard name from “Antibacterial Technical Requirements For Footwear Linings & Insoles” to “Footwear and Footwear Components - Antibacterial Performance Specifications”;
- Expand the standard scope;
- Add and change the normative application documents;
- Add the terms and definitions of antibacterial shoes;
- Add the requirements for product identification;
- Add the sampling requirements;
- Modify the antibacterial test strains.
- Add the dissolution method and oscillation method. They are respectively as annex A and annex D;
- Add the dissolution indicators in requirements;
- Add the requirements for antibacterial agent in selection, which shall not affect the environment after product disposal;
- Adjust the indicators in table 1 of previous standard;
- Add Chapter 9 “Judgment”.

This standard was proposed by China National Light Industry Council.

This standard shall be under the jurisdiction of National Technical Committee on Footwear of Standardization Administration of China (SAC/TC 305).

Drafting organizations of this standard: ANTA (CHINA) CO., LTD., China Leather and Footwear Industry Research Institute, Fujian Nan'an Bangdeng Shoes Industry Co., Ltd., Fujian Zhangping Yingchuan Light Industrial Co., Ltd., and Jinda Nano Tech (Xiamen) Co., Ltd.

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Footwear and footwear components – Antibacterial performance Specifications

Warning: The test methods specified in this document require the use of related microorganisms. Only professionals who receive the training on microbiology and have practical experience can use microbiological testing method of this standard in laboratory with microbial treatment specifications. In consideration of laws and regulations of specific countries, appropriate safety measures shall be taken.

1 Scope

This standard specifies the terms and definitions, test environment, sampling, test strains, test method, requirements, determination, identification, and report of antibacterial performances of footwear and footwear components.

This standard applies to footwear and footwear components with antibacterial performance.

2 Normative references

The articles contained in the following documents have become part of this document when they are quoted herein. For the dated documents so quoted, all the modifications (including all corrections) or revisions made thereafter shall be applicable to this document.

GB 4789.2 National food safety standard Food microbiological examination: Aerobic plate count

GB/T 8629-2001 Textiles - Domestic washing and drying procedures for textile testing

GB 19489 Laboratories - General requirements for biosafety

3 Terms and definitions

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

3.1

Antibacterial

Annex A

(Normative)

Dissolution Test Method (Inhibition-Zone Test)

A.1 Principle

Use antibacterial agent to dissolve out constantly, and form different concentration gradients through agar diffusion, so as to show bacteriostatic action. The test is judged by whether antibacterial agent dissolves out or conforms to dissolution requirements of this standard based on inhibition-zone size.

A.2 Test conditions

A.2.1 Main equipment

Constant temperature incubator (37 ± 1)°C; freezer 5°C~10°C; second-level biological safety cabinet; pressure steam sterilizer; electrically heated drying oven; Vernier calliper; sterile test tubes; sterile pipette; sterile Erlenmeyer flask; inoculating loop; and alcohol lamp.

A.2.2 Preparation of materials

A.2.2.1 Control samples

It shall be the sterile dry filter paper in round of which the diameter is 15 mm, or in square of which the side length is 15 mm.

A.2.2.2 Samples

It shall be the suitable test samples in round of which the diameter is 15 mm, or in square of which the side length; the thickness is less than 4mm; cut from the antibacterial parts.

A.2.2.3 Sterilization

Sterilize the test sample and control sample before testing. Samples that are not suitable for treatment with disinfectant may be dried directly after being rinsed with sterile water and receiving ultraviolet irradiation for 1 h. Other instruments used in test may be sterilized through hot and humid method OR hot and dry method.

A.2.3 Culture medium and reagents

A.2.3.1 Nutrient broth (NB)

Add 5.0 g of beef extract, 10.0 g of peptone, and 5.0 g of sodium chloride to 1000 mL of distilled water. After dissolution by heating, adjust the pH through 0.1 mol/L sodium

Take 0.3 mL of bacterial solution that is prepared based on A.3.3; apply evenly to culture medium; cover with plate; stand for 5 min.

A.4.2 Sample placing

Paste to 3 contamination plates; each plate is pasted with 2 test samples and 2 control samples. Use sterile forceps to paste test sample to plate surface; sample center distance is less than 25 mm, and the distance from plate edge is not less than 15 mm. After pasting in place, use sterile forceps to gently press the samples so that the samples are very close to surface of the plate.

A.4.3 Culture and measurement

Cover the dish and cultivate at $(37\pm 1)^{\circ}\text{C}$ for 16 h~18 h. Use Vernier calliper to measure inhibition-zone (including sample) and record. Note that growth of some microbes may restore and make bacteriostasis circle smaller if incubation time is too long.

Full transparent inhibition-zone (the widest place in normal direction) shall be selected for inhibition-zone measurement. Measurement diameter shall be bounded by outer edge of inhibition-zone.

A.5 Expression of test results

A.5.1 Control sample shall not generate inhibition-zone, otherwise the test is invalid.

A.5.2 Calculate the inhibition-zone width (D) based on formula (A.1); take arithmetic mean value of 3 samples, and retain 2 significant figures.

$$D = \frac{T - R}{2} \dots\dots\dots (A.1)$$

Where,

D — Bacteriostatic ring width, in millimeters (mm);

T — Total width of bacteriostatic ring outer edge, in millimeter (mm);

R — Total width of test sample, in millimeter (mm).

B.2.2.3 Sterilization

High-pressure steam sterilization is usually adopted at 115°C for 30 min. For the test samples that are not heat-resisting or that hot and humid disinfection method may easily affect antibacterial performance, other suitable methods may also be used for sterilization.

Sterilization treatment before sample test shall not affect antibacterial performance of test sample.

B.2.3 Medium and reagents

B.2.3.1 Nutrient broth culture medium (NB)

See A.2.3.1.

B.2.3.2 Nutrient agar culture medium (NA)

See A.2.3.2.

B.2.3.3 Potato Dextrose Agar (PDA)

Add 200.0 g of peeled and diced potatoes; add 1000 mL of distilled water; boil for 10 min~20 min; filter with gauze; add additional distilled water to 1 000mL. Then add 20.0 g of glucose and 20.0 g of agar; after heating to dissolve and packing, place into pressure steam sterilizer at 115°C for 30 min.

B.2.3.4 Plate count agar (PCA)

Add 2.5 g of yeast extract, 5.0 g of tryptone, 1.0 g of glucose, and 15.0 g of agar to 1000 mL of distilled water or deionized water; place into a conical flask to mix; sufficiently dissolve in boiling water. Then use 0.1mol/L sodium hydroxide solution or 0.1mol/L hydrochloric acid to adjust the pH to 7.0~7.2 (25°C); apply tampon; then place into pressure steam sterilizer for sterilization at 115°C for 30 min.

B.2.3.5 Phosphate buffered saline (PBS)

Add 2.83 g of anhydrous disodium hydrogen phosphate and 1.36 g of potassium dihydrogen phosphate to 1 000 mL of distilled water; after complete dissolution, use 0.1mol/L sodium hydroxide solution or 0.1mol/L hydrochloric acid to adjust the pH to 7.1~7.4 (25°C); place into pressure steam sterilizer for sterilization at 121°C for 15 min.

B.2.3.6 Eluent

Normal saline solution that contains 0.85% of sodium chloride. To facilitate the elution, add a small amount of sterile surfactant (e.g. Tween-80); use 0.1mol/L sodium hydroxide solution or 0.1mol/L hydrochloric acid to adjust the pH so that the pH after sterilization is 7.0~7.2 (25°C); place into pressure steam sterilizer for sterilization at 121°C for 15 min after packing.

Annex C

(Normative)

Membrane Contact Method

C.1 Principle

This method is used to make microorganisms to contact surfaces of samples by membrane pasting method through inoculation of quantitative microorganisms to surface of samples to be tested; measure the viable count of sample after cultivating for certain time by membrane pasting method; then calculate the antibacterial rate of test sample.

C.2 Test conditions

C.2.1 Main equipment

See B.2.1.

C.2.2 Preparation of material

C.2.2.1 Cover film

Polyethylene film: standard size is (40 ± 2) mm x (40 ± 2) mm, thickness is 0.05 mm~0.10 mm. If boundary dimension of test sample is small, cover film size may be decreased based on its size and that the number of bacteria distributing on sample cover film is ensured unchanged. Use 70% ethanol solution to soak for 3 min; wash with sterile water and dry naturally.

C.2.2.2 Control samples

3 control samples: made of medical polyethylene sheet; size is (50 ± 2) mm× (50 ± 2) mm, thickness is less than 10 mm, or the size is same as test sample.

C.2.2.3 Test samples

Take 3 test samples, of which the size is (50 ± 2) mm× (50 ± 2) mm and the thickness is 5 mm. If test size cannot meet the requirements for standard sample, the minimum size shall not be less than 20 mm×20 mm, and the cover film shall also be decreased accordingly.

C.2.2.4 Sterilization

Use 70% ethanol solution to wipe the control samples and test samples for 2 times respectively; and wash with sterile water for 1 time; other suitable methods may also be adopted for sterilization. Sterilization treatment before test shall not affect antibacterial performance of test sample.

D.4 Preparation of bacterial solution

Strain preservation, strain activation, and strain suspension preparation process are the same as B.3; select the diluent of which the bacterial solution concentration is 2.5×10^4 CFU/mL~ 10.0×10^4 CFU/mL AS the bacterial solution for test.

D.5 Test procedures

D.5.1 Inoculation

Add (50±0.5)mL of bacterial solution that is prepared based on B.3.3 respectively to conical flasks of control samples and test samples; shake at 150 r/min for (60±5)s.

D.5.2 Vibration contact time counting

After shaking for 1 min, respectively sample the control samples and test samples to dilute; use plate count agar (PCA) to conduct viable counting according to requirements of GB 4789.2.

D.5.3 Vibration contact culture

Put the counted control samples and test samples into shaking incubator after capping; based on rotating speed of 150 r/min, cultivate the samples that are inoculated with *Klebsiella pneumoniae* (6.1) or *Staphylococcus aureus* (6.2) at (37±1)°C for 24 h; for samples inoculated with *Candida albicans* (6.3), cultivate at (28±1)°C for 48 h.

D.5.4 Viable counting after vibration contact for certain time

After vibration, and after control sample solution and test sample solution are appropriately diluted, respectively take 1.0 mL of sample solutions; and inoculate to sterile dishes. Each solution is in-parallel inoculated to 2 dishes. For *Klebsiella pneumoniae* (6.1) and *Staphylococcus aureus* (6.2), pour dissolved nutrient agar (NA) at 45°C~55°C; turn over the plate after nutrient agar (NA) solidifies; place above plates into constant temperature incubator at (37±1)°C for viable bacteria cultivation counting. For *Candida albicans* (6.3), it need to pour the dissolved potato culture medium (PDA) at 45°C~55°C; turn over the plate after potato dextrose medium (PDA) solidifies; place above plates into constant temperature incubator at (28±1)°C to conduct viable culture counting.

D.6 Expression of test results

D.6.1 Number of viable bacteria

The viable count that is obtained from colony counting according to formula (B.1).

Take 2 significant figures when recording the number of viable bacteria.

D.6.2 Effective test conditions

E.2.3 Wash for 2 min for the first time; fish out the fabrics and dehydrate for 30 s and then wash with fresh water for a second time.

E.2.4 Wash for the second time for 2 min; take out the fabrics and dehydrate for 30 s.

E.2.5 Above 3 steps E.2.2, E.2.3 and E.2.4 are deemed as a cycle, counted as 1-time washing. Repeat these 3 steps until predetermined number of washes. To prevent the detergent residue to interfere the antibacterial test, pay attention that the last-time washing shall use a lot of water for complete removal; dry the fabrics after dehydrating; then, it may be used for antibacterial performance test.

_____ **END** _____