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**Antibacterial products — Test for
antibacterial activity and efficacy**

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Foreword

This translation has been made based on the original Japanese Industrial Standard revised by the Minister of Economy, Trade and Industry through deliberations at the Japanese Industrial Standards Committee as the result of proposal for revision of Japanese Industrial Standard submitted by Society of Industrial technology for Antimicrobial Articles (SIAA)/Japanese Standards Association (JSA) with the draft being attached, based on the provision of Article 12 Clause 1 of the Industrial Standardization Law applicable to the case of revision by the provision of Article 14.

Consequently JIS Z 2801 : 2006 is replaced with this Standard.

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Antibacterial products — Test for antibacterial activity and efficacy

Introduction

This Japanese Industrial Standard has been prepared based on the first edition of ISO 22196 published in 2007 with some modifications of the technical contents to meet technology trend, actual situation, etc. in Japan.

The portions given sidelines or dotted underlines are the matters in which the contents of the original International Standard have been modified. A list of modifications with the explanations is given in Annex JA.

1 Scope

This Standard specifies the test for antibacterial activity and efficacy to bacteria on the surface of antibacterial products (including intermediate products) of plastic products, metal products, ceramics products, etc. excluding the textile products and the photocatalyst products.

Secondary effects of antibacterial efficacy such as fungal resistance, odour prevention and biodeterioration are not covered by this Standard.

NOTE 1 For the products so determined that the test method for textile products should be applied from their usage, shape, etc., clause 10 (Quantitative test) of JIS L 1902 may be applied.

NOTE 2 The International Standard corresponding to this Standard and the symbol of degree of correspondence are as follows.

ISO 22196 : 2007 *Plastics — Measurement of antibacterial activity on plastics surfaces* (MOD)

In addition, symbols which denote the degree of correspondence in the contents between the relevant International Standards and JIS are IDT (identical), MOD (modified), and NEQ (not equivalent) according to ISO/IEC Guide 21-1.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this Standard. The most recent editions of the standards (including amendments) indicated below shall be applied.

JIS K 0050 *General rules for chemical analysis*

JIS K 0950 *Sterilized plastic petri dishes*

JIS K 0970	<i>Piston operated micro-volumetric apparatus</i>
JIS K 3800	<i>Class II biological safety cabinets</i>
JIS K 8101	<i>Ethanol (99.5) (Reagent)</i>
JIS K 8150	<i>Sodium chloride (Reagent)</i>
JIS K 8180	<i>Hydrochloric acid (Reagent)</i>
JIS K 8263	<i>Agar (Reagent)</i>
JIS K 8576	<i>Sodium hydroxide (Reagent)</i>
JIS K 9007	<i>Potassium dihydrogen phosphate (Reagent)</i>
JIS K 9017	<i>Dipotassium hydrogenphosphate (Reagent)</i>
JIS R 3505	<i>Volumetric glassware</i>
JIS Z 8802	<i>Methods for determination of pH of aqueous solutions</i>

3 Terms and definitions

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

3.1 antibacterial

a state where the growth of bacteria on the surfaces of products is inhibited

3.2 antibacterial agent

agent that inhibits the growth of bacteria on the surfaces of products by using it directly or as a compounded agent

3.3 antibacterial treatment

treatment for antibacterial purpose

3.4 antibacterial product

product on which antibacterial treatment has been performed

3.5 antibacterial activity

value which shows the difference in logarithmic values of number of viable bacteria between the antibacterial product and the untreated product after inoculation followed by incubation of bacteria

3.6 antibacterial effectiveness

effectiveness of antibacterial product determined from the antibacterial activity

4 Antibacterial effectiveness

The antibacterial product is determined that it has the antibacterial effectiveness, when the antibacterial activity thereof obtained according to the testing method of this

Standard is 2.0 or more.

In addition, the value of over 2.0 may be applicable to the determination of antibacterial effectiveness upon the agreement between the parties concerned with delivery.

5 Testing method

5.1 Bacteria to be used for test

The species of bacteria to be used for the test shall be as follows, and the test shall be carried out on respective bacteria.

a) *Staphylococcus aureus*

b) *Escherichia coli*

Examples of bacterial strain to be used for the test are shown in table 1. If the bacterial strain is contributed by the agency of culture collection other than that shown in table 1, it shall be obtained from member agencies of World Federation for Culture Collections (WFCC) or Japan Society for Culture Collections (JSCC), and it shall be the bacterial strain of the same series as that shown in table 1.

Table 1 Bacterial strain used for test

Type of bacteria	Preservation number of bacterial strain	Agency of culture collection
<i>Staphylococcus aureus</i>	ATCC 6538P FDA 209P NBRC 12732	American Type Culture Collection Food and Drug Administration Bioresource Information Center, Department of Biotechnology of National Institute of Technology and Evaluation
	CIP 53.156 DSM 346	Collection des Bacteries de l'Institut Pasteur Deutsche Sammlung von Mikroorganismen und Zellkulturen GmbH
	NCIB 8625	National Collection of Industrial and Marine Bacteria Ltd.
<i>Escherichia coli</i>	ATCC 8739 NBRC 3972	American Type Culture Collection Bioresource Information Center, Department of Biotechnology of National Institute of Technology and Evaluation
	CIP 53.126 DSM 1576	Collection des Bacteries de l'Institut Pasteur Deutsche Sammlung von Mikroorganismen und Zellkulturen GmbH
	NCIB 8545	National Collection of Industrial and Marine Bacteria Ltd.

5.2 Chemicals, materials, instruments and apparatuses

The chemicals, materials, instruments and apparatuses used in this Standard shall be as follows, unless otherwise designated.

<u>Ethanol (C₂H₅OH)</u>	<u>Guaranteed reagent specified in JIS K 8101 or superior</u>
<u>Beef extract</u>	<u>For microbial test</u>
<u>Peptone</u>	<u>For microbial test</u>
<u>Sodium chloride (NaCl)</u>	<u>Guaranteed reagent specified in JIS K 8150</u>
<u>Purified water</u>	<u>Conforming to the reference of the 15th revised Japanese Pharmacopoeia</u>
<u>Agar</u>	<u>Guaranteed reagent specified in JIS K 8263 or superior</u>
<u>Yeast extract</u>	<u>For microbial test</u>
<u>Tryptone</u>	<u>For microbial test</u>
<u>Glucose</u>	<u>For microbial test</u>
<u>Casein peptone</u>	<u>For microbial test</u>
<u>Soybean peptone</u>	<u>For microbial test</u>
<u>Lecithin</u>	<u>For microbial test</u>
<u>Nonionic surfactant</u>	<u>Polyoxyethylene sorbitan monooleate</u> <u>[Polysorbate 80 (Tween80)]</u>
<u>Potassium dihydrogenphosphate (KH₂PO₄)</u>	<u>Guaranteed reagent specified in JIS K 9007</u>
<u>Dipotassium hydrogenphosphate (K₂HPO₄)</u>	<u>Guaranteed reagent specified in JIS K 9017</u>
<u>Sodium hydroxide (NaOH)</u>	<u>Guaranteed reagent specified in JIS K 8576</u>
<u>Hydrochloric acid (HCl)</u>	<u>Guaranteed reagent specified in JIS K 8180</u>
<u>Cotton stopper</u>	<u>OME cotton, or silicone stopper, metal stopper, morton stopper, etc.</u>
<u>Platinum loop</u>	<u>With a loop of about 4 mm at the point.</u>
<u>Dry-heat sterilizer</u>	<u>Capable of keeping the temperature from 160 °C to 180 °C</u>
<u>Autoclave</u>	<u>Capable of keeping at 121 °C in temperature (corresponding to 103 kPa in pressure)</u>
<u>Safety cabinet</u>	<u>Having performance conforming to JIS K 3800 or equivalent</u>
<u>pH meter</u>	<u>Conforming to JIS Z 8802</u>
<u>Chemical balance</u>	<u>Having performance conforming to JIS K 0050 or equivalent</u>
<u>Clean bench</u>	<u>For microbial test</u>
<u>Measuring pipette</u>	<u>Having precision conforming to JIS K 0970 or Class A in</u>