Voluntary Specifications for Quality and Safety

1. Objective

These detailed rules stipulate the specifications for the quality and safety of antibacterial products, antifungal products, antiviral products, or industrial sterilization coating materials (hereinafter referred to as "products"), as well as antibacterial agents, antifungal agents, antiviral agents, or industrial sterilization coating agents used to bring out their functions (hereinafter referred to as "agents") registered with this society, in order to maintain the qualities of such products and agents at constant levels.

2. Scope

(Antibacterial agents, antiviral agents, and industrial sterilization coating agents) These specifications shall apply to the antibacterial agents, antiviral agents, or industrial sterilization coating agents that are or are going to be commercially available in Japan or the countries listed in the Attached Table of the Admission Provisions Operating Manual. (Antifungal agents) These specifications shall apply to the antifungal agents that are or are going to be commercially available in Japan.	(Antibacterial products, antiviral products, and industrial sterilization coating materials) These specifications shall apply to the antibacterial products, antiviral products, or industrial sterilization coating materials that are or are going to be commercially available in Japan or the countries listed in the Attached Table of the Admission Provisions Operating Manual. (Antifungal products) These specifications shall apply to antifungal products that are or are going to be commercially available in Japan.

3. Terminology

Term 3 of the "Provisions Concerning Labeling, Terminology, etc." shall apply.

4. Antibacterial Performance Criteria

(Antibacterial agents) The antimicrobial agent shall meet the antimicrobial performance criteria based on the minimum inhibitory concentration (MIC) shown in Table 1, depending on the type of antimicrobial agent.	(Antibacterial products) After being treated by the "Durability Test Method," an antibacterial product shall conform to the antibacterial performance criteria shown in Table 2[1)].

Note 1) Clearance of the antibacterial performance criteria for antibacterial products shall be determined by a JNLA-certified test institution that is a member of this society and certified by a logo-bearing test result certificate issued by JNLA. However, if the determination is made using a test method other than that specified in Term 5.2 of JIS Z2801, a test result certificate shall be issued but shall not bear the JNLA logo. A durability test shall also be performed at a JNLA-certified test institution that is a member of this society.

Table 1. Antibacterial Performance Criteria for Antibacterial Agents

		Test method (Competent institution)	Antibacterial performance criteria	Remarks
Minimum inhibitory concentration	Bacteria	Minimum inhibitory concentration determination method I[1)] (Society of Industrial Technology for Antimicrobial Articles)	Not more than 800 μg/mL	Applied to slightly soluble antibacterial agents.
		Minimum inhibitory concentration determination method[2)] (Japan Society of Chemotherapy)	Not more than 800 μg/mL	Applied to freely soluble or freely dispersible antibacterial agents.

Note 1) The "minimum inhibitory concentration determination method I" specified by this society shall be used.

2) One of the minimum inhibitory concentration (MIC) determination methods specified by the Japan Society of Chemotherapy shall be used.

Table 2. Antibacterial Performance Criteria for Antibacterial Products

	Test method	Antibacterial performance criteria	Remarks
Bacteria	Methods specified in Term 5.2 of JIS Z 2801[1-1)-1-2)]	Antibacterial activity value not less than 2.0[3)]	This test method shall, as a rule, be used except for photocatalytic antibacterial products. For products having a shape such that this method is inapplicable, the test may be performed using a test piece in tabular form.
	JIS K 6400-9	Antibacterial activity value not less than 2.0[3)]	Shall be used only for products having a shape such that none of the JIS Z 2801 methods is applicable. (Example: soft foam material)
	Antibacterial power test method II[2)] (shaking method)	Antibacterial activity value not less than 2.0[3)]	Shall be used only for products having a shape such that none of the JIS Z 2801 methods is applicable. (Example: soft foam material)
	Antibacterial power test method IV[4)] (Film contact method for liquid water-absorbent substances)	Antibacterial activity value not less than 2.0[3)]	Shall be used only for products having a shape such that none of the JIS Z 2801 methods is applicable. (Example: sheets)

Note 1-1) For products that can undergo interference of the manifestation of their antibacterial performance due to air blockade caused by the film placed thereon, products that allow the bacterial liquid to diffuse over the entire surface of the test piece even without the film mounted thereon because of water absorption or any other reason, and the like, the film-mounting step may be omitted from this method. Note that according to the definition established by this society, an untreated test piece refers to a test piece collected directly from an untreated product.

1-2) Untreated sample pieces

(i) In "JIS Method 5.2.6 (b) Preparation of Test Pieces", the statement appears: "If no untreated test pieces are available, the film defined in 5.2 may be used." Regarding this, the following rule shall apply."An untreated sample piece must be derived from a product that has not undergone antibacterial treatment. An untreated test piece must be prepared

using the same material and treatment method as for the test sample. However, if such an untreated sample is unavailable, a sample prepared from a material of the same quality of chemical composition and structure* having undergone the same treatment method may be used. In this case, details of the untreated test piece shall be specified in the description of the test method.

Footnote*) As used herein, the term material of the same quality of refers to a material having the same chemical ingredients and chemical structure."

(ii) If it is impossible to fulfill the requirements for test validity of JIS Z 2801(2010) 5.8a) 2) ～3) because there is the decrease of the bacterial count in the untreated test piece per se, the culture medium concentration of the test liquid inoculum may be increased above 1/500 NB, but the culture medium concentration of the treated test piece shall be the same culture medium concentration of the untreated test piece. In this case, the testing method shall be the "film contact method" and the diluted concentration shall be indicated. If this testing method was used, the SIAA brand mark without ISO number shall be indicated.

2) The "antibacterial power test method II for antibacterial products (shaking method)" specified by this society shall be used.
3) For all test microorganisms specified for each test method, the antibacterial activity value must not be less than 2.0.
4) The "antibacterial power test method IV for antibacterial products (film contact method for liquid-absorbing materials)" specified by this society shall be used.

5. Antifungal Performance Criteria

(Antifungal agents)	(Antifungal products)
An antifungal agent shall be an antifungal agent that meets the antifungal performance criteria shown in Table 3, which are based on the evaluation test method for the antifungal effect for antifungal agents.	After being treated by the "Durability Test Method," an antifungal product shall conform to the antifungal performance criteria shown in Table 4.[1)]

Note 1) The report of Antifungal Test issued by supporting member or Antibacterial and Antifungal Test Manager of this society shall be used.

Table 3. Antifungal Performance Criteria for Antifungal Agents

		Test method (Competent institution)	Antifungal performance criteria	Remarks
Minimum inhibitory concentration	Molds	The evaluation test method for the antifungal effect for antifungal agents[1)] (SIAA)	Not more than 800 μg/mL	

Note 1) The "evaluation test method for the antifungal effect for antifungal agents, minimum inhibitory concentration determination method and MIC determination method to fungi by the agar plate dilution method" specified by this society shall be used.

Table 4. Antifungal Performance Criteria for Antifungal Products

	Test method	Antifungal performance criteria	Remarks
Molds	JIS Z 2911-2000 methods[1)] ASTM G21-96 method	Shall be rated lesser by one grade or more than untreated products[2), 3)].	For products having a shape such that this method is inapplicable, the test may be performed using a test piece in tabular form.

Note 1) The JIS Z 2911 (2010) methods include a variety of methods by material and intended use. Choose the appropriate test method in accordance with the standard "antibacterial power. If the rating criteria are 5 levels or more, the processed product is 0 to 2 and the unprocessed product is 2 or more.
Note 2) In ASTM G21-96 method, the processed product is 0 to 2 and the unprocessed product is 2 or more.
Note 3) If the judgment results vary between test pieces of the same level, conformity with the antifungal performance standard shall be judged by the median.

6. Antiviral Performance Criteria

(Antiviral agents) (The antiviral performance of an antiviral agent shall be determined based on its antiviral activity, and no performance criteria is specified for antiviral agents.	(Antiviral products) After being treated by the "Durability Test Method," an antiviral product shall conform to the antiviral performance criteria shown in Table 5.

Table 5. Antiviral Performance Criteria for Antiviral Products

	Test method	Antiviral performance criteria	Remarks
Viruses	ISO 21702 methods	Antiviral activity: 2.0 or higher Shall be tested using at least one type of influenza virus or feline calicivirus.	For products having a shape such that this method is inapplicable, the test may be performed using a test piece in tabular form.

Note 1) The antiviral performance of antiviral products shall be tested by any of the following seven test institutions, and the antiviral test report issued by the relevant test institution shall be submitted:
Japan Food Research Laboratories, KAKEN TEST CENTER General Incorporated Foundation, Boken Quality Evaluation Institute, Japan Textile Products Quality and Technology Center, Nissenken Quality Evaluation Center, Technical Evaluation Center, DAIWA CHEMICAL INDUSTRY CO.,LTD., Kanagawa Institute of Industrial Science and Technology.

7. Performance Criteria for Industrial Sterilization Coating Materials

(Industrial sterilization coating agents) The performance of an industrial sterilization coating agent shall be determined based on the performance of the industrial sterilization coating material, and no performance criteria are specified for industrial sterilization coating agents.	(Industrial sterilization coating materials) An industrial sterilization coating material shall conform to the performance criteria shown in Table 6, after being treated in a durability test performed using a test piece which is made of an appropriate material chosen from among the applications of the registered product and is coated with this material.

Table 6. Performance Criteria for Industrial Sterilization Coating Materials

	Test method	Performance criteria for industrial sterilization coating materials[1)]	Remarks

Bacteria	JIS Z 2811	All of the following three criteria shall be satisfied: - Initial reduction value: 2.0 or higher - Repetitive reduction value: 2.0 or higher - Comparative repetitive reduction value: 2.0 or higher	A test piece[2)] that is coated under the specified coating conditions shall be used.

1) The effects on all test microorganisms specified by the test method shall satisfy the above criteria.
2) The material of the test piece shall be indicated in a voluntary registration data sheet.

* The performance of industrial sterilization coating materials shall be tested by any of the following test institutions that are the members of the committee drafting JIS Z 2811:2021, and a copy of the test report issued by the relevant test institution shall be submitted:
Japan Food Research Laboratories, Boken Quality Evaluation Institute, Japan Textile Products Quality and Technology Center

8. Safety Criteria

8.1 Basic Considerations

None of the chemical substances listed below shall be used intentionally as a component of an antibacterial, antifungal, antiviral, or industrial sterilization coating agent.

Note) The chemical substances that must not be included as ingredients of antibacterial agents and antifungal agents are as follows:

(i) Chemical substances not listed in the Law Concerning the Examination and Regulation of Manufacture etc. of Chemical Substances (1973 Law No. 117) (hereinafter referred to as Chemical Substances Examination Law) and relevant regulations

(ii) Specified chemical substances of 1st kind (Article 2-2 of Chemical Substances Examination Law), specified chemical substances of 2nd kind (Article 2-3 of Chemical Substances Examination Law), chemical substances designated as monitoring chemical substances (Article 2-4 of Chemical Substances Examination Law) by the Enforcement Rules for the Chemical Substances Examination Law. Regarding the products designated as priority assessment chemical substances (Article 2-5 of Chemical Substances Examination Law), Term 3-6 of the provisions for voluntary registration of quality and safety data etc. shall apply.

(iii) The radioactive substances specified in Article 2, paragraph (2), of the Regulation on the Prevention of Ionizing Radiation Hazards.

(iv) The substances regulated by the Restriction of Hazardous Substances (RoHS) Directive.

(v) The poisonous or deleterious substances specified by the Poisonous and Deleterious Substances Control Act or Cabinet Order for the Designation of the Poisonous and Deleterious Substances. (The exceptions to this control act or cabinet order specifying substance names or concentrations shall apply, if set forth.)

(vi) The chemical substances subject to control by the Law governing the Control of Household Products Containing Harmful Substances (1973 Law No. 112) and relevant regulations.

(vii) Other substances recognized by this society as being problematic regarding safety.

8.2 Safety Criteria for Antibacterial Agents, Antiviral Agents, or Industrial Sterilization Coating Agents

Antibacterial agents, antiviral agents, or industrial sterilization coating agents shall meet all the safety criteria shown in Table 7 when evaluated by safety tests performed by a public organization or equivalent organization.

Table 7. Safety Criteria for Antibacterial Agents, Antiviral Agents, or Industrial Sterilization Coating Agents[1)]

Safety test item	Safety test method[2)]	Example of official method [3)]	Safety criteria[4)]
Acute oral toxicity	Single-dose toxicity tests using rodents	- OECD TG420 (Fixed dose procedure) - OECD TG423 (Toxic class procedure) - OECD TG425 (Up-and-down procedure)	The determined LD_{50} shall exceed 2,000 mg/kg weight.
Primary skin irritation	Primary skin irritation tests or in vitro alternative methods using rabbits	- OECD TG404 (Rabbit skin irritation test/corrosivity) - ASTM (F719-81) - Draise method	No irritable reactions shall be observed, or the irritancy shall be weak if any (primary irritancy index P.I.I. < 2.00).
		- OECD TG439 (*in vitro* skin irritancy)	Non-irritant
Mutagenicity	Reverse mutation test (Ames test)	- Methods stipulated in the notification of the Industrial Safety and Health Act - Test methods related to new chemical substances listed in the Chemical Substances Examination Law - OECD TG471 (Preincubation method or Plate method shall be used. Five strains or more shall be used.)	The sample shall test negative for mutagenicity[7)].
Skin sensitization potential	Sensitization test using guinea pigs or local lymph node assay (LLNA) using mice	- Guidance on Test Methods for Biological Safety Evaluation of Medical Devices (Attachment to the Notification No. 0106 1 of the Ministry of Health, Labour and Welfare, Pharmaceutical and Food Safety Bureau, Evaluation and Licensing Division)[6)] (Adjuvant and Patch Test or Maximization Test) - OEcD TG406 (Maximization Test or Buehler method)	The sample shall test negative.
		- Guidance on Test Methods for Biological Safety Evaluation of Medical Devices (Attachment to the Notification No. 0106 1 of the Ministry of Health, Labour and Welfare,	

		Pharmaceutical and Food Safety Bureau, Evaluation and Licensing Division)[6)] (LLNA method) - OECD/TG429 (LLNA/RI) - OECD/TG442A (LLNA/DA) - OECD/TG442B (LLNA/Brdu-ELISA)	

Note 1) Safety testing shall be performed on bulk material, and the criteria shall be fulfilled. If the criteria are not met with bulk material, dilute the bulk material and perform the test to confirm the fulfillment of the criteria. In this case, however, the concentration used in the product, in view of data dispersion, shall not be more than half the maximum concentration for confirmed safety.

2) As safety test data on agents, test results published in public evaluation documents may be cited. For the reliability of such data, "Concerning reliability assessment of hazardousness data on human health effects in the Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture" shall be referred to, and such data shall be able to withstand the evaluation. However, safety tests shall be carried out separately for nanomaterials.

3) Other test methods, which are generally recognized as equivalent or more rigid, may also be used.

4) Regarding primary skin irritation, mutagenicity and skin sensitization potential, fulfillment of the safety criteria by the bulk material shall be deemed the clearance of the criteria by the diluted material.

5) If a positive result is obtained in the Ames test, mutagenicity can be evaluated comprehensively by carrying out more than one advanced test [Example: any one of the chromosome aberration test using cultured mammalian cells (OECD/TG473), mouse lymphoma TK test (OECD/TG476), or in vitro mammalian cell chromosomal aberration test (OECD/TG473), as well as micronucleus test using rodents (OECD/TG474)].

6) Although the test methods are based on extraction, as a rule, because they are for medical equipment, the tests shall be carried out using bulk material or dilutions according to this standard.

8.3 Safety Criteria for Antibacterial Products, Antiviral Products, or Industrial Sterilization Coating Materials

1) The concentration of an antibacterial agent, antiviral agent, or industrial sterilization coating agent[1)] contained in an antibacterial product, antiviral product, or industrial sterilization coating material shall not be more than the maximum concentration (based on weight) confirmed to be safe. If safety is evaluated using diluted bulk material, however, the diluted concentration shall not be more than half the maximum concentration confirmed to be safe.

2) The antibacterial agents, antiviral agents, or industrial sterilization coating agents used in antibacterial products, antiviral products, or industrial sterilization coating materials shall meet all the safety criteria [2)] shown in Table 7.

3) For products for which safety test data for antibacterial agents or antiviral agents are unavailable, such as antibacterial metals and antiviral metals, the safety criteria shown in Table 8 shall be met[2)].

4) For products for which a safety test cannot be performed using the agents themselves, such as products manufactured through ion exchange and coupling treatment, the safety test may be performed using a sample collected from the surface of a product. In such a case, however, it is not allowed to perform the safety test using extract of the product.

Note 1) For surfaces such as painted surfaces which are formed by post-treatment such as painting, the concentration shall be determined as the concentration (based on weight) of the antibacterial agent, antiviral agent, or industrial sterilization coating agent in the paint film.

2) Other safety tests deemed appropriate are not precluded from being additionally performed.

Table 8. Safety Criteria for Antibacterial Metals or Antiviral Metals

Safety criteria for antibacterial products		Safety criteria
Category	Test method	
Material test Dissolution test	1959 Ministry of Health and Welfare Notification No. 370[1)]	Shall meet the specifications.
Skin patch test[2)]	Closed patch test (48 hours) or Kawai's method (replica method)	Shall test negative in closed patch test or test negative or semi-negative in Kawai's method.

Note 1) Standards and criteria for food and food additives, etc.No.3 Apparatus and Containers/ Packages
Specifications for 4. Metal can in A: "General Specifications for Instruments or Containers/Packages or Their Raw Materials" and D: "Specifications by Material for Instruments or Containers/Packages or Their Raw Materials".

2) It is not required for applications where the product is not in constant contact with the skin (applications where the product is in constant contact: Ring, earrings, and so on). Although "skin patch test" is exempt from submission in the case of voluntary registration, a document stating that the product is not used for application where it contacts the skin constantly shall be submitted to the secretariat.

8.4 Safety Criteria for Antifungal Agents

1) The antifungal agents which may be included in antifungal products shall be listed in Attached Table 1 "Antifungal Agent Positive List" 1).
2) Antifungal agents listed in the "Antifungal Agent Positive List" shall meet all the safety requirements shown in Table 9. Only the antifungal agents whose safety information, environmental impact information and products use restriction information shall be listed in such list [2)].

Note 1) Attached Table 1 (Antifungal Agent Positive List) shall be disclosed on the website of this society.

2) Detailed procedures for the listing of antifungal agents in the Antifungal Agent Positive List shall be separately stipulated by the "Judging Rules for Listing of Antifungal Agent in the Positive List".

Table 9. Safety Requirement Necessary for Listing in the Antifungal Agent Positive List

1. The mutagenicity shall be negative.
   However, even if the mutagenicity is positive, the case in which the mutagenicity is proven to be negative in the high-level carcinogenicity test shall be acceptable.
2. The following information on antifungal agents shall be specified.
   1) Chemical name of effective ingredients (nonproprietary name)
   2) Blending concentration of the effective ingredient
   3) Safety information [1)]
      Required items) Acute oral toxicity, primary skin irritation and skin sensitization potential
      Optional items) Carcinogenicity
   4) Environmental impact information
      Required items) Toxicity of fish
      Optional items) Octanol-water partition coefficient, solvent solubility and BOD/COD value
   5) Information on restriction of product use
      (1) Recommended amount to be added (highest acceptable compounded amount): Level I
      (2) Maximum blending amount according to each service condition (service conditions and the conditional amount to be added): Level II
      (3) Prohibited intended use (specific intended use): Level III

Note 1) Regarding the testing method of safety, the standards stipulated in Table 7 shall be applied.

8.5 Safety Criteria for Antifungal Products

1) All the antifungal agents contained in antifungal products shall be selected for use only from the antifungal agents shown in Attached Table 1 "Antifungal Agent Positive List"[1)] and shall not include any other antifungal power ingredients not included in such table.
2) In the use of all the antifungal agents contained in antifungal products, the conditions of the products use restriction information of each antifungal agent stipulated in Attached Table 1 shall be met.

Note 1) Attached Table 1 (Antifungal Agent Positive List) shall be disclosed on the website of this society.

9. Safety of Components other than Agents Contained in Products

The safety of components other than antibacterial agents, antifungal agents, antiviral agents, or industrial sterilization coating agents contained in products or coating materials shall be subject to product safety control (voluntary control) by the companies registering the relevant products or coating materials.

10. Material Safety Data Sheets (SDSs)

(Antibacterial, antifungal, antiviral, and industrial sterilization coating agents) A SDS bearing information on physicochemical properties and handling instructions, etc. for the antibacterial agent, antifungal agent, antiviral agent, and industrial sterilization coating agent shall be available.	(Antibacterial, antifungal, and antiviral products as well as industrial sterilization coating materials) SDSs for the raw materials shall be available[1)].

Note 1) For products that do not permit generation of SDS, such as regenerated feedstock, the safety criteria for material test and dissolution test shown in Table 7 shall be met. In addition, when the dissolution test of D "Standards for appliances or containers and packaging or materials of these raw materials" is carried out, products made of materials other than metals conform to the dissolution test according to the type of material in the standard.

11. Periodical Performance Check

Antibacterial product manufacturers which registered an antibacterial product for this society satisfying the antibacterial performance criteria described in Term 4 shall undergo the performance check of the registered product every five year, with the details stipulated separately.

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Amended: June 22, 2000
Amended: June 22, 2001
Amended: June 22, 2002
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Amended: September 13, 2016
Amended: February 7, 2017
Amended: May 18, 2017
Amended: September 15, 2017
Amended: March 26, 2019
(Antiviral products shall be operated after ISO 21702 is issued)
Amended: May 18, 2020
Amended: December 1, 2020
Amended: March 16, 2021
Amended: August 1 , 2021
Amended: November 22, 2021
Amended: March 8, 2022
(The registration of industrial sterilization coating materials shall be operated on or after April 1, 2022)