PS: 5453/2020

ICS: 71.100.40

PAKISTAN STANDARD

FOR

HAND SANITIZER AND DISINFECTANTS

Pakistan Standards

PAKISTAN STANDARDS AND QUALITY CONTROL AUTHORITY,
STANDARDS DEVELOPMENT CENTRE,
PSQCA Complex Plot # ST-7/A, Block-3,
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PAKISTAN STANDARD SPECIFICATION
FOR
HAND SANITIZER

0. FOREWORD

0.1 This Pakistan Standard was adopted by the Pakistan Standards and Quality Control Authority on 5-5-2020 after the draft finalized by the Fine Chemical Technical Committee had been approved by the National Standards Committee for Chemical.

0.2 This standard is intended chiefly to cover the technical provisions relating to the supply of material & it does not include all the necessary provisions of a contract.

0.3 For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test or analysis shall be rounded off in accordance with PS: 103. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard

1.0 Scope

This Pakistan Standard prescribes the requirements and methods of test for alcohol based instant hand sanitizers. The standard does not cover non-alcohol based hand sanitizers.

2.0 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

EAS 104, alcoholic beverages – Method of sampling and test

EAS 377 - 2: Specification for classification of cosmetic raw materials & adjuncts:

Part 2: List of substances which must not form part of the composition of cosmetic products

Ref No 3: Guide to local production WHO- recommended Hand rub formulation. Revised April 2010.

3.0 Terms and Definitions

For the purposes of this standard terms and definitions specified under ISO 862 and the following apply.

3.1 **Hand Sanitizers**
Antiseptic agents used to cleanse the hands when soap and water are unavailable. They are often used to protect and prevent the passage of bacteria, virus and other pathogens that can cause infections.

4.0 Requirements

4.1 The sanitizer shall have an acceptable odour.

4.2 The sanitizer shall be in the form of liquid or gel, clear colourless.

4.3 The sanitizer shall not have any disagreeable odour or smell.

4.4 The sanitizer shall not contain any material listed as a forbidden material in EAS 377-2

Approved

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Table 1

Requirements for Instant Hand Sanitizer

Sl. No	Characteristic	Requirement	Test method
i)	pH, neat	6 - 8	Annex A
ii)	Bactericidal efficacy	to pass test	Annex B
iii)	Alcohol content (ethanol and/or isopropanol, n- propanol), %, v/v, min.	96-98%	*Annex C

Table 2

Requirements for Instant Hand Sanitizer (Liquid)

Sl. No	Characteristic	Required Purity	Required Volume for 10-liter batch	Test method
i)	Alcohol content (ethanol and/or isopropanol, n- propanol), %, v/v, min.	96-98%	8333 ml	Annex A
ii)	Hydrogen peroxide	2 -3 %	417 ml ± 2	Annex B
iii)	Glycerol/Glycerin	95-98%	145 ml ± 1	*Annex C
iv)	Sterile distilled or boiled cold water	100%	1105 ml ± 3	

Table 3

Requirements for Instant Hand Sanitizer (Gel)

Sl. No	Characteristic	Required Purity	Required Volume for 10-liter batch	Test method
i)	Alcohol content (ethanol and/or isopropanol, n- propanol), %, v/v, min.	96-98%	7515 - 8300 ml	Annex A
ii)	Hydrogen peroxide	2 -3 %	417 ml ± 2	Annex B
iii)	Glycerol/Glycerin	95-98%	145 ml ± 1	*Annex C
iv)	Aloevera Gel/ Carbomer Gel	100%	1100-1300 ml ± 3	

Table 4

Requirements for spray for walk through gate/surface area disinfectants

Sl. No	Characteristic	Required Purity	Required Volume for 10-liter batch	Test method
i)	Alcohol content (ethanol and/or isopropanol, n- propanol), %, v/v, min.	65-75%	7515 - 8300 ml	Annex A
ii)	Hydrogen peroxide	2 -3 %	417 ml ± 3	Annex B
iii)	Glycerol/Glycerin	95-98%	145 ml ± 1	*Annex C
iv)	Sterile distilled or boiled cold water	100%	1138 ml ± 3	

***pH method of analysis using pH Meter**

Important Note:

Glycerol: used as humectant, but other emollients may be used for skin care, provided that they are cheap, widely available and miscible in water and alcohol and do not add to toxicity, or promote allergy.

• Hydrogen peroxide: used to inactivate contaminating bacterial spores in the solution and is not an active substance for hand antisepsis.

• Any further additive to both formulations should be clearly labelled and be non-toxic in case of accidental ingestion.

• A colorant may be added to allow differentiation from other fluids, but should not add to toxicity, promote allergy, or interfere with antimicrobial properties. The addition of perfumes or dyes is not recommended due to risk of allergic reactions.

5.0 Packaging and Labeling

5.1 Packing

5.1.1 The sanitizer shall be supplied in suitable well-closedcontainers/packages

5.1.2 The containers/packages (including the closures) shall not interact chemically or physically with the sanitizer and shall be strong enough to protect the sanitizer adequately during normal handling, transportation and storage.

5.1.3 Only containers/packages of the same size and bearing the same batch identification shall be packed together in a bulk container.

5.1.4 Containers/packages should mention the volume of ingredients by proper labeling.

5.2 Marking

The container/package shall be securely closed and marked legibly and indelibly with the following information:

a) The name and address and/or registered trade mark if any of the manufacturer ordistributor.

b) Product name and the words "instant handsanitizer"

c) Batch or code number

d) Net weight

e) A list of ingredients used

f) General instructions for use (be in either English, Kiswahili or French or in combination as agreed between the manufacturer and supplier)

g) Date of manufacture and expiry date

h) Country of origin/manufacture

i) The following cautionary warnings:

1) Do not allow the sanitizer to come into contact with eye

2) Keep out reach of children

3) If swallowed contact with doctor

4) Highly flammable, keep away from fire or flame.

5) Mentioned regarding the possibility of allergies in special cases.

ANNEX A
(Normative)
Determination of disinfecting efficacy

A1. Outline of the method

A1.1 The sanitizer is tested at the recommended 'use'-dilution' and concurrently at 0.5 and 1.5 times that dilution. The test consists of challenging the diluted sanitizer with bacterial inoculum, withdrawing a sample after a given time and culturing the sample in a suitable recovery medium. After this sampling, the mixtureis again challenged by a second inoculum and after a second interval, is again sampled for culturing. This process is then repeated to provide a third challenge.

A1.2 The sample is considered to have passed or failed the test according to the extent of growth shown in the first two cultured samples.

A2. Apparatus

A2.1 Facility, for incubation at 37 ± 1 °C

A2.2 Facility, for incubation at 27 ± 1 °C

A2.3 *Stop clock*, indicating in seconds

A2.4 Facility, for refrigeration at 4 ±1°C

A2.5 Universal containers — Made of glass and having metal tops with rubber liners. Plastic containers or glass containers with plastic tops shall not be used.

A2.6 Test tubes — 19 mm X 150 mm.

A2.7 Filter paper, No. 4 whatman (sterile) or equivalent

A2.8 Facility, for autoclaving at 121 ±1°C

A2.9 Pipette, capable of dispensing 0.02 ± 1°C 0.005 ml

A2.10 pH meter

A2.11 Facility, to sterilize by filtration

A2.12 150 µm test sieve

A2.13 Oven, capable of maintaining temperature at 100 ± 1 °C

A3. Media

A3.1 *Growth media for test organisms.*Wright and Mundy Broth with Dextrose (WMBD).

A3.1.1 Dispense 10 ml and 6 ml quantities of the Wright and Mundy Broth into universal bottles, and autoclave at 121 ± 1°C for 12 minutes.

A3.1.2 Add to this medium, 10 per cent (m/V) dextrose solution sterilized by filtration, to give a final dextrose concentration of 0.1 percent (m/v), (i.e. to 10 mL broth add 0.1 dextrose solution and to 6.0 mL broth add 0.06 mL dextrose solution).

A3.2 **Recovery medium** — A nutrient broth prepared asfollows:

A3.2.1 Composition

-Beef extract 10 g

-Peptone 10 g

-Sodium chloride 5 g

-Polyoxyethylenesorbitan mono-oleate 30 g

A3.2.2 Preparation — Add the ingredients to 1000 mL of water. Mix well. Dispense 10 ml quantities into test tubes

and autoclave at 121 ± 1°C for 15 minutes.

A3.3 **Hard water** — Standard hard water with 342 mg/L (ppm) hardness prepared as follows:

Dissolve 0.304 g of anhydrous calcium chloride hexahydrate ($MgCl_2$-$6H_20$) in distilled water and make up the volume to one litre. Sterilize the standard hard water by autoclaving at 121 ± 1° C for 15 minutes. Allow this to reach room temperature before use.

A3.4 Yeast suspension

A3.4.1 Weigh to the nearest gram about 65 g of active dry yeast. Cream by the gradual addition of sterile hard water (A.3.3) using a heavy glass rod for stirring. Decant the creamed portion into a flask, add more hard water to any lumpy residue remaining and repeat the creaming and decantation until no residue remains, and 500 ml of hard water has been used.

A3.4.2 Shake the contents of the flask vigorously and strain-through a 150 µm sieve (A2.12) breaking down any remaining lumps.

A3.4.3 Add 500 mL sterile hard water, shakevigorously.

A3.4.4 Transfer 50 ml or 100 mL portions into screw-capped bottles, screw the caps tightly and autoclave at 121±1°C for 15 minutes. Allow the autoclave to cool without releasing the pressure. Store cold but not freezing.

A3.4.5 Dry two glass petri-dishes to constant mass. Into each of these dishes, pipette 25 mL of sterilized yeast suspension and dry to constant mass at 100°C. Calculate the average solids content of thesuspension.

A3.4.6 Before use, pipette 25 ml of the sterilized yeast suspension into a beaker. Determine the pH using a glass electrode, and determine the volume of 40 g/L sodium hydroxide solution needed to adjust the pH to7.0± 0.1.

A3.4.7 Immediately before use, add to each bottle of sterilized yeast suspension a volume of sterile hard water and a volume of 40 g/l sodium hydroxide calculated to adjust the concentration of dry yeast to 5 percent (m/V) and the pH to 7.0 ± 0.1. Discard prepared yeast, two weeks afterpreparation.

A3.5 Ringers solution, 25 percent (v/v), Dissolve 9.0 g of sodium chloride, 0.42 g of potassium chloride, 0.24 g of anhydrous calcium chloride and 0.20 g of sodium bicarbonate in water and dilute to 1000 ml. Add 1 volume of this solution to 3 volumes of water to give a 25 percent solution. Dispense into test tubes fitted with suitable closures and sterilized by auto-claving at 121±1°C for 15 minutes.

A 4 Selection of the most resistant organism by the minimum inhibitory concentration test:

A 4.1 The following organisms shall be used for the test:

Pseudomonas aeruginosa (NCTC 6749 or equivalent)
Proteus vulgaris (NCTC 4635 or equivalent)
Staphyloccus aureus (NCTC 4163 or equivalent)

These organisms may be obtained as freeze dried cultures. Once sub-cultured, the organisms shall be maintained on agar slopes of suitable nutrient medium at 4±1°C.

A 4.2 Subculture each organism daily into a universal bottle containing 6 ml of growth medium (A3.1) and incubate for 24 ± 2 h at 37 ± 1°C.

A 4.3 Dilute one part of freshly grown sub-culture of each organism, which is at least a fifth sub-culture and not more than a fourteenth, with ten parts of the growth medium (A3.1) before dilution, the *P. aeruginosa*, culture shall be filtered using a what man No.4 filter paper.

A 4.4 Prepared three sets of ten, doubling dilutions of the sanitizer in universal containers (A2.5). For this purpose dilute the neat sanitizer in the growth medium (A3.1) or the recovery medium (A3.2) to give a final volume of 5 ml of the diluted sanitizer for each dilution.

A 4.5 Inoculate each dilution in one set with 0.02 mL of a diluted culture of one organism (see A4.3)).

A 4.6 Incubate all the three sets of inoculate dilutions at 37 ± 1°C for 72 hours, and examine to determine the

organism most resistant to the sanitizer, that is the organism for which the minimum inhibitory concentration is highest.

A 5 Preparation of inoculum

A5.1 Daily sub-cultures of the test organism selected as in A4.6 shall be grown in 6 ml quantities of the growth medium (A3.1) and incubated at 37 ± 1°C for 24 ± 2hours.

A 5.2 The day before the test, inoculate 10 ml of the growth medium (A3.1) with the test organism from a daily sub-culture and not more than a fourteenth. Incubate the inoculated, broth at 37 ± 1°C for 24 ± 2hours.

A 5.3 Add 6 ml of the test organism culture (A5.1) and (A5.2) to 4 ml of the yeast suspension (A3.4) thus making a final concentration of 2 percent (m/V) of yeast in the yeast/organism suspension. If a culture of *P. aeruginosa* is used, it shall be filtered using a what man No.4 filter paper before addition.

A 5.4 Shake the yeast/organism suspension for one minute with a few sterile glass beads. Immediately before the test, count the number of viable organisms in the inoculum by decimal dilutions in 25 percent Ringers solution (see A3.5) and by the drop plate method. The viable count shall be not less than 10^8 organisms/ml or more than 10^{10} organisms/ml or the test results are considered invalid.

A 6 Preparation of the sanitizer dilutions

Prepare three dilutions of the sanitizer in hard water (A3.3) based on the recommended 'use dilution' of the sanitizer, as follows:

A = 0.5 times the recommended 'use-dilution'
B = 1.0 times the recommended'use-dilution'
C = 1.5 times the recommended'use-dilution'

The sanitizer dilutions shall be prepared and tested on the same day.

A7 Test procedure

A7.1 The test shall be carried out at 27 ±1°C.

A7.2 Dispense 3 mL of each dilution of sanitizer (A6) into separate universal bottles labeled A, B, and C, then allow to equilibrate to 27 ±1°C.

A7.3 Add 1 mL of the inoculum to A, B and C at 0, 1 and 5 minutes respectively and mix by swirlinggently

A 7.4 Eight minutes after the addition of the inoculum, remove a sample of the inoculum/sanitizer mixture and put 0.02 ml into each of the first group of five tubes of recovery broths. Return the remainder of the mixture in the pipette to the universal container.

A 7.5 Ten minutes after the first addition of the inoculum, add another 1 ml of the inoculum to each of the sanitizer dilutions and mix by swirling gently

A 7.6 Eight minutes later, remove a sample of the mixture as put before (A7.4) and put 0.02 mL into each of the second group of five tubes of recovery broths.

A 7.7 Twenty minutes after the first addition of the inoculum, add a further 1 m/ of inoculum to each of the sanitizer dilutions and mix by swirling gently.

A 7.8 Eight minutes later, remove a sample of the mixture as before and place 0.02 ml into each of the third group of five tubes of recovery broths.

A 7.9 Swirl the recovery broths and incubate at 37 ± 1°C for 48 ± 2 h. Examine the growth and record the results.

A 8 Interpretation of results

A 8.1 The Instant hand sanitizer, shall be regarded as having passed the test at the recommended 'use dilution' if there is no growth in at least two of the five recovery broths for the first and second additions of the

inoculum.

A 8.2 To be acceptable, an instant hand sanitizer shall pass the test on three separate occasions using freshly prepared sanitizer and freshly prepared inoculum on each occasion.

ANNEX B
Determination of percentage of ethyl alcohol

B.1 General

Ethanol content of a liquor preparation may be quantitatively determined by specific gravity determination. However, prior to this determination ethanol contained in the liquor shall be obtained practically free from all other dissolved and undissolved substances except water. Simple direct distillation suffices where the admixed or dissolved ingredients are not volatile with steam. When volatile substances are present, it is necessary either to render them incapable of distillation or to remove them. All liquor preparations containing volatile acids or ammonia (or amines) are neutralized by an alkali or acid (sodium hydroxide or sulfuric acid). Free iodine, if present, may first be converted into sodium iodide by treatment with sodium thiosulfate. Volatile oils, solvents etc. are removed by adopting the single, double, treble or quadruple bulk method. Through use of any of these methods a definite volume of the distillate is collected and its specific gravity determined by pyknometer method.

B.2 Apparatus

B.2.1 Distillation assembly — The apparatus are assembled a[illegible]. The distillate end of the condenser is attached to a 50 ml pipette suitably shortened at the upper end and attached to the condenser nozzle by means of rubber tubing. The lower part of this pipette is suitably curved so as to reach the bottom of the receiver where it is slipped into the minimum quantity of distilled water.

B.2.2 Receiver, 200 ml.

B.2.3 Pyknometer, [illegible], 25- 50 ml capacity.

B.2.4 Thermometer, with the range of 0 °C to 50 °C shall be used.

B.3 Reagents

B.3.1 Sodium chloride, analytical grade,

B.3.2 Petroleum ether, 60/80

B.4

B.4.1 Pyknometer Method

B.4.2 Apparatus

a) Distillation assembly, the delivery end of the condenser is attached to a glass tube with a bulb by means of a ground glass joint. The lower part of this tube should reach the bottom of the receiver and dip into the minimum quantity of distilled water.

b) Pyknometer, 25 to 50-ml capacity.

c) Thermometer, 0 to 50°C.

d) Measuring flask, 200-ml capacity.

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B.4.3 Procedure

B.4.4 Take 200 ml of sample in a 500-ml distillation flask containing about 25 ml of distilled water and a few pieces of pumice stone. Complete the distillation in about 35 min and collect the distillate in a 200 ml measuring flask till the volume in the flask nears the mark. /allow the distillate to come to room temperature. Make up the volume to 200 ml with distilled water and mix thoroughly.

B.4.5 Find out the specific gravity of the distillate at the required temperature with the help of a pyknometer. Obtain corresponding alcohol, percent by volume.

B.4.6 Method 2. Distillation Method

B.4.7 Distillation Assembly

B.4.8 Apparatus

a) Measuring flask, 200- ml capacity.

b) Separating funnels, 500-ml capacity

B4.9 Reagents

B.4.10 Sodium chloride, powder

B.4.11 Petroleum ether, 40 to 60°C

B.4.12 Sodium hydroxide, 0.1 N

B.4.13 Phenolphthalein, powder

B.4.14 Procedure

B.4.15 Measure 200 ml of the liquor sample in a measuring flask. Transfer to a separating funnel, wash, the measuring flask with about 100 ml of water, add the washings to the content of the separation funnel and add sufficient powdered sodium chloric to saturate the liquid. Add about 100 ml of petroleum ether and shake vigorously for 2 to 3 min. Allow the mixture to stand for 15 to 30 min and run the lower layer into a distillation flask. Wash the petroleum layer twice with about 20 ml of the saturated solution of sodium chloride. Add these washings to the distillation flask. Make the mixed solutions just alkaline with sodium hydroxide solution using phenolphthalein powder as indicator, add a little pumice powder and distil. Collect the distillate in the measuring flask till it nears the mark. Bring the distillate to room temperature, make up the volume to with distilled water and mix thoroughly.

ANNEX C
Determination of pH

- It is convenient measure of acidity / alkalinity of a aqueous solution at a specific temperature
- It is measured on a continuous scale from 0 to 14.
- In a chemical laboratory, pH is commonly measured using an electronic pH meter with a scale 0.01 pH meter.
- Operate the pH meter by using the appropriate instruction of Manual.

Required chemicals: Distilled water, Buffers for calibration.
Glassware: beakers, pipette and tissue paper