



CARICOM Regional Standard

HAND SANITIZERS – ALCOHOL-BASED HAND SANITIZERS - SPECIFICATION

DCRS 76:202X

CARICOM Regional Organisation for Standards and Quality, CROSQ

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Committee representation

This CARICOM Regional Standard was developed under the supervision of the Regional Project Team for hand Sanitizers, (hosted by the CARICOM Member State, Antigua and Barbuda), which at the time comprised the following members:

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Foreword

This CARICOM Regional Standard *CRS :202X, Hand Sanitizers – Alcohol-based hand sanitizers - Specification* has been developed under the authority of the CARICOM Regional Organisation for Standards and Quality (CROSQ). It was approved as a CARICOM Regional Standard by the CARICOM Council for Trade and Economic Development (COTED).

Hands are frequently in contact with other surfaces and contaminated hands readily transfer microorganisms to other surfaces. The hands play a significant role in the spread of these microorganisms and to help prevent the spread, proper and regular hygiene is crucial. Hand sanitizers aid in interrupting the spread of microorganisms.

This standard was developed to establish minimum requirements for hand sanitizers and to ensure that the product is safe and suitable for its intended use.

This regional standard is intended for use by all manufacturers, importers, distributors and other entities engaged in the production and/or trade of alcohol-based hand sanitizers.

The following documents were used in the formulation of this regional standard:

- Guide to Local Production: WHO-recommended Handrub Formulations
- Health Canada 2020
- JS 351: 2020 Specification for Instant Hand Sanitizers
- KS EAS 789:2013 Instant hand sanitizers – Specification
- Rwanda FDA Guidelines on preparation of alcohol-based hand sanitizers
- PS: 5453/2020 Pakistan Standard for hand sanitizer and disinfectants
- USP Hand Sanitizer Tool Kit
- Excerpted USP-NF and FCC Standards: A Hand Sanitizer Resource, August 17, 2020
- The United States Pharmacopeia. The National Formulary, Rockville, Md.: United States Pharmacopeial Convention, Inc., 1979.

1 Scope

This Regional Standard outlines requirements and test methods for alcohol-based hand sanitizers.

The standard does not include requirements for non-alcohol-based hand sanitizers.

2 Normative references

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

ASTM International

- ASTM E3058, Standard Test Method for Determining the Residual Kill Activity of Hand Antiseptic Formulations
- ASTM E2011, Standard Test Method for Evaluation of Hygienic Handwash and Handrub Formulations for Virus-Eliminating Activity Using the Entire Hand E2613 – 14 Standard Test Method for Determining Fungus-Eliminating Effectiveness of Hygienic Handwash and Handrub Agents Using Fingerpads of Adults
- ASTM E1838, Standard Test Method for Determining the Virus-Eliminating Effectiveness of Hygienic Handwash and Handrub Agents Using the Fingerpads of Adults
- ASTM E2613, Standard Test Method for Determining Fungus-Eliminating Effectiveness of Hygienic Handwash and Handrub Agents Using Fingerpads of Adults

CARICOM Regional Organisation for Standards and Quality

- CRS 55-1, Labelling of goods – Part 1: General requirements
- CRS 55-2, Labelling of goods — Part 2: Specific requirements for prepackaged goods

European Committee for Standardization

- EN 12791, Chemical disinfectants and antiseptics - Surgical hand disinfection - Test method and requirements (phase 2, step 2)
- EN 14885, Chemical disinfectants and antiseptics - Application of European Standards for chemical disinfectants and antiseptics
- EN 1500, Hygienic handrub method
- European Pharmacopoeia

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International Organization for Standardization

— ISO 10523, Water quality — Determination of pH

United States Standards

— United States Pharmacopeia, 2020

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply:

3.1

alcohol-based hand sanitizer

alcohol-containing preparation (liquid, gel or foam) designed for application to the hands to inactivate microorganisms and/or temporarily suppress their growth.

NOTE Such preparations may contain one type of the specified alcohol, other active ingredients with excipients, and humectants.

3.2

ethanol

ethyl alcohol

compound with chemical formula C_2H_5OH

3.3

isopropyl alcohol

isopropanol

2-propanol

n-propanol

compound with chemical formula C_3H_7OH

3.4

methanol

methyl alcohol

compound with chemical formula CH_3OH

3.5

impurity

constituent of the hand sanitizer not intended to be part of the final formulation

3.6 sterile

free from viable microorganisms

[SOURCE: ISO/TS 11139:2006, definition 2.43]

3.7 potable water

water which is intended for direct human consumption

3.8 non-toxic

materials which, under the intended conditions of their use, will not cause the product to be harmful to humans or domestic animals
 [ISO 14159:2002(en), 3.16]

4 General requirements

4.1 The hand sanitizer shall be in the form of liquid, foam or gel.

4.2 The hand sanitizer shall comply with the requirements outlined in Tables 1 and 2 when tested in accordance with the appropriate methods.

4.3 Alcohol used in the manufacturing of hand sanitizers shall comply with the US Pharmacopeia, EU Pharmacopeia specifications or any other pharmacopeia which provides equivalent requirements and test methods as outlined in Table 2.

4.4 Sterile, potable water shall be used in the production of hand sanitizers.

4.5 Thickening agents and humectants used in the manufacture of hand sanitizers shall be non-toxic.

NOTE See Annex A for recommended guidelines for establishments producing hand sanitizers.

4.6 Containers used for hand sanitizers shall be clean.

Table 1 — Requirements for alcohol-based Hand Sanitizer

Characteristics	Requirements	Test methods
Ethanol (v/v) *	60%-80%	US Pharmacopeia Chapter 611
Isopropanol (v/v) *	70%-80%	US Pharmacopeia Chapter 611
pH	6-8	ISO 10523
Bactericidal efficacy	to pass test	ASTM E3058 ASTM E2011 ASTM E2613 ASTM E1838 EN 12791 EN 1500 EN 14885
NOTE 1 Only ONE alcohol shall be used (ethanol or isopropyl alcohol) in the formulation of alcohol-based		

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Characteristics	Requirements	Test methods
hand sanitizers.		
NOTE 2 Any one of the test methods referenced for bactericidal efficacy shall be used.		

Table 2 - Requirements for alcohol used in the manufacture of hand sanitizers

Chemical impurity	Limits	Test Methods
Methanol	< 0.02% (200 ppm)	US Pharmacopeia or EU Pharmacopeia monograph on alcohol
Acetaldehyde and acetal	<0.001% (10 ppm), expressed as acetaldehyde	
Benzene	<0.0002% (2 ppm)	
Sum of all other impurities	< 0.03% (300 ppm)	

5 Labelling requirements

In addition to the requirements of CRS 55-1, Labelling of goods – Part 1: General requirements and CRS 55-2, Labelling of goods — Part 2: Specific requirements for prepackaged goods, the following shall apply:

- a) type and percentage of alcohol used;
- b) the following cautionary warnings:
 - i. “Do not allow the sanitizer to come into contact with eyes”;
 - ii. “Keep out of reach of children”;
 - iii. “If swallowed contact a doctor”; and
 - iv. “Highly flammable, keep away from fire or flame”.

6 Storage

Hand sanitizers and raw materials shall be stored in a cool, dry place and shall be kept out of direct sunlight.

Annex A
(Informative)

Guidelines for establishments producing hand sanitizers

The following document contains the recommended guidelines for establishments producing hand sanitizers:

- JS 351: 2020 Jamaican Standard Specification for Instant hand sanitizers

END OF DOCUMENT

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