स्तर - ०१/०७६

Instant Hand Sanitizer (Alcohol Based)

सम्बन्धि स्तर

२०७६

नेपाल सरकार

स्वास्थ्य तथा जनसंख्या मन्त्रालय

औषधि व्यवस्था विभाग

बिजुलिबजार, काठमाण्डौ, नेपाल

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Director General

1. Scope

This 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. 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.

1. Drug Act 2035
2. Drug Standard Regulation 2043
3. Health Technology Product and Medical Device Directives 2074
4. Drug Enquiry and Inspection Regulation 2040

3. Terms and Definitions

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. Requirements

1. The sanitizer should have an acceptable odor or color.
2. The sanitizer should be in the form of liquid or gel.
3. The sanitizer should not contain any material that is toxic, carcinogenic and promote allergy or interfere with antimicrobial properties.
4. Glycerol 1.45%v/v, minimum or other humectant and other permissible excipient (allopathic or herbal) may be used.
5. The hand sanitizer should also comply with the requirements given in Table 1 when tested in accordance with the corresponding test method.

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Table 1 — Requirements for Instant Hand Sanitizer

S. No.	Characteristic	Requirement
1.	Ethyl alcohol content or Isopropyl alcohol content	70% to 80%v/v
2.	pH	6 - 8
3.	Microbicidal activity	≥ 5 log reduction within 1 minute

Hydrogen peroxide content as H_2O_2 0.125%v/v or Chlorhexidine Gluconate content 0.5%v/v may be used.

5. Raw materials

Purity of the raw materials should be as below:

1. Ethyl alcohol- 96%, Minimum
2. Isopropyl alcohol- 99.8%, Minimum
3. Hydrogen Peroxide- 3%
4. Glycerol- 98%
5. Sterile distilled or boiled cold water

All raw materials used should be pharmacopoeial grade and should be preferably free of viable spores.

6. Packaging and Labelling

6.1 Packing

1. The sanitizer should be supplied in suitable well-closed containers.

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

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3. Only containers of the same size and bearing the same batch identification should be packed together in a bulk container.

6.2 Labelling

Labelling should be in accordance with national regulation and should include the following:

1. Name of the product and quantity.
2. The name of the ingredients and quantity.
3. The name of the product manufacturing company, address and country.
4. The serial number of production license provided for the manufacturing of the product.
5. The Batch No. of the product.
6. The date of production of the product.
7. The date of expiry for the product that expires.
8. The price of the product.
9. The storing method (technique) and management of the product.
10. The method of use of the product.
11. For external use only
12. Use: Apply a palmful of alcohol-based handrub and cover all surfaces of the hands. Rub hands until dry
13. Avoid contact with eyes
14. Keep out of the reach of children
15. Flammable: keep away from flame and heat.

7. Method of Analysis

The product should be tested for Ethyl alcohol or Iso-Propropyl alcohol content and Microbicidal activity by standard method or validated company method.

8. Shelf Life:

Shelf life will be given for one year and can be extended based on ongoing stability data.

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