

Annex I, Part 9(ii)

GUIDELINE FOR HAND SANITIZER PRODUCT

1. OBJECTIVE

The objective of the guideline is to ensure that hand sanitizers in the market demonstrate that the product is sufficiently effective according to the defined requirements for its use.

2. SCOPE

This guideline applies only to hand sanitizers that classified as cosmetic products.

3. CLASSIFICATION OF HAND SANITIZERS:

- i. Hand sanitizers for general hand hygiene are classified as cosmetic products.
- ii. Hand sanitizers/ hand disinfectants / hand surgical scrubs that are used in healthcare facilities by healthcare practitioners before or after a medical procedure are classified as Generic Medicine (non-scheduled poison / over-the-counter). Please refer to the Drug Registration Guidance Document (DRGD) for further details.

Note: Sanitizers used for the purpose of disinfecting surfaces are not classified as cosmetic products.

4. ACTIVE INGREDIENTS ALLOWED IN HAND SANITIZERS:

4.1 Alcohol-based hand sanitizers

Products must contain at least 60% (v/v) alcohol (ethanol and/or isopropyl alcohol)

4.2 Non-alcohol based hand sanitizers

4.2.1 Relevant and sufficient documentation and scientific evidence must be provided to support the efficacy of the product as a hand sanitizer.

4.2.2 Efficacy tests must be conducted to show that non-alcohol based hand sanitizers have the antimicrobial activity. The efficacy tests should follow established international standards. The products shall show all three antimicrobial activities listed below and must have equal efficacy to hand sanitizers containing at least 60% alcohol.

	Antimicrobial activity	Suggested International Standard
i.	Bactericidal activity	EN 1276 or EN 13727
ii.	Yeasticidal / Fungicidal activity	EN 1650 or EN 13624
iii.	Virucidal activity	EN 14476

Note:

- i. Other equivalent standards can also be used, such as ASTM.
- ii. Any modification to the test method must be justified.

5. ACCEPTABLE AND UNACCEPTABLE CLAIMS FOR HAND SANITIZERS:

Hand sanitizers classified as cosmetic products may only claim to have anti-bacterial activity.

The following claims are unacceptable; disinfectant, antiseptic, antimicrobial, antiviral, virucidal, antifungal, fungicidal, reference to specific microbes (including specific bacteria) and reference to disease-causing/harmful microbes (including bacteria).

Note: This guideline subject to review when necessary.