MEDICINES REGULATORY UNIT
PUBLIC HEALTH AUTHORITY
MINISTRY OF HEALTH

Medicines Regulatory Unit (MRU) Requirements for Importation of Alcohol-Based Hand Sanitizers

1. Introduction

As of October 2020, Alcohol-Based Hand Sanitizers are classified as restricted goods and an import permit is required to import hand sanitizers in the Seychelles.

2. Purpose

This guideline is to facilitate the import permit process, to ensure transparency, that all necessary documents are produced, and to prevent avoidable delays.

This guideline focuses on Certificates of Analysis (CoA) required by the Department of Health Policy for Preparation of Alcohol-Based Hand Sanitizer Products during the Public Health Emergency (COVID-19) - Guidance for Manufacturers and Importers.

3. Scope

This guideline applies to all importers and manufacturers of hand sanitizers for commercial purposes.

This guideline does not apply to surface disinfectants, liquid hand soap or hand cream/gel products.

This guideline does not apply to importation of hand sanitizers for personal use.

4. Required Documents

Certificate of Analysis (CoA) - This is generated following completion of quality assurance and quality control testing. The document should include the assay (quantitative) methods as well as the results obtained using those methods.

Other documents may be included with the application but it is not compulsory. Examples include Material Safety Data Sheet (MSDS), Product Registration Certificate, Composition Certificate and etcetera. **These documents will not replace the requirement for producing a Certificate of Analysis (chemical analysis) which quantifies the alcohol percentage in the hand sanitizer.**

5. CoA

The CoA must be for the batch of hand sanitizer that is being considered for importation. It should include the following information:

- the name and address (physical address) of the laboratory issuing the CoA;
- the identification number of the CoA, the page number and the total number of pages to ensure that every page is recognized as a part of the certificate;

- the name, address and contact person representing the originator of the request for analysis;
- the number assigned to the sample by the laboratory during registration upon receipt or a lab code;
- the date on which the sample was received in the laboratory and the quantity of sample (number of units or packages);
- the name, description (for example, active ingredient, dosage form [liquid, gel, foam etcetera], strength, package size; type and material of the primary packaging), batch number (used by the original manufacturer and repacker or trader) of the sample for which the certificate is issued, the expiry date (or retest date, where applicable) and date of manufacture (if available);
- the name and address of the original manufacturer; in addition, if supplied by repackers or traders, the certificate should show the name and address of the repacker or trader;
- specifications for testing and a reference to the test procedure(s) used, including the acceptance criteria (limits);
- the results of all tests performed on the sample for which the certificate is issued (in numerical form, where applicable) and a comparison with the established acceptance criteria (limits); results of tests performed by subcontractors should be identified as such;
- any comments, observations or information on specific test conditions, where these are necessary for the interpretation of the results;
- a conclusion as to whether or not the sample was found to be within the limits of the specification;
- the date, signature and name of the head of the laboratory or other authorized person approving the certificate.

If appropriate, the CoA may include a photograph(s) of the packaging and/or product tested.

If new certificates are issued by or on behalf of repackers or traders, these certificates should show the name and address of the laboratory that performed the tests and the name and address of the original manufacturer. A copy of the CoA generated by the original manufacturer should be attached.

When the certificate is used in trade it may also include a statement of the expected conditions for shipping, packaging, storage and distribution, deviation from which would invalidate the certificate.

6. Methods of Analysis

The most accurate method of analysis available at the site must be used for quantification of alcohol content in samples of the finished drug product.

Methods can include gas chromatography (GC), alcoholmeter, hydrometer, or other chemical analysis of at least equivalent accuracy.

7. Alcohol Composition

The CoA must verify the percentage of Ethanol or Isopropyl Alcohol within the sanitizer. The units must be stated in the CoA, e.g. % v/v or % m/m. Where percentage by weight (% m/m) is utilized, relevant densities must be provided to confirm the percentage by volume (% v/v).

Minimum acceptance value is 70.0% v/v for Ethanol or Isopropyl Alcohol. It is the responsibility of the applicant (importer) to ensure that it meets the minimum value and that import permits are approved before the hand sanitizer is exported to the Seychelles.

8. Methanol Substitution or Contamination in Hand Sanitizers

Methanol cannot safely be used as an ingredient, or as a denaturant, in hand sanitizer.

Substantial methanol exposure can result in nausea, vomiting, headache, blurred vision, permanent blindness, seizures, coma, permanent damage to the nervous system or death.

9. References

Department of Health Seychelles (2020) *Department of Health Policy for Preparation of Alcohol-Based Hand Sanitizer Products during the Public Health Emergency (COVID-19) - Guidance for Manufacturers and Importers.*

United States Food and Drug Administration (2021) *Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19) - Guidance for Industry*

World Health Organization & WHO Expert Committee on Specifications for Pharmaceutical Preparations. (2018). *Fifty-second report of the WHO Expert Committee on Specifications for Pharmaceutical Preparations. World Health Organization.* https://apps.who.int/iris/handle/10665/272452. License: CC BY-NC-SA 3.0 IGO

DRUG QUALITY CONTROL LABORATORY
CHEMISTRY LABORATORY

English River Health Centre, Ministry of Health
Telephone: 4388000 Ext. 8586 / 8505

CERTIFICATE OF ANALYSIS **CH-TR001**

1. **Customer Reference Number** :
2. **OTHER Reference Number** :
3. **Laboratory Reference Number** :
4. **Pre/post marketing sample** :
5. **Generic Name** :
6. **Product Name** :
7. **Manufacturer** :
8. **Batch Number** :
9. **Date of Manufacture** :
10. **Expiry Date** :
11. **Sampling Date** :
12. **Quantity of Sample Received** :
13. **Date Sample Received** :
14. **Date Sample Analysed** :
15. **Sample Analysed By** :
16. **Issue Date of Report** :
17. **Customer Name** :
18. **Customer Address** :
19. **Contact Person** :
20. **Contact Phone (or Fax) Number** :
21. **Contact E-mail Address** :

Sign: _____ _____ _____

Analyst **Technical Signatory** **HoL/Designated**

Customer Ref. No.	Other Ref. No.	Laboratory Ref. No.

22. Test Results

Test(s)	Specification(s)	Result(s)	Comment(s)
Appearance			
pH			
Identification			
Assay			

Sign: _____ _____ _____

Analyst **Technical Signatory** **HoL/Designated**

Customer Ref. No.	Other Ref. No.	Laboratory Ref. No.

23. Comment(s)/opinion(s)/Interpretation(s):

The sample **XXXX** analysis for the tests done. These results are only valid for this particular sample of batch **XXXX** that was collected from **XXXXXX** and analysed.

These results applies to the sample as received.

These results cannot be used on any other sample of the different batch collected anywhere else in the distribution chain.

Prepared By: _____ _____ _____
Analyst Name **Signature** **Date**

Checked By: _____ _____ _____
Technical Signatory Name **Signature** **Date**

Approved By: _____ _____ _____
HOL /Designate Name **Signature** **Date**