



**FDA CIRCULAR**  
No. 2020-011

25 MAR 2020

**SUBJECT: GUIDELINES ON PHARMACY COMPOUNDING OF ALCOHOL-BASED HAND SANITIZER FORMULATIONS IN LIGHT OF THE DECLARATION OF STATE OF CALAMITY DUE TO COVID-19**

**I. BACKGROUND/RATIONALE**

Since the recent declaration of the World Health Organization (WHO) of the Coronavirus Disease 2019 (COVID-19) outbreak as pandemic, and Proclamation No. 929 s. 2020, declaring a State of Calamity throughout the Philippines, there has been increased demand for alcohol-based products to limit and eliminate the spread of the disease.

Aside from large-scale manufacturing and distribution by duly authorized establishments, licensed retail drug outlets such as drugstores/ pharmacies/ boticas and similar establishments may also prepare alcohol-based products such as hand sanitizers through compounding as provided for under Republic Act (RA) No. 10918 or the Philippine Pharmacy Act.

Consistent with the Food and Drug Administration's (FDA's) mandate to ensure the safety, efficacy, and quality of health products, and in line with the definition of "drugs" as an article recognized in official pharmacopeias and formularies which are recognized and adopted by FDA as provided for in RA No. 9711 or the Food and Drug Administration Act of 2009, this Circular is hereby issued as an interim guideline for the pharmacy compounding of alcohol-based hand sanitizer in response to the need for increased production of these products in the Philippines.

**II. OBJECTIVES**

This Circular aims to provide guidelines that will enable licensed drug retail outlets to perform compounding of alcohol-based hand sanitizers of acceptable quality, safety, and efficacy for consumer and health care personnel use.

**III. SCOPE**

This Circular shall apply to all licensed drugstores/ pharmacies/ boticas, including hospital pharmacies and institutional pharmacies, and other concerned stakeholders.

#### IV. POLICIES AND GUIDELINES

##### A. Adopted Guidelines

- a) The “*United States Pharmacopoeia (USP) General Chapter <795> Pharmaceutical Compounding of Nonsterile Preparations*,” *USP Compounding Alcohol-Based Hand Sanitizer During COVID-19 Pandemic* (Annex A) and the “*Guide to Local Production of World Health Organization (WHO)-recommended Handrub Formulations*” are hereby adopted as references for the compounding of these products.
- b) The adopted guidelines shall be made available in the FDA website.

##### B. Compounding Personnel Requirement

1. Pursuant to RA 10918, compounding shall only be done by a duly registered and licensed pharmacist, employed by a licensed retail drug outlet.
2. Personnel engaged in compounding shall comply with hygiene and personnel protective equipment requirements provided for in the adopted guidelines.

##### C. Facility and Equipment

1. A dedicated area shall be designated for compounding. It should (a) have adequate space and (b) provide for the orderly placement of equipment and (c) practice occupational health and safety, good housekeeping and sanitation.
2. All equipment to be used in compounding shall be cleaned, properly maintained, used appropriately, and shall comply with the requirements provided for in the adopted guidelines.
3. Compounding shall be done in air conditioned or well-ventilated rooms. Appropriate measures shall be in place against fire hazards.
4. Compounded hand sanitizer formulations shall not be produced in quantities exceeding 50 liters per batch.

##### D. Raw Materials

1. Alcohol-based hand sanitizers shall be compounded using only pharmaceutical-grade ingredients.
2. The finished product shall contain the following ingredients in their respective concentrations:
  - a) Alcohol (Ethanol), 80%, v/v in an aqueous solution; or Isopropyl Alcohol, 75%, v/v in an aqueous solution;
  - b) Glycerol, 1.45% v/v
  - c) Hydrogen peroxide, 0.125% v/v
3. Water to be used in compounding may be distilled water, reverse osmosis water, or filtered water.
4. The FDA strongly discourages the addition of other ingredients (e.g. fragrances or gelling agents) as these may impact the quality and potency of the product.



E. Quality Control and Documentation

1. The establishment shall maintain written procedures, formulations, and other records as provided in the adopted guidelines (e.g., Master Formulation Record and Compounding Record).
2. Appropriate quality control measures and compounding controls as provided in the adopted guidelines shall be performed for both the raw materials and the finished product.

F. Packaging and Labelling

1. Finished products shall be packed in plastic bottles with leak-proof caps or screw tops.
2. The following mandatory information shall appear in the label of the finished product:
  - a) Generic Name and Strength (i.e., Alcohol 80%, or Isopropyl Alcohol 75%)
  - b) Indication (i.e., Antiseptic)
  - c) The statement "For external use only" rendered in capital letters against a red background or printed in red font.
  - d) Directions for Use and Warning Statements
  - e) Date of Production and Batch Number
  - f) Beyond Use Date (i.e., 30 days or the expiration date of any component, whichever is earlier)
  - g) Name and Address of Compounding Pharmacy

Sample labels are attached as Appendix A.

- G. Consumers and health care professionals shall be encouraged to report adverse events experienced with the use of hand sanitizers to our online reporting facility, eReport, at [www.fda.gov.ph/ereport](http://www.fda.gov.ph/ereport), or email via [report@fda.gov.ph](mailto:report@fda.gov.ph).

**V. REPEALING CLAUSE/SEPARABILITY CLAUSE**

Provisions of previous FDA circulars and memoranda that are inconsistent with this issuance are hereby withdrawn, repealed, and/or revoked accordingly. In case any part, term or provision of this FDA Circular is declared contrary to law or unconstitutional, other provisions which are not affected remain in force and effect.

**VI. EFFECTIVITY**

This Circular shall take effect immediately and until further notice.

  
**ROLANDO ENRIQUE D. DOMINGO, MD**  
Director General

**Appendix A**  
Sample Labels

Name of Pharmacy	
Address of Pharmacy	
<b>Alcohol 80%</b>	
Antiseptic	
<b>FOR EXTERNAL USE ONLY</b>	
Directions for Use:	
Apply enough product to cover all surfaces of the hands. Rub hands until dry.	
Avoid contact with eyes	
Keep out of reach of children	
Flammable: Keep away from flame and heat	
Date of production:	Beyond Use Date:
Batch Number:	

Name of Pharmacy	
Address of Pharmacy	
<b>Isopropyl Alcohol 75%</b>	
Antiseptic	
<b>FOR EXTERNAL USE ONLY</b>	
Directions for Use:	
Apply enough product to cover all surfaces of the hands. Rub hands until dry.	
Avoid contact with eyes	
Keep out of reach of children	
Flammable: Keep away from flame and heat	
Date of production:	Beyond Use Date:
Batch Number:	





# Compounding Alcohol-Based Hand Sanitizer During COVID-19 Pandemic

March 18, 2020

This document is for informational purposes only and is intended to address shortages of alcohol-based hand sanitizers associated with the COVID-19 pandemic. This does not reflect the Compounding Expert Committee's opinions on future development or revisions to official text of the *USP-NF*. USP is actively monitoring the evolving situation and will update this document accordingly.

## Background and Introduction

In light of the rapidly evolving COVID-19 pandemic, there is an expected shortage of alcohol-based hand sanitizers. The Centers for Disease Control (CDC) recommends washing hands with soap and water whenever possible because handwashing reduces the amounts of all types of germs and chemicals on hands. If soap and water are not available, using a hand sanitizer with **a final concentration of at least 60% alcohol** can help you avoid getting sick and spreading germs to others.<sup>1</sup> Noting that consumers are experiencing difficulties in accessing alcohol-based hand sanitizers containing at least 60% alcohol, on March 14, 2020, FDA released an Immediately in Effect Guidance titled, "[Policy for Temporary Compounding of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency](\"#\")\"".<sup>2</sup>

During this pandemic, USP supports State Boards and other regulators using **risk-based enforcement discretion** related to the compounding of alcohol-based hand sanitizers for consumer use.

The USP Compounding Expert Committee (CMP EC) provides the following recommendations for compounding alcohol-based hand sanitizers for use during shortages associated with the COVID-19 pandemic. In light of the public health emergency posed by COVID-19, this document was developed without a public comment period. This document is not a USP compendial standard; rather, it reflects considerations developed by the USP CMP EC, based on their scientific and professional expertise, and with input from regulatory agencies at the federal and state level.

If implementing the provisions in this document, the expectation is that compounders follow USP General Chapter <795> *Pharmaceutical Compounding – Nonsterile Preparations*, including the following:<sup>3</sup>

- ▶ Personnel trained in the compounding procedures
- ▶ *USP, NF or Food Chemicals Codex (FCC)* grade ingredients as the recommended source of ingredients
  - When components meeting compendial quality standards are not obtainable, components of equivalent quality – such as those that are chemically pure, analytical reagent grade or American Chemical Society-certified – may be used.
- ▶ All equipment to be clean, properly maintained, and used appropriately
- ▶ A Master Formulation Record and Compounding Record to be prepared
- ▶ A Beyond-Use Date to be assigned

<sup>1</sup> <https://www.cdc.gov/handwashing/show-me-the-science-hand-sanitizer.html>

<sup>2</sup> <https://www.fda.gov/media/136118/download>

<sup>3</sup> Free digital access to <795>: <https://www.usp.org/compounding/general-chapter-795>



## Compounding Alcohol-Based Hand Sanitizer During COVID-19 Pandemic



- ▶ The preparation to be appropriately labeled
  - Label to note the final concentration of ethanol or isopropyl alcohol

The following are three formulations for compounding alcohol-based hand sanitizers. Formulation 1 and 2 were developed based on WHO recommendations.<sup>4</sup>

### Formulation 1: Ethanol Antiseptic 80% Topical Solution

Prepare Ethanol Antiseptic Topical Solution containing ethanol 80% (v/v) as follows (see *Pharmaceutical Compounding—Nonsterile Preparations* <795>).

Ethanol 96%	8333 mL
Hydrogen Peroxide 3%	417 mL
Glycerol 98%	145 mL
Water, <sup>a</sup> a sufficient quantity to make	10000 mL

<sup>a</sup> Water may be distilled water, cold boiled potable water, reverse osmosis water, or filtered water.

Measure the quantities of *Ethanol*, *Hydrogen Peroxide*, and *Glycerol* in suitable containers. Transfer the *Ethanol* and *Hydrogen Peroxide* into a suitable calibrated container and mix gently. Transfer the *Glycerol* stepwise and quantitatively into the calibrated container and mix gently after each addition. Rinse the container containing glycerol several times with *Water* and add the contents to the calibrated container. Add sufficient *Water* to bring to final volume. Mix well. Transfer the solution into suitable containers.

- ▶ **Packaging and Storage:** Package in suitable containers and store at controlled room temperature.
- ▶ **Labeling:** Label to state for external use only, the percentage of ethanol, and the *Beyond-Use Date*.
- ▶ **Beyond-Use Date:** NMT 30 days after the date on which it was compounded, when stored at controlled room temperature.

### Formulation 2: Isopropyl Alcohol Antiseptic 75% Topical Solution

Prepare Isopropyl Alcohol Antiseptic Topical Solution containing isopropyl alcohol 75% (v/v) as follows (see *Pharmaceutical Compounding—Nonsterile Preparations* <795>)

Isopropyl Alcohol 99%	7576 mL
Hydrogen Peroxide 3%	417 mL
Glycerol 98%	75 mL
Water, <sup>a</sup> a sufficient quantity to make	10000 mL

<sup>a</sup> Water may be distilled water, cold boiled potable water, reverse osmosis water, or filtered water.

Measure the quantities of *Isopropyl Alcohol*, *Hydrogen Peroxide*, and *Glycerol* in suitable containers. Transfer the *Isopropyl Alcohol* and *Hydrogen Peroxide* into a suitable calibrated container and mix gently. Transfer the *Glycerol* stepwise and quantitatively into the calibrated container. Mix gently after each addition. Rinse the container containing glycerol several times with *Water* and add the contents to the calibrated container. Add sufficient *Water* to bring to final volume. Mix well. Transfer the solution into suitable containers.

- ▶ **Packaging and Storage:** Package in suitable containers and store at controlled room temperature.
- ▶ **Labeling:** Label to state for external use only, the percentage of isopropyl alcohol, and the *Beyond-Use Date*.
- ▶ **Beyond-Use Date:** NMT 30 days after the date on which it was compounded, when stored at controlled room temperature.

<sup>4</sup> [https://www.who.int/gpsc/5may/Guide\\_to\\_Local\\_Production.pdf](https://www.who.int/gpsc/5may/Guide_to_Local_Production.pdf)

## Compounding Alcohol-Based Hand Sanitizer During COVID-19 Pandemic



### Formulation 3: Isopropyl Alcohol Antiseptic 60% Topical Solution

Prepare Isopropyl Alcohol Antiseptic Topical Solution containing isopropyl alcohol 60% (v/v) as follows (see *Pharmaceutical Compounding—Nonsterile Preparations* <795>).

Isopropyl Alcohol 70%	8571 mL
Hydrogen Peroxide 3%	417 mL
Glycerol 98%	75 mL
Water, <sup>a</sup> a sufficient quantity to make	10000 mL

<sup>a</sup>Water may be distilled water, cold boiled potable water, reverse osmosis water, or filtered water.

Measure the quantities of *Isopropyl Alcohol*, *Hydrogen Peroxide*, and *Glycerol* in suitable containers. Transfer the *Isopropyl Alcohol* and *Hydrogen Peroxide* into a suitable calibrated container and mix gently. Transfer the *Glycerol* stepwise and quantitatively into the calibrated container. Mix gently after each addition. Rinse the container containing glycerol several times with *Water* and add the contents to the calibrated container. Add sufficient *Water* to bring to final volume. Mix well. Transfer the solution into suitable containers.

- ▶ **Packaging and Storage:** Package in suitable containers and store at controlled room temperature.
- ▶ **Labeling:** Label to state for external use only, the percentage of isopropyl alcohol, and the *Beyond-Use Date*.
- ▶ **Beyond-Use Date:** NMT 30 days after the date on which it was compounded, when stored at controlled room temperature.