Compounding Alcohol-Based Hand Sanitizer During COVID-19 Pandemic

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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.[1] 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."[2]

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:[3]

- 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

[1] https://www.cdc.gov/handwashing/show-me-the-science-hand-sanitizer.html

[2] https://www.fda.gov/media/136118/download

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

- 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.[4]

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,[a] a sufficient quantity to make	10000 mL

[a] *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,[a] a sufficient quantity to make	10000 mL

[a] *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.

[4] https://www.who.int/gpsc/5may/Guide_to_Local_Production.pdf

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,[a] a sufficient quantity to make	10000 mL

[a] *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.