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Suggested Formula	Alcohol Antiseptic 80% Topical Solution (Solution, 100 mL)	FIN	F 008 630
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SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Denatured Alcohol (95%), USP*	84.21	mL				
Glycerin, USP	1.45	mL				
Hydrogen Peroxide Concentrate (30% w/w), USP	0.42	mL				
Purified Water, USP	q.s. to 100.0	mL				

*Refer to Pharmacist Instructions section for FDA Guidance on Denaturing Alcohol.





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SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Light Sensitive (protect from light whenever possible): *Hydrogen Peroxide Concentrate*

Hygroscopic (protect from moisture whenever possible): *Glycerin*

Heat Sensitive (protect from heat whenever possible): *Hydrogen Peroxide Concentrate*

Flammable (Keep away from heat and flame) *Denatured Alcohol*

Suggested Preparatory Guidelines

☒ Non-Sterile Preparation ☐ Sterile Preparation

Processing Error / Testing Considerations:

To account for processing error considerations during preparation, it is suggested to measure an additional **5 to 9%** of the required quantities of ingredients.

Special Instruction:

This formula may contain one or more Active Pharmaceutical Ingredients (APIs) that may be classified as hazardous, please refer & verify the current NIOSH list of Antineoplastic and Other Hazardous Drugs in Healthcare Settings. At this time, **General Chapter <800> Hazardous Drugs – Handling in Healthcare Settings** is informational and not compendially applicable unless otherwise specified by regulators and enforcement bodies. For information on the scope, intended applicability, and implementation context for USP General Chapter <800>, see: <https://www.usp.org/compounding/general-chapter-hazardous-drugs-handling-healthcare>.

This formula must be prepared within the appropriate facilities under adequate environmental conditions, following the necessary guidelines and procedures as stated within *USP 795* and *USP 800*, when handling hazardous drugs. Only trained and qualified personnel must prepare this formula.

All required personal protective equipment (hazardous if applicable), such as but not limited to, lab coat, protective sleeves, gloves both inner and outer if applicable, dedicated shoe covers, hairnet, beard cover, eyewear, appropriate face mask, respirator and face shield, etc., where applicable must be worn at all times.

If applicable, follow all required procedures for hazardous drug handling including but not limited to procurement, transport, storage, preparation, dispensing, administration, clean up (spills) & disposal.

If you are a registered 503B facility, please refer to all relevant guidance documents including but not limited to the Code of Federal Regulations (CFR), Guidance for Industry (GFI) and Compliance Policy Guides (CPGs).

This procedure requires the use of very small quantities of ingredients. All calculations and preparation techniques must be verified before dispensing the final product.



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SUGGESTED PREPARATION (for 100 mL)

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor (*): _____	Processing Error	Qty. to measure
Denatured Alcohol (95%), USP §	84.21	mL			
Glycerin, USP §	1.45	mL			
Hydrogen Peroxide Concentrate (30% w/w), USP §	0.42	mL			
Purified Water, USP	q.s. to 100.0	mL			

§ Weigh / measure just prior to use.

* Takes into account increased batch size conversions and density conversions, if required.

Preparatory Instruction	
1.	<u>Medium preparation:</u> A. In the given order, sequentially add the following ingredients to the Denatured Alcohol (95%): -Glycerin -Hydrogen Peroxide Concentrate (30% w/w) <u>Specifications:</u> Continuously mix. <u>End result:</u> Homogeneous liquid-like solution. <u>Note:</u> Add the next ingredient, once the previous one has been completely added and dissolved.
2.	<u>Filling to Volume:</u> A. Add Purified Water to the homogeneous liquid-like solution (Step 1A) to fill to the required batch size (100.0 mL <i>plus</i> processing error adjustments). <u>Specifications:</u> Continuously mix. <u>End result:</u> Homogeneous liquid-like solution.
3.	<u>Product transfer:</u> Transfer the final product into the specified dispensing container (see "Packaging Requirements").



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SUGGESTED PRESENTATION

Estimated Beyond-Use Date	30 days, as per USP.	Packaging Requirements	- Tightly closed, light-resistant container. - To be administered with a metered-dose measuring device.
Auxiliary Labels	1 Use as directed. Do not exceed prescribed dose.	5	Protect from light.
	2 Keep out of reach of children.	6	Cap tightly after use.
	3 Consult your health care practitioner if any other prescription or over-the-counter medications are currently being used or are prescribed for future use.	7	For external use only.
	4 Keep at controlled room temperature (20°C – 25°C).	8	If swallowed, get medical help or contact a Poison Control Center right away.
Pharmacist Instructions	<p>IMPORTANT: Non-sterile preparation, do not use in the presence of an open wound.</p> <p>PER FDA GUIDANCE: The alcohol (ethanol) is denatured either by the alcohol producer or at the point of production of the finished hand sanitizer product. If using un-denatured ethanol, the Alcohol and Tobacco Tax and Trade Bureau Regulations in 27 CFR part 20 and 21 provide a number of formulas for denaturing alcohol, which include Formula 40A or 40B and Formula 3C. Formula 3C states that to every 100 gallons of alcohol add 5 gallons of isopropyl alcohol.</p> <p>Intended for use in a pharmaceutical compounded preparation, as specified. Please ensure appropriate denatured ethanol is used.</p> <p>Please see labeling requirements as stated in Appendix A of the FDA's Policy for Temporary Compounding of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency.</p> <p>Add any auxiliary labels specific to the API to the dispensing container as deemed necessary.</p>		
Patient Instructions	<p>Contact your pharmacist in the event of adverse reactions.</p> <p>IMPORTANT: The quantity of API administered is directly dependent on the quantity of product applied.</p>		



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REFERENCES

1.	Solutions. In: Allen, LV, Jr. <i>The Art, Science, and Technology of Pharmaceutical Compounding Fifth Edition</i> . American Pharmacists Association; 2016: 263.
2.	Ethanol. In: Sheskey, P.J., ed. <i>Handbook of Pharmaceutical Excipients, 8th Edition</i> . Pharmaceutical Press and American Pharmacists Association; 2017: 356.
3.	Glycerin. In: Sheskey, P.J., ed. <i>Handbook of Pharmaceutical Excipients, 8th Edition</i> . Pharmaceutical Press and American Pharmacists Association; 2017: 401.
4.	Hydrogen Peroxide. In: Sheskey, P.J., ed. <i>Handbook of Pharmaceutical Excipients, 8th Edition</i> . Pharmaceutical Press and American Pharmacists Association; 2017: 402.
5.	Alcohol. In: Brayfield, A., ed. <i>Martindale: The Complete Drug Reference, 38th Edition</i> . London, England: The Pharmaceutical Press; 2014: 1733.
6.	Alcohol (Monograph). <i>United States Pharmacopeia XLII / National Formulary 37</i> . Rockville, MD. US Pharmacopeial Convention, Inc. 2019: 114.
7.	Hydrogen Peroxide Concentrate (Monograph). <i>United States Pharmacopeia XLII / National Formulary 37</i> . Rockville, MD. US Pharmacopeial Convention, Inc. 2019: 2199.
8.	USP <795>. <i>United States Pharmacopeia XLII / National Formulary 37</i> . Rockville, MD. US Pharmacopeial Convention, Inc. 2019: 6951.

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Contains Nonbinding Recommendations

Appendix A. Labeling for Ethyl Alcohol Formulation

PRINCIPAL DISPLAY PANEL (FRONT OF PACKAGE):

**Alcohol Antiseptic 80%
Topical Solution**

**Hand Sanitizer
Non-sterile Solution**

[Insert Volume of Product in mL]

DRUG FACTS LABEL

Drug Facts	
Active ingredient[s]	Purpose
Alcohol 80% v/v.....	Antiseptic
Use[s]	
Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
Warnings	
For external use only. Flammable. Keep away from heat or flame	
Do not use	
<ul style="list-style-type: none">• in children less than 2 months of age• on open skin wounds	
When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.	
Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.	
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
Directions	
<ul style="list-style-type: none">• Place enough product on hands to cover all surfaces. Rub hands together until dry.• Supervise children under 6 years of age when using this product to avoid swallowing.	
Other information	
<ul style="list-style-type: none">• Store between 15-30C (59-86F)• Avoid freezing and excessive heat above 40C (104F)	
Inactive ingredients	
glycerin, hydrogen peroxide, purified water USP	