



Suggested Formula	Alcohol Antiseptic 80% Topical Solution (Solution, 100 mL)	FIN	F 008 671
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SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
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				

*Hydrogen Peroxide Topical Solution (3% w/w), USP could be used and will be equivalent to 4.17 mL.





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SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

<i>Light Sensitive (protect from light whenever possible):</i>	<i>Hydrogen Peroxide Concentrate</i>
<i>Hygroscopic (protect from moisture whenever possible):</i>	<i>Glycerin</i>
<i>Heat Sensitive (protect from heat whenever possible):</i>	<i>Hydrogen Peroxide Concentrate</i>
<i>Flammable (Keep away from heat and flame)</i>	<i>Alcohol</i>

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
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.	<p><u>Medium preparation:</u></p> <p>A. In the given order, sequentially add the following ingredients to the Alcohol (95%):</p> <ul style="list-style-type: none"> -Glycerin -Hydrogen Peroxide Concentrate (30% w/w) <p><u>Specifications:</u> Continuously mix.</p> <p><u>End result:</u> Homogeneous liquid-like solution.</p> <p><u>Note:</u> Add the next ingredient, once the previous one has been completely added and dissolved.</p>
2.	<p><u>Filling to Volume:</u></p> <p>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).</p> <p><u>Specifications:</u> Continuously mix.</p> <p><u>End result:</u> Homogeneous liquid-like solution.</p>
3.	<p><u>Product transfer:</u></p> <p>Transfer the final product into the specified dispensing container (see “Packaging Requirements”).</p>



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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>Please verify with your local, state, federal or provincial regulations on the labeling requirements and appropriateness of compounding this formula.</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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