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3/17/2020; Page 1

Suggested Formula	Isopropyl Alcohol Antiseptic 75% Topical Solution (Solution, 100 mL)	FIN	F 008 631
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SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Isopropyl Alcohol (Alcohol 99%), USP	75.76	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				





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SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

<i>Light Sensitive</i> (protect from light whenever possible):	<i>Hydrogen Peroxide Concentrate</i>
<i>Hygroscopic</i> (protect from moisture whenever possible):	<i>Glycerin</i>
<i>Heat Sensitive</i> (protect from heat whenever possible):	<i>Isopropyl Alcohol, Hydrogen Peroxide Concentrate</i>
<i>Flammable</i> (Keep away from heat and flame)	<i>Isopropyl 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, 2016. **General Chapter <800> Hazardous Drugs – Handling in Healthcare Settings** was formally published February 1, 2016 in the First Supplement to USP 39-NF 34 and has a delayed **official implementation date of December 31st, 2019**.

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 (GFIs) 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
Isopropyl Alcohol (Alcohol 99%), USP	75.76	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 Isopropyl Alcohol (Alcohol 99%):</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 room temperature (20°C – 23°C).		
Pharmacist Instructions	<p>IMPORTANT: Non-sterile preparation, do not use in the presence of an open wound.</p> <p>Please see labeling requirements as stated in Appendix B 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.	Isopropyl Alcohol. In: Sheskey, P.J., ed. <i>Handbook of Pharmaceutical Excipients, 8th Edition</i> . Pharmaceutical Press and American Pharmacists Association; 2017: 491.
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.	Isopropyl Alcohol. In: Brayfield, A., ed. <i>Martindale: The Complete Drug Reference, 38th Edition</i> . London, England: The Pharmaceutical Press; 2014: 1758.
6.	Isopropyl Alcohol (Monograph). In: O'Neil MJ. <i>The Merck Index 15th Edition</i> . Whitehouse Station, NJ: Merck & Co, Inc.; 2013: Monograph #5254.
7.	Isopropyl Alcohol (Monograph). <i>United States Pharmacopeia XLII / National Formulary 37</i> . Rockville, MD. US Pharmacopeial Convention, Inc. 2019: 2383.
8.	Hydrogen Peroxide Concentrate (Monograph). <i>United States Pharmacopeia XLII / National Formulary 37</i> . Rockville, MD. US Pharmacopeial Convention, Inc. 2019: 2199.
9.	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 B. Labeling for Isopropyl Alcohol Formulation

PRINCIPAL DISPLAY PANEL (FRONT OF PACKAGE):

**Isopropyl Alcohol Antiseptic 75%
Topical Solution**

**Hand Sanitizer
Non-sterile Solution**

[Insert Volume of Product in mL]

DRUG FACTS LABEL

Drug Facts	
Active ingredient[s]	Purpose
Isopropyl alcohol 75% 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	