



Suggested Formula	Hydroquinone 8% Topical Gel (Suspension, 15 g)	FIN	F 006 651
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### SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Hydroquinone, USP	1.200	g				
Polysorbate 80, NF	1.0	mL				
Medisca CopaSil™	12.72	g				

### SPECIAL PREPARATORY CONSIDERATIONS

#### Ingredient-Specific Information

**Light Sensitive** (protect from light whenever possible): Hydroquinone, Polysorbate 80, CopaSil™

**Hygroscopic** (protect from moisture whenever possible): Polysorbate 80

**Oxygen sensitive** (protect from air whenever possible): Hydroquinone, Polysorbate 80

#### 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 **15 to 20%** of the required quantities of ingredients.

Special Instruction: Protective apparel, such as a lab coat, disposable gloves, eyewear and face-masks should always be worn.

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 15 g)**

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor (*): _____	Processing Error	Qty. to measure
Hydroquinone, USP §	1.200	g			
Polysorbate 80, NF §	1.0	mL			
Medisca CopaSil™ §	12.72	g			

§ Weigh / measure just prior to use.

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

Preparatory Instruction	
1.	<b><u>Powder-liquid preparation:</u></b>  A. Triturate the Hydroquinone to form a fine, homogeneous powder.  B. Levigate the fine homogeneous powder (Step 1A) with the Polysorbate 80.  <u>End result:</u> Homogeneous paste-like dispersion.
2.	<b><u>Powder-liquid to medium integration:</u></b>  A. Incrementally add the homogeneous paste-like dispersion (Step 1B) to the CopaSil™.  <u>Specifications:</u> Continuously mix, using high-shear mixing techniques.  <u>End result:</u> Homogeneous gel-like dispersion.  B If the final result is gritty, pass it through the ointment mill until it becomes smooth and uniform.
3.	<b><u>Product transfer:</u></b>  Transfer the final product into the specified dispensing container (see “Packaging Requirements”).



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**SUGGESTED PRESENTATION**

Estimated Beyond-Use Date	6 months, as per USP*.	Packaging Requirements	Tightly closed, light-resistant container with topical applicator.	
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.	7	Cap tightly after use.
	2	Keep out of reach of children.	8	Do not allow applicator tip to come into contact with surrounding tissue.
	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.	9	Keep in a dry place.
	4	Keep at room temperature (20°C – 23°C).	10	Protect from light.
	5	Do not touch the medication with your hands.	11	For external use only.
	6	Do not allow to come into contact with eyes/ears/nose/mouth.		
Pharmacist Instructions	Add any auxiliary labels specific to the API to the dispensing container as deemed necessary.			
Patient Instructions	Contact your pharmacist in the event of adverse reactions. <b>IMPORTANT:</b> The quantity of API administered is directly dependent on the quantity of product applied.			

\* The BUD is not later than the time remaining until the earliest expiration date of any API or 6 months, whichever is earlier.

**REFERENCES**

1.	Gels. In: Allen, LV, Jr. <i>The Art, Science and Technology of Pharmaceutical Compounding Fourth Edition</i> . American Pharmaceutical Association; 2012: 285.
2.	Polyoxyethylene Sorbitan Fatty Acid Esters. In: Rowe RC. <i>Handbook of Pharmaceutical Excipients, 7<sup>th</sup> Edition</i> . American Pharmaceutical Association; 2012: 620.
3.	Hydroquinone. In: Sweetman SC, ed. <i>Martindale: The Complete Drug Reference, 36<sup>th</sup> Edition</i> . London, England: The Pharmaceutical Press; 2009: 1598.
4.	Hydroquinone (Monograph). In: O’Neil MJ. <i>The Merck Index 15<sup>th</sup> Edition</i> . Whitehouse Station, NJ: Merck & Co, Inc.; 2013: Monograph #4845.



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5.	Hydroquinone. In: Trissel LA. <i>Trissel's Stability of Compounded Formulations, 5<sup>th</sup> Edition</i> . American Pharmaceutical Association; 2012: 246.
6.	Hydroquinone (Monograph). <i>United States Pharmacopeia XXXVIII / National Formulary 33</i> . Rockville, MD. US Pharmacopeial Convention, Inc. 2015: 3804.
7.	USP <795>. <i>United States Pharmacopeia XXXVIII / National Formulary 33</i> . Rockville, MD. US Pharmacopeial Convention, Inc. 2015: 559.



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