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Suggested Formula	Clotrimazole 2%, Hydrocortisone 2% Topical Gel (Suspension, 30 g)	FIN	F 008 968
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### SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Clotrimazole, USP	0.600	g				
Hydrocortisone (Micronized), USP	0.600	g				
Ethoxy Diglycol, NF	1.2	mL				
Medisca VersaPro™ Anhydrous Base	27.61	g				





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## SPECIAL PREPARATORY CONSIDERATIONS

### Ingredient-Specific Information

**Hygroscopic** (protect from moisture whenever possible):      *Ethoxy Diglycol*

**Light Sensitive** (protect from light whenever possible):      *Hydrocortisone, Clotrimazole*

### 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 **12 to 15%** 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 30 g)

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor (*): _____	Processing Error	Qty. to measure
Clotrimazole, USP §	0.600	g			
Hydrocortisone (Micronized), USP §	0.600	g			
Ethoxy Diglycol, NF §	1.2	mL			
Medisca VersaPro™ Anhydrous Base	27.61	g			

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

§ Weigh / measure just prior to use.

#### Preparatory Instruction

1.	<b><u>Powder-liquid preparation:</u></b>  A. Triturate the Clotrimazole to form a fine, homogeneous powder.  B. Combine and mix the following ingredients together:  -Fine, homogeneous powder (Step 1A): -Hydrocortisone (Micronized)  <u>End result:</u> Homogeneous powder blend.  C. Levigate the homogeneous powder blend (Step 1B) with the Ethoxy Diglycol.  <u>End result:</u> Homogeneous liquid-like dispersion.
2.	<b><u>Phase integration:</u></b>  A. Incrementally add the homogeneous liquid-like dispersion (Step 1C) to the VersaPro™ Anhydrous Base.  <u>Specifications:</u> Continuously mix, using high-shear mixing techniques.  <u>End result:</u> Homogeneous gel-like dispersion.
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		Packaging Requirements		
	6 months, as per USP 795*.		- Tightly closed, light-resistant ointment tube/jar. - To be administered with a metered-dose measuring device.	
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.	6	Protect from light.
	2	Keep out of reach of children.	7	Consult your health care practitioner if any other prescription or over-the-counter medications are currently being used or are prescribed for future use.
	3	For external use only.	8	Cap tightly after use.
	4	Keep at controlled room temperature (20°C – 25°C).	9	May impair mental and or physical ability. Use care when operating a car or machinery.
	5	Do not take with alcohol, sleep aids, tranquilizers or other CNS depressants.	10	Keep in a dry place.
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.



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## REFERENCES

1.	Ointments, Creams, and Pastes. In: Allen, LV, Jr. <i>The Art, Science, and Technology of Pharmaceutical Compounding Fifth Edition</i> . American Pharmacists Association; 2016: 317.
2.	Clotrimazole. In: Sweetman SC, ed. <i>Martindale: The Complete Drug Reference, 38<sup>th</sup> Edition</i> . London, England: The Pharmaceutical Press; 2014: 576.
3.	Hydrocortisone. In: Sweetman SC, ed. <i>Martindale: The Complete Drug Reference, 38<sup>th</sup> Edition</i> . London, England: The Pharmaceutical Press; 2014: 1640.
4.	Clotrimazole (Monograph). In: O'Neil MJ. <i>The Merck Index 15<sup>th</sup> Edition</i> . Whitehouse Station, NJ: Merck & Co, Inc.; 2013: Monograph #2401.
5.	Hydrocortisone (Monograph). In: O'Neil MJ. <i>The Merck Index 15<sup>th</sup> Edition</i> . Whitehouse Station, NJ: Merck & Co, Inc.; 2013: Monograph #4824.
6.	Clotrimazole. In: Trissel LA. <i>Trissel's Stability of Compounded Formulations, 5<sup>th</sup> Edition</i> . American Pharmaceutical Association; 2012: 131.
7.	Hydrocortisone. In: Trissel LA. <i>Trissel's Stability of Compounded Formulations, 5<sup>th</sup> Edition</i> . American Pharmaceutical Association; 2012: 241.
8.	Clotrimazole (Monograph). <i>United States Pharmacopeia XLIII / National Formulary 38</i> . Rockville, MD. US Pharmacopeial Convention, Inc. 2020: 1118.
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