MEDISCA® NETWORK INC.
TECHNICAL SUPPORT SERVICES
FORMULATION CHEMISTRY DEPARTMENT
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Suggested Formula	Clotrimazole 1% Mucoadhesive Oral Rinse (Suspension, 100 mL)	FIN	F 008 649

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Clotrimazole, USP	1.000	g				
Medisca NovaFilm™ Gel Base	30.0	mL				
Propylene Glycol, USP	5.0	mL				
Cherry Flavor	1.0	mL				
Medisca Oral Mix™ SF (Sugar-Free Flavored Suspending Vehicle)	60.0	mL				
Medisca Oral Mix™ SF (Sugar-Free Flavored Suspending Vehicle)	q.s. to 100.0	mL				
Sodium Hydroxide 10% Solution	As required					
Hydrochloric Acid 10% Solution	As required					

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SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Light Sensitive *(protect from light whenever possible):* *Clotrimazole, Propylene Glycol, NovaFilm™ Gel Base*

Hygroscopic *(protect from moisture whenever possible):* *Propylene Glycol*

Suggested Preparatory Guidelines

■ Non-Sterile Preparation ☐ Sterile Preparation

Processing Error / Testing Considerations: To account for processing error and pH testing 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 (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
Clotrimazole, USP §	1.000	g			
Medisca NovaFilm™ Gel Base §	30.0	mL			
Propylene Glycol, USP §	5.0	mL			
Cherry Flavor	1.0	mL			
Medisca Oral Mix™ SF (Sugar-Free Flavored Suspending Vehicle)	60.0	mL			
Medisca Oral Mix™ SF (Sugar-Free Flavored Suspending Vehicle)	q.s. to 100.0	mL			
Sodium Hydroxide 10% Solution	As required				
Hydrochloric Acid 10% Solution	As required				

§ Weigh / measure just prior to use.
* Takes into account increased batch size conversions and density conversions, if required.

	Preparatory Instruction
1.	**Powder-liquid preparation:** A. Triturate the Clotrimazole to form a fine, homogeneous powder. B. Levigate the fine, homogeneous powder (Step 1A) with the Propylene Glycol. End result: Homogeneous liquid-like dispersion.
2.	**Powder-liquid to medium integration:** A. Sequentially add the following ingredients to the Oral Mix™ SF (Sugar-Free Flavored Suspending Vehicle) (60.0 mL *plus* processing error adjustments): -Homogeneous liquid-like dispersion (Step 1B) -NovaFilm™ Gel Base -Cherry Flavor Specifications: Continuously mix, using high-shear mixing techniques. End result: Homogeneous liquid-like dispersion. Note: Add the next ingredient, once the previous one has been completely added and dispersed.

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3. **pH testing:**

A. Draw an appropriate amount of the mixture (Step 2A).

B. Test the pH of the sample. It should lie between 5.0 and 7.0.

C. If the pH < 5.0, carefully add, in a dropwise fashion, the Sodium Hydroxide 10% Solution to the mixture:

1. Draw and transfer 1 or 2 drops of the Sodium Hydroxide 10% Solution to the mixture.
2. Stir for at least 5 minutes to evenly disperse the Sodium Hydroxide 10% Solution.
3. Re-test the pH.
4. Continue to add the Sodium Hydroxide 10% Solution until the pH of 5.0 to 7.0 is obtained.

IMPORTANT: Do not allow the pH to rise above 7.0.

D. If the pH > 7.0, carefully add, in a dropwise fashion, the Hydrochloric Acid 10% Solution to the mixture:

1. Draw and transfer 1 or 2 drops of the Hydrochloric Acid 10% Solution to the mixture.
2. Stir for at least 5 minutes to evenly disperse the Hydrochloric Acid 10% Solution.
3. Re-test the pH.
4. Continue to add the Hydrochloric Acid 10% Solution until the pH of 5.0 to 7.0 is obtained.

IMPORTANT: Do not allow the pH to fall below 5.0.

4. **Filling to volume:**

A. Add additional Oral Mix™ SF (Sugar-Free Flavored Suspending Vehicle) to the above mixture to fill to the required batch size (100.0 mL *plus* processing error adjustments).

Specifications: Continuously mix, using high-shear mixing techniques.

End result: Homogeneous liquid-like dispersion.

5. **Product transfer**

Transfer the final product into the specified dispensing container (see "Packaging requirements").

Note: Continuously mix the final product during the transfer process into the recommended dispensing containers in order to maintain homogeneity.

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SUGGESTED PRESENTATION

Estimated Beyond-Use Date		14 days, refrigerated, as per USP.	Packaging Requirements		- Tightly closed, light-resistant mouth rinse bottle. - To be administered with a metered dosing device.
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.		6	Keep refrigerated (2°C – 8°C). Do not freeze.
	2	Keep out of reach of children.		7	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.		8	For local (oral) use only.
	4	Protect from light.		9	**To be used as a mouth rinse; not to be swallowed.**
	5	**Shake well before use.**			
Pharmacist Instructions		**IMPORTANT: -Non-sterile preparation, do not use in the presence of an open wound.** **-Use of this formula is intended for local treatment and not for systemic treatment.** 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. **IMPORTANT:** The quantity of API administered is directly dependent on the quantity of product applied.			

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REFERENCES

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