Medisca
PARTNERS IN WELLNESS

Compounding Services Department
Formulation Support

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Suggested Formula	Clotrimazole 10 mg Oral Troches (Solid Suspension, 30 x 0.9 mL Troches)	**FIN**	F 005 278

Suggested Formulation

Ingredient Listing	Qty	Unit	Product Code	Supplier	LOT No.	Expiry Date
Clotrimazole, USP	0.300	g				
Polyethylene Glycol 400, NF	2.1	mL				
Gelatin, NF	0.30	g				
Polyethylene Glycol 1450, NF	26.47	g				

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Special Preparatory Considerations

Ingredient-Specific Information

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

Hygroscopic (protect from moisture whenever possible): *Polyethylene Glycol 400, Polyethylene Glycol 1450*

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 (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

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty	Unit	Multiplication factor (*): ____	Processing Error	Qty to measure
Clotrimazole, USP §	0.300	g			
Polyethylene Glycol 400, NF §	2.1	mL			
Gelatin, NF	0.30	g			
Polyethylene Glycol 1450, NF §	26.47	g			

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

	Preparatory Instruction
1.	Preparatory step: A. Prepare a hot water bath. Specifications: Temperature: 60 to 65°C.
2.	Powder-liquid preparation: A. Combine and triturate the following ingredients together to form a fine, homogeneous powder blend: -Clotrimazole -Gelatin B. Levigate the fine, homogeneous powder blend (Step 2A) with the Polyethylene Glycol 400. End result: Homogeneous liquid-like dispersion.

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3. Powder-liquid to medium integration:

A. Using the hot water bath, melt the Polyethylene Glycol 1450.

Specifications: Continuously mix.
Maintain temperature between 60°C and 65°C.

End result: Homogeneous liquid-like solution.

B. Using the hot water bath, sequentially add the homogeneous liquid-like dispersion (Step 2B) to the homogeneous liquid-like solution (Step 3A).

Specifications: Continuously mix.
Maintain temperature between 60°C and 65°C.

End result: Homogeneous liquid-like dispersion.

Note: Add the next ingredient, once the previous one has been completely added and dispersed.

Important: Do not allow the temperature to exceed 65°C.

4. Mold filling:

A. Fill the 30 mold cavities with the homogeneous liquid-like dispersion (Step 3B). If the mixture starts to solidify while filling, reheat to 60 to 65°C, and continue.

B. Allow to cool until the API mixture has completely solidified.

Note: Continuously mix the final product during the mold filling in order to maintain homogeneity.

5. Validation technique:

A. Weigh 6 troches separately.

B. The final weight of each troche from Step 5A (not including the weight of the troche mold) shall not be less than 90% and not more than 110% of the theoretically calculated weight 0.98 g in accordance to USP guidelines.

6. Product transfer:

Transfer the final product into the specified dispensing container (see “Packaging Requirements”).

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Suggested Presentation

Estimated Beyond-Use Date		180 days, controlled room temperature or refrigerator, as per USP 795*.	**Packaging Requirements**	Individually wrapped in a tight, light-resistant foil and placed in a box or wide-mouth jar, or dispensed in a troche mold and covered with light-resistant sleeve.
Auxiliary Labels	**1.**	Use as directed. Do not exceed prescribed dose.	**5.**	Cap tightly after use.
	2.	Keep out of reach of children.	**6.**	Keep in a dry place.
	3.	Consult your health care practitioner if any prescription or over-the-counter medications are currently being used or are prescribed for future use.	**7.**	Protect from light.
	4.	Keep at controlled room temperature (20°C – 25°C) OR keep refrigerated (2°C – 8°C). Do not freeze.		
Pharmacist Instructions	Add any auxiliary labels specific to the API to the dispensing container as deemed necessary.			
Patient Instructions	If allergic reactions occur, consult your pharmacist.			

*** If the API or any other components in the CNSP have an expiration date that is earlier than the assigned BUD, the expiration date supersedes the assigned BUD and must be the assigned shortest date.**

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References

1.	Lozenges/Troches. In: Allen, LV, Jr. *The Art, Science and Technology of Pharmaceutical Compounding.* American Pharmaceutical Association; 2008: 153.
2.	Gelatin. In: Rowe RC. *Handbook of Pharmaceutical Excipients, 6th Edition*. American Pharmaceutical Association; 2009: 278.
3.	Polyethylene Glycol. In: Rowe RC. *Handbook of Pharmaceutical Excipients, 6th Edition*. American Pharmaceutical Association; 2009: 517.
4.	Clotrimazole. In: Sweetman SC, ed. *Martindale: The Complete Drug Reference, 36th Edition.* London, England: The Pharmaceutical Press; 2009: 530.
5.	Clotrimazole (Monograph). In: O'Neil MJ. *The Merck Index 14th Edition*. Whitehouse Station, NJ: Merck & Co, Inc.; 2006: #2417.
6.	Clotrimazole (Monograph). *United States Pharmacopeia XXXV / National Formulary 30.* Rockville, MD. US Pharmacopeial Convention, Inc. 2012: 2740.
7.	Clotrimazole. Thomson Micromedex. *USP DI – Drug Information for the Health Care Professional, 26th Edition.* Taunton, MA: US Pharmacopeial Convention, Inc; 2006: 928.
8.	USP <795>. *United States Pharmacopeia XXXV / National Formulary 30.* Rockville, MD. US Pharmacopeial Convention, Inc. 2012: 344.