



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

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	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				

SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

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

Light sensitive (protect from light whenever possible): 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 **10 to 12%** 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 30 x 0.9 mL Troches)

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 mold size conversions and density conversions, if required.

§ Weigh / measure just prior to use.

Preparatory Instruction	
1.	<u>Preparatory step:</u> A. Prepare a hot water bath. <u>Specifications:</u> Temperature: 60 to 65°C.
2.	<u>Powder-liquid preparation:</u> 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. <u>End result:</u> Homogeneous liquid-like dispersion.



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3.	<p><u>Powder-liquid to medium integration:</u></p> <p>A. Using the hot water bath, melt the Polyethylene Glycol 1450.</p> <p><u>Specifications:</u> Continuously mix. Maintain temperature between 60°C and 65°C.</p> <p><u>End result:</u> Homogeneous liquid-like solution.</p> <p>B. Using the hot water bath, sequentially add the homogeneous liquid-like dispersion (Step 2B) to the homogeneous liquid-like solution (Step 3A).</p> <p><u>Specifications:</u> Continuously mix, using high-shear mixing techniques. Maintain temperature between 60°C and 65°C.</p> <p><u>End result:</u> Homogeneous liquid-like dispersion.</p> <p><u>Note:</u> Add the next ingredient, once the previous one has been completely added and dispersed.</p> <p>Important: Do not allow the temperature to exceed 65°C.</p>
4.	<p><u>Mold filling:</u></p> <p>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.</p> <p>B. Allow to cool until the API mixture has completely solidified.</p> <p><u>Note:</u> Continuously mix the final product during the mold filling in order to maintain homogeneity.</p>
5.	<p><u>Validation technique:</u></p> <p>A. Weigh 6 troches separately.</p> <p>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.</p>
6.	<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	6 months, as per USP*.	Packaging Requirements	Individually wrapped in a tight, light-resistant foil and placed in a box or a wide-mouth jar.	
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 room temperature (20°C – 23°C).		
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.			

* 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.	Lozenges/Troches. In: Allen, LV, Jr. <i>The Art, Science and Technology of Pharmaceutical Compounding</i> . American Pharmaceutical Association; 2008: 153.
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5.	Clotrimazole (Monograph). In: O'Neil MJ. <i>The Merck Index 14th Edition</i> . Whitehouse Station, NJ: Merck & Co, Inc.; 2006: #2417.
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8.	USP <795>. <i>United States Pharmacopeia XXXV / National Formulary 30</i> . Rockville, MD. US Pharmacopeial Convention, Inc. 2012: 344.

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