



Suggested Formula	Terbinafine Hydrochloride 250 mg/mL Oral Liquid (Suspension, 15 mL)	FIN	F 002 943v2
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### SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Terbinafine Hydrochloride	3.750	g				
Glycerin, USP	3.0	mL				
Medisca Oral Suspend (Suspending Vehicle)	4.5	mL				
Medisca Oral Syrup (Flavored Vehicle)	q.s. to 15.0	mL				

### SPECIAL PREPARATORY CONSIDERATIONS

#### Ingredient-Specific Information

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

*Glycerin*

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

*Terbinafine Hydrochloride*

#### 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 mL)

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor (*): ____	Processing Error	Qty. to measure
Terbinafine Hydrochloride §	3.750	g			
Glycerin, USP §	3.0	mL			
Medisca Oral Suspend (Suspending Vehicle)	4.5	mL			
Medisca Oral Syrup (Flavored Vehicle)	q.s. to 15.0	mL			

§ Weigh / measure just prior to use.

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

Preparatory Instruction	
1.	<p><b><u>Powder-liquid preparation:</u></b></p> <p>A. Triturate the Terbinafine Hydrochloride to form a fine, homogeneous powder.</p> <p>B. Levigate the fine, homogeneous powder (Step 1A) with the Glycerin.</p> <p><u>End result:</u> Homogeneous paste-like dispersion.</p>
2.	<p><b><u>Medium integration:</u></b></p> <p>A. Incrementally add the homogeneous paste-like dispersion (Step 1B) to the Oral Suspend (Suspending Vehicle).</p> <p><u>Specifications:</u> Continuously mix, using high-shear mixing techniques.</p> <p><u>End result:</u> Homogeneous liquid-like dispersion.</p>
3.	<p><b><u>Filling to volume:</u></b></p> <p>A. Add Oral Syrup (Flavored Vehicle) to the mixture (Step 2A) to fill to the required batch size (15.0 mL <i>plus</i> processing error adjustments).</p> <p><u>Specifications:</u> Continuously mix, using high-shear mixing techniques.</p> <p><u>End result:</u> Homogeneous liquid-like dispersion.</p>



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4.	<p><b><u>Product transfer:</u></b></p> <p>A. Transfer the final product into the specified dispensing container (see “Packaging requirements”).</p> <p><u>Note:</u> Continuously mix the final product during the transfer process into the recommended dispensing containers in order to maintain homogeneity.</p>
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**SUGGESTED PRESENTATION**

Estimated Beyond-Use Date		Packaging Requirements	
	14 days, refrigerated, as per USP.		- Tightly closed, light-resistant dispensing bottle. - To be administered with a metered dose-measuring device.
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.	6 Cap tightly after use.
	2	Keep out of reach of children.	7 <b>Shake well before use.</b>
	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 Keep refrigerated. Do not freeze.
	4	Do not take with alcohol, sleep aids, tranquilizers or other CNS depressants.	9 Protect from light.
	5	For veterinary use only.	
Pharmacist Instructions	Add any auxiliary labels specific to the active to the dispensing container as deemed necessary. <b>IMPORTANT: To be dispensed and administered only under the close supervision of the prescribing physician.</b>		
Patient Instructions	Contact your pharmacist in the event of adverse reactions.		



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## REFERENCES

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