



Suggested Formula	Finasteride 0.1%, Minoxidil 3% Topical Foam (Solution, 50 mL)	FIN	F 006 887v2
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SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Finasteride 2% Stock Solution †	2.50	mL				
Minoxidil, USP	1.500	g				
Medisca Foamil™ Base	45.0	mL				
Medisca Foamil™ Base	q.s. to 50.0	mL				
† Finasteride 2% Stock Solution						
Finasteride, USP	0.100	g				
Alcohol (95%), USP	4.5	mL				
Alcohol (95%), USP	q.s. to 5.0	mL				

SPECIAL PREPARATORY CONSIDERATIONS

<u>Ingredient-Specific Information</u>	
Light sensitive (protect from light whenever possible):	<i>Minoxidil, Foamil™ Base</i>
Narrow Therapeutic Index:	<i>Minoxidil</i>
<u>Suggested Preparatory Guidelines</u>	
<input checked="" type="checkbox"/> Non-Sterile Preparation	<input type="checkbox"/> Sterile Preparation
<u>Processing Error / Testing Considerations:</u>	To account for processing error considerations during preparation, it is suggested to measure an additional 10 to 12% of the required quantities of ingredients.
<u>Special Instruction:</u>	Protective apparel, such as a lab coat, disposable gloves, eyewear and face-masks should always be worn. Minoxidil has a narrow therapeutic index. 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 50 mL)

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor (*): ____	Processing Error	Qty. to measure
Finasteride 2% Stock Solution †	2.50	mL			
Minoxidil, USP §	1.500	g			
Medisca Foamil™ Base §	45.0	mL			
Medisca Foamil™ Base §	q.s. to 50.0	mL			
† Finasteride 2% Stock Solution					
Finasteride, USP	0.100	g	---	---	
Alcohol (95%), USP	4.5	mL	---	---	
Alcohol (95%), USP	q.s. to 5.0	mL	---	---	

§ Weigh / measure just prior to use.

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

Preparatory Instruction

1.	<p>† Finasteride 2% Stock Solution preparation:</p> <p>A. Triturate the Finasteride (0.100 g) to form a fine, homogeneous powder.</p> <p>B. Incrementally add the fine, homogeneous powder (Step 1A) to the Alcohol (95%) (4.5 mL).</p> <p><u>Specifications:</u> Continuously mix until all solid particles have completely dissolved.</p> <p><u>End result:</u> Homogeneous liquid-like solution.</p> <p>C. Add additional Alcohol (95%) to the mixture (Step 1B) to fill to the required batch size (5.0 mL).</p> <p><u>Specifications:</u> Continuously mix.</p> <p><u>End result:</u> Homogeneous liquid-like solution.</p>
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2.	<p><u>Powder to medium integration:</u></p> <p>A. Triturate the Minoxidil to form a fine, homogeneous powder.</p> <p>B. Incrementally add the fine, homogeneous powder blend (Step 2A) into the Foamil™ Base (45.0 mL <i>plus</i> processing error adjustments).</p> <p><u>Specifications:</u> Continuously mix until all solid particles have completely dissolved.</p> <p><u>End result:</u> Homogeneous liquid-like solution.</p>
3.	<p><u>Liquid to medium integration:</u></p> <p>A. Incrementally add the homogeneous liquid-like solution (Step 2B) into the Finasteride 2% Stock Solution (2.50 mL <i>plus</i> processing error adjustments).</p> <p><u>Specifications:</u> Continuously mix until homogeneous.</p> <p><u>End result:</u> Homogeneous liquid-like solution.</p>
4.	<p><u>Filling to volume:</u></p> <p>A. Add additional Foamil™ Base to the homogeneous liquid-like solution (Step 3A) to fill to the required batch size (50.0 mL <i>plus</i> processing error adjustments).</p> <p><u>Specifications:</u> Continuously mix until homogeneous.</p> <p><u>End result:</u> Homogeneous liquid-like solution.</p>
5.	<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	30 days, as per USP.	Packaging Requirements	- Tightly closed, light-resistant topical 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	May impair mental and/or physical ability. Use care when operating a car or machinery.	7	Do not take with alcohol, sleep aids, tranquilizers or other CNS depressants.
	3	Keep out of reach of children.	8	Protect from light.
	4	Consult your health care practitioner if any other prescription or over-the-counter medications are currently being used or are prescribed for future use.	9	For external use only.
	5	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	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

1.	Cosmetics for special populations and for use as vehicles. In: Allen, LV, Jr. <i>The Art, Science and Technology of Pharmaceutical Compounding Fourth Edition</i> . American Pharmaceutical Association; 2012: 441.
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4.	Minoxidil (Monograph). In: O'Neil MJ. <i>The Merck Index 15th Edition</i> . Whitehouse Station, NJ: Merck & Co, Inc.; 2013: #6285.
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