



Suggested Formula	Minoxidil 5.5% Topical Foam (Solution, 50 mL)	FIN	F 006 844v2
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SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Minoxidil, USP	2.750	g				
Medisca Foamil™ Base	37.5	mL				
Medisca Foamil™ Base	q.s. to 50.0	mL				

SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Light sensitive (protect from light whenever possible):

Minoxidil, Foamil™ Base

Narrow Therapeutic Index:

Minoxidil

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.

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
Minoxidil, USP §	2.750	g			
Medisca Foamil™ Base §	37.5	mL			
Medisca Foamil™ Base §	q.s. to 50.0	mL			

§ Weigh / measure just prior to use.

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

Preparatory Instruction

1.	<p><u>Powder-liquid preparation:</u></p> <p>A. Triturate the Minoxidil to form a fine, homogeneous powder.</p> <p>B. Dissolve the fine, homogeneous powder (Step 1A) in the Foamil™ Base (37.5 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>
2.	<p><u>Filling to volume:</u></p> <p>A. Add additional Foamil™ Base to the homogeneous liquid-like solution (Step 1B) to fill to the required batch size (50.0 mL <i>plus</i> processing error adjustments).</p> <p><u>Specifications:</u> Continuously mix.</p> <p><u>End result:</u> Homogeneous liquid-like solution.</p>
3.	<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.
2.	Minoxidil. In: Sweetman SC, ed. <i>Martindale: The Complete Drug Reference, 36th Edition</i> . London, England: The Pharmaceutical Press; 2009: 1342.
3.	Minoxidil (Monograph). In: O'Neil MJ. <i>The Merck Index 15th Edition</i> . Whitehouse Station, NJ: Merck & Co, Inc.; 2013: #6285.
4.	Minoxidil. In: Trissel LA. <i>Trissel's Stability of Compounded Formulations, 5th Edition</i> . American Pharmaceutical Association; 2012: 334.
5.	Minoxidil (Monograph). <i>United States Pharmacopeia XXXIX / National Formulary 34</i> . Rockville, MD. US Pharmacopeial Convention, Inc. 2016: 4986.
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