



Suggested Formula	Ketoconazole 2%, Salicylic Acid 2% Topical Shampoo (Solution, 100 mL)	FIN	F 006 819v2
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SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Ketoconazole, USP	2.000	g				
Salicylic Acid (Hydrosoluble, 50%)	4.00	mL				
Citric Acid 25% Solution	6.0	mL				
Medisca ADA™ Shampoo Base	80.0	mL				
Purified Water, USP	q.s. to 100.0	mL				

SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Light sensitive (protect from light whenever possible):

Ketoconazole, Salicylic Acid

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 **5 to 9%** 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 100 mL)

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor (*): ____	Processing Error	Qty. to measure
Ketoconazole, USP §	2.000	g			
Salicylic Acid (Hydrosoluble, 50%) §	4.00	mL			
Citric Acid 25% Solution	6.0	mL			
Medisca ADA™ Shampoo Base	80.0	mL			
Purified Water, USP	q.s. to 100.0	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. Incrementally add the Ketoconazole to the Citric Acid 25% Solution.</p> <p><u>Specifications:</u> Continuously mix until homogeneous.</p> <p><u>End result:</u> Homogeneous liquid-like dispersion.</p>
2.	<p><u>Powder-liquid preparation:</u></p> <p>A. Incrementally add the ADA™ Shampoo Base to the homogeneous liquid-like dispersion (Step 1A).</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>B. Incrementally add the Salicylic Acid (Hydrosoluble, 50%) to the homogeneous liquid-like solution (Step 2A).</p> <p><u>Specifications:</u> Continuously mix.</p> <p><u>End result:</u> Homogeneous liquid-like solution.</p>



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3.	<p><u>Filling to volume:</u></p> <p>A. Add Purified Water to the mixture (Step 2B) to fill to the required batch size (100.0 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>
4.	<p><u>Product transfer:</u></p> <p>Transfer the final product into the specified dispensing container (see “Packaging requirements”).</p>

SUGGESTED PRESENTATION

Estimated Beyond-Use Date		Packaging Requirements		
	30 days, as per USP.		- 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	Keep out of reach of children.	7	Protect from light.
	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	For external use only.
	4	Keep at room temperature (20°C – 23°C).	9	Do not take with alcohol, sleep aids, tranquilizers or other CNS depressants.
	5	May impair mental and/or physical ability. Use care when operating a car or machinery.		
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

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