



Suggested Formula	Fluocinolone Acetonide 0.01%, Salicylic Acid 1% Topical Shampoo (Solution, 100 mL)	FIN	F 006 825v2
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SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Fluocinolone Acetonide 1% Stock Solution †	1.00	mL				
Salicylic Acid (Hydrosoluble, 50%)	2.00	mL				
Medisca U-Mild™ Shampoo Base	70.0	mL				
Purified Water, USP	q.s. to 100.0	mL				
† Fluocinolone Acetonide 1% Stock Solution						
Fluocinolone Acetonide (Anhydrous) (Micronized), USP	0.100	g				
Alcohol (95%), USP	0.5	mL				
Alcohol (95%), USP	q.s. to 10.0	mL				

SPECIAL PREPARATORY CONSIDERATIONS

<u>Ingredient-Specific Information</u>	
<i>Light sensitive (protect from light whenever possible):</i>	<i>Salicylic Acid</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 5 to 9% 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. 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
Fluocinolone Acetonide 1% Stock Solution †	1.00	mL			
Salicylic Acid (Hydrosoluble, 50%) §	2.00	mL			
Medisca U-Mild™ Shampoo Base	70.0	mL			
Purified Water, USP	q.s. to 100.0	mL			
† Fluocinolone Acetonide 1% Stock Solution					
Fluocinolone Acetonide (Anhydrous) (Micronized), USP	0.100	g	---	---	
Alcohol (95%), USP	0.5	mL	---	---	
Alcohol (95%), USP	q.s. to 10.0	mL	---	---	

§ Weigh / measure just prior to use.

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

Preparatory Instruction

1. † **Fluocinolone Acetonide 1% Stock Solution preparation:**
 - A. Levigate the Fluocinolone Acetonide (Anhydrous) (Micronized) (0.100 g) with the Alcohol (95%) (0.5 mL).
End result: Homogeneous liquid-like dispersion.
 - B. Add additional Alcohol (95%) to the mixture (Step 1A) to fill to the required amount (10.0 mL).
Specifications: Continuously mix until all solid particles have completely dissolved.
End result: Homogeneous liquid-like solution.



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2.	<p><u>Powder-liquid to medium integration:</u></p> <p>A. In the given order, sequentially add the following ingredients to the U-Mild™ Shampoo Base:</p> <ul style="list-style-type: none">-Fluocinolone Acetonide 1% Stock Solution (1.00 mL <i>plus</i> processing error adjustments)-Salicylic Acid (Hydrosoluble, 50%) <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><u>Note:</u> Add the next ingredient, once the previous one has been completely added and dissolved.</p>		
3.	<p><u>Filling to volume:</u></p> <p>A. Add Purified Water to the mixture (Step 2A) 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>		



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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.	5	Cap tightly after use.
	2	Keep out of reach of children.	6	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.	7	For external use only.
	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	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.	Fluocinolone (Monograph). In: O'Neil MJ. <i>The Merck Index 15th Edition</i> . Whitehouse Station, NJ: Merck & Co, Inc.; 2013: #4181.
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7.	Fluocinolone Acetonide (Monograph). <i>United States Pharmacopeia XXXIX / National Formulary 34</i> . Rockville, MD. US Pharmacopeial Convention, Inc. 2016: 3953.
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