



Suggested Formula	Fluocinolone Acetonide 0.01% Topical Shampoo (Suspension, 100 mL)	FIN	F 006 829v2
-------------------	---	-----	-------------

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Fluocinolone Acetonide 1% Stock Solution †	1.00	mL				
Medisca ADA™ Shampoo Base	70.0	mL				
Purified Water, USP	q.s. to 100.0	mL				
Hydrochloric Acid 10% Solution	As required					
† Fluocinolone Acetonide 1% Stock Solution						
Fluocinolone Acetonide, Anhydrous (Micronized), USP	0.100	g				
Alcohol 95%, USP	9.0	mL				
Alcohol 95%, USP	q.s. to 10.0	mL				

SPECIAL PREPARATORY CONSIDERATIONS

Suggested Preparatory Guidelines

Non-Sterile Preparation Sterile Preparation

Processing Error / Testing Considerations: To account for processing error and pH testing 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.



Suggested Formula	Fluocinolone Acetonide 0.01% Topical Shampoo (Suspension, 100 mL)	FIN	F 006 829v2
-------------------	---	-----	-------------

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			
Medisca ADA™ Shampoo Base	70.0	mL			
Purified Water, USP	q.s. to 100.0	mL			
Hydrochloric Acid 10% Solution	As required				
† Fluocinolone Acetonide 1% Stock Solution					
Fluocinolone Acetonide, Anhydrous (Micronized), USP	0.100	g	---	---	
Alcohol 95%, USP	9.0	mL	---	---	
Alcohol 95%, USP	q.s. to 10.0	mL	---	---	

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

Preparatory Instruction	
1.	<p>† <u>Fluocinolone Acetonide 1% Stock Solution preparation:</u></p> <p>A. Levigate the Fluocinolone Acetonide, Anhydrous (Micronized) (0.100 g) with the Alcohol 95% (9.0 mL). <u>Specifications:</u> Continuously mix until all solid particles have completely dissolved. <u>End result:</u> Homogeneous liquid-like solution.</p> <p>B. Add additional Alcohol 95% to the mixture (Step 1A) to fill to the required amount (10.0 mL). <u>End result:</u> Homogeneous liquid-like solution.</p>
2.	<p><u>Powder-liquid to medium integration:</u></p> <p>A. In the given order, sequentially add the following ingredients to the ADA™ Shampoo Base (70.0 mL <i>plus</i> processing error adjustments): -Fluocinolone Acetonide 1% Stock Solution (1.00 mL <i>plus</i> processing error adjustments) <u>Specifications:</u> Continuously mix until homogeneous. <u>End result:</u> Homogeneous liquid-like dispersion.</p>



Suggested Formula	Fluocinolone Acetonide 0.01% Topical Shampoo (Suspension, 100 mL)	FIN	F 006 829v2
-------------------	---	-----	-------------

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 dispersion.</p>
4.	<p><u>pH testing:</u></p> <p>A. Draw an appropriate amount of the mixture (Step 3A).</p> <p>B. Test the pH of the sample. It should lie between 4.0 and 5.0.</p> <p>C. <u>If the pH > 5.0, carefully add, in a dropwise fashion, the Hydrochloric Acid 10% Solution to the mixture:</u></p> <ol style="list-style-type: none">1. Draw and transfer 1 or 2 drops of the Hydrochloric Acid 10% Solution to the mixture.2. Stir for at least 5 minutes to evenly disperse the Hydrochloric Acid 10% Solution.3. Re-test the pH.4. Continue to add the Hydrochloric Acid 10% Solution until the pH of 4.0 to 5.0 is obtained. <p>IMPORTANT: Do not allow the pH to rise above 5.0.</p>
5.	<p><u>Product transfer:</u></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 in order to maintain homogeneity.</p>



Suggested Formula	Fluocinolone Acetonide 0.01% Topical Shampoo (Suspension, 100 mL)	FIN	F 006 829v2
-------------------	---	-----	-------------

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).	8	Gently mix until homogenous before use.
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.			

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.	Fluocinolone Acetonide. In: Sweetman SC, ed. <i>Martindale: The Complete Drug Reference, 36th Edition</i> . London, England: The Pharmaceutical Press; 2009: 1531.
3.	Fluocinolone (Monograph). In: O'Neil MJ. <i>The Merck Index 15th Edition</i> . Whitehouse Station, NJ: Merck & Co, Inc.; 2013: #4181.
4.	Fluocinolone Acetonide (Monograph). <i>United States Pharmacopeia XXXIX / National Formulary 34</i> . Rockville, MD. US Pharmacopeial Convention, Inc. 2016: 3953.
5.	Fluocinolone Acetonide. In: Trissel LA. <i>Trissel's Stability of Compounded Formulations, 5th Edition</i> . American Pharmaceutical Association; 2012: 210.
6.	USP <795>. <i>United States Pharmacopeia XXXIX / National Formulary 34</i> . Rockville, MD. US Pharmacopeial Convention, Inc. 2016: 617.

DISCLAIMER: MEDISCA NETWORK INC., HEREBY REFERRED TO AS 'THE NETWORK', HAS PROVIDED THE FORMULA AND INSTRUCTIONS ABOVE AS A MODEL FOR EDUCATIONAL PURPOSES ONLY ON THE BASIS OF THE RECOGNIZED COMPENDIA AND TEXTS REFERENCED AT THE END OF THIS DOCUMENT. THE NETWORK TAKES NO RESPONSIBILITY FOR THE VALIDITY OR ACCURACY OF THIS INFORMATION OR FOR ITS SAFETY OR EFFECTIVENESS, NOR FOR ANY USE THEREOF, WHICH IS AT THE SOLE RISK OF THE LICENSED PHARMACIST. ADJUSTMENTS MAY BE NEEDED TO MEET SPECIFIC PATIENT NEEDS AND IN ACCORDANCE WITH A LICENSED PRESCRIBER'S PRESCRIPTION. THE PHARMACIST MUST EMPLOY APPROPRIATE TESTS TO DETERMINE THE STABILITY OF THIS SUGGESTED FORMULA. THE NETWORK CANNOT BE HELD LIABLE TO ANY PERSON OR ENTITY CONCERNING CLAIMS, LOSS, OR DAMAGE CAUSED BY, OR ALLEGED TO BE CAUSED BY, DIRECTLY OR INDIRECTLY, THE USE OR MISUSE OF THE INFORMATION CONTAINED IN THIS SUGGESTED FORMULA. IN ALL CASES IT IS THE RESPONSIBILITY OF THE LICENSED PHARMACIST TO KNOW THE LAW, TO COMPOUND ANY FINISHED PRODUCT AND TO DISPENSE THESE PRODUCTS IN ACCORDANCE WITH FEDERAL AND STATE LAW.