



Suggested Formula	Hyaluronic Acid 1%, Niacinamide 5% Topical Cream (Emulsion, 50 g)	FIN	F 006 977v2
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SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Hyaluronic Acid	TBD					
Niacinamide (Nicotinamide), USP	2.500	g				
Ethoxy Diglycol	3.0	mL				
Medisca VersaPro™ Cream Base	TBD					
Medisca LiquiGel Complex™	As required					
Sodium Hydroxide 10% Solution	As required					

SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Hygroscopic (protect from moisture whenever possible): Ethoxy Diglycol

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 **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.

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 g)

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor (*): _____	Processing Error	Qty. to measure
Hyaluronic Acid	TBD				
Niacinamide (Nicotinamide), USP	2.500	g			
Ethoxy Diglycol §	3.0	mL			
Medisca VersaPro™ Cream Base	TBD				
Medisca LiquiGel Complex™	As required				
Sodium Hydroxide 10% Solution	As required				

§ Weigh / measure just prior to use.

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

Preparatory Instruction

1. Ingredient quantification:

A. Determine the potency of Hyaluronic Acid based on the certificate of analysis:

MINUS	100%
Loss on drying (from certificate of analysis)	_____ %
DIVIDED BY	100
EQUALS	
Quantity of dried Hyaluronic Acid in decimal	_____
MULTIPLIED BY	
Assay on dried basis result (from certificate of analysis)	_____ %
DIVIDED BY	100
EQUALS	
i. Potency of Hyaluronic Acid, in decimal	_____



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2. **Ingredient quantification:**

A. Determine the quantity (in g) of Hyaluronic Acid required to make a 50 g batch of Hyaluronic Acid 1% Topical Cream:

Quantity of Hyaluronic Acid required for 50 g	0.500 g
DIVIDED BY	
Potency of Hyaluronic Acid, in decimal (Step 1Ai)	_____
EQUALS	
i. Quantity of Hyaluronic Acid needed for 50 g	_____ g
MULTIPLIED BY	
Processing error adjustments (10 to 12%)	1.10 to 1.12
EQUALS	
ii. Quantity of Hyaluronic Acid needed <i>plus</i> processing error adjustments	_____ g



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<p>3. <u>Ingredient quantification:</u></p> <p>A. Determine the actual quantity of VersaPro Cream Base to weigh for the required batch size (50 g):</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td>Total Weight of the batch</td> <td style="text-align: right;">50 g</td> </tr> <tr> <td>MINUS</td> <td></td> </tr> <tr> <td>The amount of other ingredient except Hyaluronic Acid</td> <td style="text-align: right;">5.464 g</td> </tr> <tr> <td>MINUS</td> <td></td> </tr> <tr> <td>The weight of Hyaluronic Acid (Step 2Ai)</td> <td style="text-align: right;">_____ g</td> </tr> <tr> <td>EQUALS</td> <td></td> </tr> <tr> <td>i. Quantity of VersaPro Cream Base needed for 50 g</td> <td style="text-align: right;">_____ g</td> </tr> <tr> <td>MULTIPLIED BY</td> <td></td> </tr> <tr> <td>Processing error adjustments (10 to 12%)</td> <td style="text-align: right;">1.10 to 1.12</td> </tr> <tr> <td>EQUALS</td> <td></td> </tr> <tr> <td>ii. Weight of VersaPro Cream Base required <i>plus</i> processing error adjustments</td> <td style="text-align: right;">_____ g</td> </tr> </table>	Total Weight of the batch	50 g	MINUS		The amount of other ingredient except Hyaluronic Acid	5.464 g	MINUS		The weight of Hyaluronic Acid (Step 2Ai)	_____ g	EQUALS		i. Quantity of VersaPro Cream Base needed for 50 g	_____ g	MULTIPLIED BY		Processing error adjustments (10 to 12%)	1.10 to 1.12	EQUALS		ii. Weight of VersaPro Cream Base required <i>plus</i> processing error adjustments	_____ g	
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<p>4. <u>Powder-liquid preparation:</u></p> <p>A. Combine and triturate the following ingredients together to form a fine, homogeneous powder blend:</p> <ul style="list-style-type: none"> -Hyaluronic Acid (amount determined in Step 2Aii) -Niacinamide (Nicotinamide) <p>B. Levigate the fine homogeneous powder (Step 4A) with the Ethoxy Diglycol.</p> <p><u>End result:</u> Homogeneous paste-like dispersion.</p>																							



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5.	<p><u>Medium integration:</u></p> <p>A. Incrementally add the homogeneous paste-like dispersion (Step 4B) to the VersaPro Cream Base (amount determined in Step 3Aii).</p> <p><u>Specifications:</u> Continuously mix, using high-shear mixing techniques.</p> <p><u>End result:</u> Homogeneous cream-like dispersion.</p>
6.	<p><u>Viscosity adjustment</u></p> <p>A. If the final result is too liquid or not thick enough, incrementally add the LiquiGel Complex™, about 0.5 mL at a time, to the homogeneous cream-like dispersion (Step 5A) and thoroughly mix for 2 minutes. Repeat the procedure until the desired viscosity is attained.</p> <p><u>Note:</u> The amount of LiquiGel Complex™ could be within the range of 1% to 6%.</p> <p>If the final result is gritty, pass it through the ointment mill until it becomes smooth and uniform.</p>
7.	<p><u>pH testing:</u></p> <p>A. Draw an appropriate amount of the mixture (Step 6A).</p> <p>B. Test the pH of the sample. It should lie between 5.6 and 6.5.</p> <p>C. <u>If the pH < 5.6, carefully add, in a dropwise fashion, the Sodium Hydroxide 10% Solution to the mixture:</u></p> <ol style="list-style-type: none">1. Draw and transfer 1 or 2 drops of the Sodium Hydroxide 10% Solution to the mixture.2. Stir for at least 5 minutes to evenly disperse the Sodium Hydroxide 10% Solution.3. Re-test the pH.4. Continue to add the Sodium Hydroxide 10% Solution until the pH of 5.6 to 6.5 is obtained. <p>IMPORTANT: Do not allow the pH to rise above 6.5.</p>
8.	<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 ointment tube/jar with topical applicator.	
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.	5	Keep in a dry place.
	2	Keep out of reach of children.	6	Do not take with alcohol, sleep aids, tranquilizers or other CNS depressants.
	3	For external use only.	7	Consult your health care practitioner if any other prescription or over-the-counter medications are currently being used or are prescribed for future use.
	4	May impair mental and/or physical ability. Use care when operating a car or machinery.	8	Cap tightly after 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. IMPORTANT: The quantity of API administered is directly dependent on the quantity of product applied.			



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REFERENCES

1.	Ointments, Creams, and Pastes. In: Allen, LV, Jr. <i>The Art, Science and Technology of Pharmaceutical Compounding Fourth Edition</i> . American Pharmaceutical Association; 2012: 265.
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9.	USP <795>. <i>United States Pharmacopeia XXXIX / National Formulary 34</i> . Rockville, MD. US Pharmacopeial Convention, Inc. 2016: 617.

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