



Suggested Formula	Capsaicin 0.001% Topical Shampoo (Solution, 100 mL)	FIN	F 006 827v2
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SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Capsaicin 0.1% Stock Solution †	1.00	mL				
Medisca VersaPro™ Shampoo Base	70.00	g				
Purified Water, USP	q.s. to 100.0	mL				
† Capsaicin 0.1% Stock Solution						
Capsaicin (Natural), USP	0.100	g				
Propylene Glycol, USP	80.0	mL				
Propylene Glycol, USP	q.s. to 100.0	mL				

SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Light sensitive (protect from light whenever possible): Capsaicin, Propylene Glycol

Hygroscopic (protect from moisture whenever possible): Propylene Glycol

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
Capsaicin 0.1% Stock Solution † §	1.00	mL			
Medisca VersaPro™ Shampoo Base	70.00	g			
Purified Water, USP	q.s. to 100.0	mL			
† Capsaicin 0.1% Stock Solution					
Capsaicin (Natural), USP §	0.100	g	---	---	
Propylene Glycol, USP §	80.0	mL	---	---	
Propylene Glycol, 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>† Capsaicin 0.1% Stock Solution preparation:</p> <p>A. Incrementally add the Capsaicin (Natural) to the Propylene Glycol (80.0 mL) and continue to mix until all solid particles have completely dissolved.</p> <p><u>End result:</u> Homogeneous liquid-like solution.</p> <p>B. Add additional Propylene Glycol to the homogeneous liquid-like solution (Step 1A) to fill the required amount (100.0 mL).</p> <p><u>Specifications:</u> Continuously mix until homogeneous.</p> <p><u>End result:</u> Homogeneous liquid-like solution.</p>
2.	<p>Powder-liquid to medium integration:</p> <p>A. Incrementally add the Capsaicin 0.1% Stock Solution (1.00 mL <i>plus</i> processing error adjustments) to the VersaPro™ Shampoo Base.</p> <p><u>Specifications:</u> Continuously mix until homogeneous.</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 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>

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 at room temperature (20°C – 23°C).	6	For external use only.
	3	Keep out of reach of children.	7	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.		
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.	Capsaicin. In: Sweetman SC, ed. <i>Martindale: The Complete Drug Reference, 36th Edition</i> . London, England: The Pharmaceutical Press; 2009: 32.
3.	Capsaicin (Monograph). In: O'Neil MJ. <i>The Merck Index 15th Edition</i> . Whitehouse Station, NJ: Merck & Co, Inc.; 2013: #1770.
4.	Capsaicin (Monograph). <i>United States Pharmacopeia XXXIX / National Formulary 34</i> . Rockville, MD. US Pharmacopeial Convention, Inc. 2016: 2903.
5.	USP <795>. <i>United States Pharmacopeia XXXIX / National Formulary 34</i> . Rockville, MD. US Pharmacopeial Convention, Inc. 2016: 617.

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