



Suggested Formula	Coal Tar Solution 5%, Salicylic Acid 2% Topical Shampoo (Suspension, 100 mL)	FIN	F 006 814v3
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SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Coal Tar Topical Solution 20%, USP	5.00	mL				
Salicylic Acid (Hydrosoluble, 50%)	4.00	mL				
Sodium Hydroxide, NF	0.60	g				
Purified Water, USP	5.0	mL				
Medisca VersaPro™ Shampoo Base	70.0	mL				
Purified Water, USP	q.s. to 100.0	mL				
Sodium Chloride 25% Solution	As needed					

SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Light sensitive (protect from light whenever possible): *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
Coal Tar Topical Solution 20%, USP	5.00	mL			
Salicylic Acid (Hydrosoluble, 50%)	4.00	mL			
Sodium Hydroxide, NF	0.60	g			
Purified Water, USP	5.0	mL			
Medisca VersaPro™ Shampoo Base	70.0	mL			
Purified Water, USP	q.s. to 100.0	mL			
Sodium Chloride 25% Solution	As needed				

§ 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. In the given order, sequentially add the following ingredients to the Purified Water (5.0 mL <i>plus</i> processing error adjustments):</p> <ul style="list-style-type: none">-Sodium Hydroxide-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>
2.	<p><u>Medium preparation:</u></p> <p>A. Incrementally add the Coal Tar Topical Solution 20% to the VersaPro™ Shampoo Base.</p> <p><u>Specifications:</u> Continuously mix until homogeneous.</p> <p><u>End result:</u> Homogeneous liquid-like dispersion.</p>



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3.	<p><u>Powder-liquid to medium integration:</u></p> <p>A. Incrementally add the homogeneous liquid-like solution (Step 1A) to the homogeneous liquid-like dispersion (Step 2A).</p> <p><u>Specifications:</u> Continuously mix until homogeneous.</p> <p><u>End result:</u> Homogeneous liquid-like dispersion.</p>
4.	<p><u>Filling to volume and viscosity adjustment:</u></p> <p>A. Add additional Purified Water to the mixture (Step 3A) 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> <p>B. If the final result is not thick enough, incrementally add the Sodium Chloride 25% Solution in a dropwise manner, to the homogeneous liquid-like dispersion (Step 4) and thoroughly mix for 2 minutes. Repeat the procedure until the desired viscosity is attained.</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>



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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).	8	Shake well 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. 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.	Coal Tar (Monograph). In: O'Neil MJ. <i>The Merck Index 15th Edition</i> . Whitehouse Station, NJ: Merck & Co, Inc.; 2013: #2409.
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