



Suggested Formula	Mupirocin 2% Topical Cream (Emulsion, 100 g)	FIN	F 006 936v2
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SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Mupirocin Calcium, USP	TBD					
Ethoxy Diglycol	2.0	mL				
Medisca VersaPro™ Cream Base	TBD					

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 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 g)

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor (*): ____	Processing Error	Qty. to measure
Mupirocin Calcium, USP	TBD				
Ethoxy Diglycol §	2.0	mL			
Medisca VersaPro™ Cream Base	TBD				

§ 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 quantity (in g) of Mupirocin Calcium required to make a **Mupirocin** 2% Topical Cream, batch size (100 g):

Quantity of Mupirocin required for 100 g	2000 mg
DIVIDED BY	
Assay (base equivalent) on anhydrous basis result (from certificate of analysis: $\mu\text{g}/\text{mg} = \text{mg}/\text{g}$)	_____ $\mu\text{g}/\text{mg}$
EQUALS	
i. Quantity of Mupirocin Calcium needed for 100 g	_____ g
MULTIPLIED BY	
Processing error adjustments (5 to 9%)	1.05 to 1.09
EQUALS	
ii. Quantity of Mupirocin Calcium needed <i>plus</i> processing error adjustments	_____ g



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2.	<p><u>Ingredient quantification:</u></p> <p>A. Determine the actual quantity of VersaPro™ Cream Base to weigh for the required batch size (100 g):</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 80%;">Total Weight of the batch</td> <td style="text-align: right;">100 g</td> </tr> <tr> <td colspan="2">MINUS</td> </tr> <tr> <td>The amount of other ingredient except Mupirocin Calcium</td> <td style="text-align: right;">1.976 g</td> </tr> <tr> <td colspan="2">MINUS</td> </tr> <tr> <td>The weight of Mupirocin Calcium (Step 1Ai)</td> <td style="text-align: right;">_____ g</td> </tr> <tr> <td colspan="2">EQUALS</td> </tr> <tr> <td>i. Quantity of VersaPro™ Cream Base needed for 100 g</td> <td style="text-align: right;">_____ g</td> </tr> <tr> <td colspan="2">MULTIPLIED BY</td> </tr> <tr> <td>Processing error adjustments (5 to 9%)</td> <td style="text-align: right;">1.05 to 1.09</td> </tr> <tr> <td colspan="2">EQUALS</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	100 g	MINUS		The amount of other ingredient except Mupirocin Calcium	1.976 g	MINUS		The weight of Mupirocin Calcium (Step 1Ai)	_____ g	EQUALS		i. Quantity of VersaPro™ Cream Base needed for 100 g	_____ g	MULTIPLIED BY		Processing error adjustments (5 to 9%)	1.05 to 1.09	EQUALS		ii. Weight of VersaPro™ Cream Base required <i>plus</i> processing error adjustments	_____ g
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3.	<p><u>Powder-liquid preparation:</u></p> <p>A. Triturate the Mupirocin Calcium (amount determined in Step 1Aii) to form a fine, homogeneous powder.</p> <p>B. Levigate the fine, homogeneous powder (Step 3A) with the Ethoxy Diglycol.</p> <p><u>End result:</u> Homogeneous liquid-like dispersion.</p>																						
4.	<p><u>Powder-liquid to medium integration:</u></p> <p>A. Incrementally add the homogeneous liquid-like dispersion (Step 3B) to the VersaPro™ Cream Base (amount determined in Step 2Aii).</p> <p><u>Specifications:</u> Continuously mix, using high-shear mixing techniques.</p> <p><u>End result:</u> Homogeneous cream-like dispersion.</p>																						



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5.	<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. - To be administered with a metered-dose measuring device.	
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.	5	Keep at room temperature (20°C – 23°C).
	2	Keep out of reach of children.	6	Cap tightly after use.
	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 in a dry place.		
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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3.	Mupirocin (Monograph). In: O'Neil MJ. <i>The Merck Index 15th Edition</i> . Whitehouse Station, NJ: Merck & Co, Inc.; 2013: #6388.
4.	Mupirocin. In: Trissel LA. <i>Trissel's Stability of Compounded Formulations, 5th Edition</i> . American Pharmaceutical Association; 2012: 344.
5.	Mupirocin Calcium (Monograph). <i>United States Pharmacopeia XXXIX / National Formulary 34</i> . Rockville, MD. US Pharmacopeial Convention, Inc. 2016: 4953.
6.	USP <795>. <i>United States Pharmacopeia XXXIX / National Formulary 34</i> . Rockville, MD. US Pharmacopeial Convention, Inc. 2016: 617.

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