MEDISCA® NETWORK INC.
TECHNICAL SUPPORT SERVICES
FORMULATION CHEMISTRY DEPARTMENT
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Suggested Formula	Mupirocin 2% Topical Cream (Emulsion, 100 g)	FIN	F 006 936v3

SUGGESTED FORMULATION

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

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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: This formula may contain one or more Active Pharmaceutical Ingredients (APIs) that may be classified as hazardous, please refer & verify the current NIOSH list of Antineoplastic and Other Hazardous Drugs in Healthcare Settings. At this time, **General Chapter <800> Hazardous Drugs – Handling in Healthcare Settings** is informational and not compendially applicable unless otherwise specified by regulators and enforcement bodies. For information on the scope, intended applicability, and implementation context for USP General Chapter <800>, see: https://www.usp.org/compounding/general-chapter-hazardous-drugs-handling-healthcare.

This formula must be prepared within the appropriate facilities under adequate environmental conditions, following the necessary guidelines and procedures as stated within *USP 795* and *USP 800,* when handling hazardous drugs. Only trained and qualified personnel must prepare this formula.

All required personal protective equipment (hazardous if applicable), such as but not limited to, lab coat, protective sleeves, gloves both inner and outer if applicable, dedicated shoe covers, hairnet, beard cover, eyewear, appropriate face mask, respirator and face shield, etc., where applicable must be worn at all times.

If applicable, follow all required procedures for hazardous drug handling including but not limited to procurement, transport, storage, preparation, dispensing, administration, clean up (spills) & disposal.

If you are a registered 503B facility, please refer to all relevant guidance documents including but not limited to the Code of Federal Regulations (CFR), Guidance for Industry (GFIs) and Compliance Policy Guides (CPGs).

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, NF §	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: µg/mg = mg/g)	_____ µg/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 *plus* processing error adjustments	_____ **g**

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2. **Ingredient quantification:**

A. Determine the actual quantity of VersaPro™ Cream Base to weigh for the required batch size (100 g):

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 *plus* processing error adjustments	_____ g

3. **Powder-liquid preparation:**

A. Triturate the Mupirocin Calcium (amount determined in Step 1Aii) to form a fine, homogeneous powder.

B. Levigate the fine, homogeneous powder (Step 3A) with the Ethoxy Diglycol.

End result: Homogeneous liquid-like dispersion.

4. **Powder-liquid to medium integration:**

A. Incrementally add the homogeneous liquid-like dispersion (Step 3B) to the VersaPro™ Cream Base (amount determined in Step 2Aii).

Specifications: Continuously mix, using high-shear mixing techniques.

End result: Homogeneous cream-like dispersion.

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5.	**Product transfer:** Transfer the final product into the specified dispensing container (see "Packaging requirements").

SUGGESTED PRESENTATION

Estimated Beyond-Use Date		30 days, as per USP 795.	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 controlled room temperature (20°C – 25°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. *The Art, Science and Technology of Pharmaceutical Compounding Fourth Edition.* American Pharmaceutical Association; 2012: 265.
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