MEDISCA® NETWORK INC.
TECHNICAL SUPPORT SERVICES
FORMULATION CHEMISTRY DEPARTMENT
TOLL-FREE: 866-333-7811
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technicalservices@medisca.net

Suggested Formula	Mupirocin 2% Nasal Ointment (Emulsion, 50 g)	FIN	F 006 938v3

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Mupirocin Calcium, USP	TBD					
Mineral Oil (Light), NF	5.0	mL				
Medisca OleaBase™ Plasticized	TBD					

SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Light Sensitive *(protect from light whenever possible):* *Mineral Oil*

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SPECIAL PREPARATORY CONSIDERATIONS (CONTINUED)

Suggested Preparatory Guidelines

☐ Non-Sterile Preparation ■ Sterile Preparation

Processing Error / Testing Considerations: To account for processing error and sterility testing considerations during preparation, it is suggested to measure an additional **10 to 12%** 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 797* and *USP 800,* when handling hazardous drugs. Only trained and qualified personnel must prepare this formula.

All heat stable, reusable materials and equipment must be sterilized and depyrogenated by dry heat sterilization at 250°C for 2 hours prior to use.

Compounder needs to verify as per USP, if every batch of final product compounded using this procedure must be sterility and endotoxin tested before being dispensed.

All required personal protective equipment (sterile and hazardous if applicable), such as but not limited to, gowns, aprons, sleeves, gloves both inner and outer if applicable, shoe covers, hairnet, head cap, beard cover, eyewear, appropriate face mask, respirator and face shield, etc., where applicable must be worn at all times. In addition, proper personnel cleansing must be done before entering the buffer or clean area.

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.

Filter integrity must be validated by performing a filter stress test. If the test demonstrates that the filter might be defective, the solution must be discarded and remade.

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 50 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				
Mineral Oil (Light), NF §	5.0	mL			
Medisca OleaBase™ Plasticized §	TBD				

§ Weigh / measure just prior to use.
* Takes into account increased batch size conversions and density conversions, if required.

Preparatory Instruction

IMPORTANT: All preparatory procedures must be performed using proper Aseptic Technique

1. **Ingredient quantification:**

A. Determine the quantity (in g) of Mupirocin Calcium required to make a **Mupirocin** 2% Nasal Ointment, batch size (50 g):

Quantity of Mupirocin required for 50 g	1000 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 50 g	_____ **g**
MULTIPLIED BY	
Processing error adjustments (10 to 12%)	1.10 to 1.12
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 OleaBase™ Plasticized to weigh for the required batch size (50 g):

Total Weight of the batch	50 g
MINUS	
The amount of other ingredient except Mupirocin Calcium	4.245 g
MINUS	
The weight of Mupirocin Calcium (Step 1Ai)	_____ g
EQUALS	
i. Quantity of OleaBase™ Plasticized needed for 50 g	_____ g
MULTIPLIED BY	
Processing error adjustments (10 to 12%)	1.10 to 1.12
EQUALS	
ii. Weight of OleaBase™ Plasticized required *plus* processing error adjustments	_____ g

3. **Sterilization:**

Following the manufacturer's specifications, autoclave sterilize the OleaBase™ Plasticized (amount determined in Step 2Aii), then return to ambient temperature and pressure.

Specifications:

Heating temperature: 121°C
Heating time: 30 minutes
Pressure: 15 psi

IMPORTANT: The temperature of the heated chamber must reach 121°C before the exposure duration is timed.

4. **Powder-liquid preparation:**

A. Aseptically filter the Mineral Oil (Light) through a 0.22-µm sterile filter into Mupirocin Calcium (amount determined in Step 1Aii) and levigate the mixture into a homogeneous liquid-like dispersion.

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5.	**Powder-liquid to medium integration:** A. Incrementally add the homogeneous liquid-like dispersion (Step 4A) to the Sterilized OleaBase™ Plasticized (Step 3). Specifications: Continuously mix, using high-shear mixing techniques. End result: Homogeneous ointment-like dispersion.
6.	**Terminal Sterilization:** In relation to the chemical composition of the formulation, final packaging, etc., select and validate an end-stage sterilization method and follow the manufacturer's specification.
7.	**Microbial Enumeration testing:** Test the product for microbial count and specified microorganisms to meet the requirements for Mupirocin Nasal Ointment, in accordance to current USP <61> and <62> procedures.
8.	**Product transfer:** Transfer the final product into the specified dispensing container (see "Packaging requirements").

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SUGGESTED PRESENTATION

Estimated Beyond-Use Date		24 hours controlled room temperature, 3 days refrigerated, or 45 days frozen, as per USP 797.	Packaging Requirements		- Tightly closed, light-resistant ointment tube/jar. - To be administered with a metered-dose measuring device.
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.		5	Protect from light.
	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 nasal use only.
	4	Keep at controlled room temperature, (20°C – 25°C), refrigerated (2°C – 8°C) or frozen (-25°C to -10°C).			
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.	Ophthalmic, Otic, and Nasal Preparations. In: Allen, LV, Jr. *The Art, Science and Technology of Pharmaceutical Compounding Fourth Edition.* American Pharmaceutical Association; 2012: 307.
2.	Mupirocin Calcium. In: Sweetman SC, ed. *Martindale: The Complete Drug Reference, 36th Edition.* London, England: The Pharmaceutical Press; 2009: 302.
3.	Mupirocin (Monograph). In: O'Neil MJ. *The Merck Index 15th Edition*. Whitehouse Station, NJ: Merck & Co, Inc.; 2013: #6388.
4.	Mupirocin. In: Trissel LA. *Trissel's Stability of Compounded Formulations, 5th Edition.* American Pharmaceutical Association; 2012: 344.
5.	Mupirocin Calcium (Monograph). *United States Pharmacopeia XXXIX / National Formulary 34.* Rockville, MD. US Pharmacopeial Convention, Inc. 2016: 4953.
6.	USP <797>. *United States Pharmacopeia XXXIX / National Formulary 34.* Rockville, MD. US Pharmacopeial Convention, Inc. 2016: 626.