MEDISCA® NETWORK INC.
TECHNICAL SUPPORT SERVICES
FORMULATION CHEMISTRY DEPARTMENT
TOLL-FREE: 866-333-7811
TELEPHONE: 514-905-5096
FAX: 514-905-5097
technicalservices@medisca.net

Suggested Formula	Mupirocin 2% Nasal Ointment (Emulsion, 50 g)	FIN	F 006 938v2

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*

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 must be prepared within the appropriate facilities under adequate environmental conditions, following the necessary guidelines and procedures as stated within *USP 797*. 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.

Every batch of final product compounded using this procedure must be sterility and endotoxin tested before being dispensed.

Protective apparel, such as a sterile gown, sterile gloves, shoe covers, head cap, eyewear and face-masks should always be worn. In addition, proper personnel cleansing must be done before entering the buffer or clean area.

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.

This procedure requires the use of very small quantities of ingredients. All calculations and preparation techniques must be verified before dispensing the final product.

MEDISCA® NETWORK INC.
TECHNICAL SUPPORT SERVICES
FORMULATION CHEMISTRY DEPARTMENT
TOLL-FREE: 866-333-7811
TELEPHONE: 514-905-5096
FAX: 514-905-5097
technicalservices@medisca.net

Suggested Formula	Mupirocin 2% Nasal Ointment (Emulsion, 50 g)	FIN	F 006 938v2

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**

MEDISCA® NETWORK INC.
TECHNICAL SUPPORT SERVICES
FORMULATION CHEMISTRY DEPARTMENT
TOLL-FREE: 866-333-7811
TELEPHONE: 514-905-5096
FAX: 514-905-5097
technicalservices@medisca.net

Suggested Formula	Mupirocin 2% Nasal Ointment (Emulsion, 50 g)	FIN	F 006 938v2

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.

MEDISCA® NETWORK INC.
TECHNICAL SUPPORT SERVICES
FORMULATION CHEMISTRY DEPARTMENT
TOLL-FREE: 866-333-7811
TELEPHONE: 514-905-5096
FAX: 514-905-5097
technicalservices@medisca.net

Suggested Formula	Mupirocin 2% Nasal Ointment (Emulsion, 50 g)	FIN	F 006 938v2

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.	**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.
7.	**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.		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 room temperature (20°C – 23°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.			

MEDISCA® NETWORK INC.
TECHNICAL SUPPORT SERVICES
FORMULATION CHEMISTRY DEPARTMENT
TOLL-FREE: 866-333-7811
TELEPHONE: 514-905-5096
FAX: 514-905-5097
technicalservices@medisca.net

Suggested Formula	Mupirocin 2% Nasal Ointment (Emulsion, 50 g)	FIN	F 006 938v2

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.