MEDISCA® NETWORK INC.
TECHNICAL SUPPORT SERVICES
FORMULATION CHEMISTRY DEPARTMENT
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Suggested Formula	Betamethasone 0.05%, Miconazole Nitrate 2%, Mupirocin 1% Topical Ointment (Suspension, 30 g)	FIN	F 009 633

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Betamethasone 1% Stock Solution †	1.50	mL				
Miconazole Nitrate, USP	0.600	g				
Mupirocin, USP	TBD					
Medisca AlpaWash®	TBD					
† Betamethasone 1% Stock Solution						
Betamethasone Valerate, USP*	0.121	g				
Alcohol (95%), USP	9.0	mL				
Alcohol (95%), USP	q.s. to 10.0	mL				

*Betamethasone Valerate 0.121 g is equivalent to Betamethasone 0.100 g.

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SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Light Sensitive *(protect from light whenever possible):* *Betamethasone Valerate, Miconazole Nitrate, Mupirocin*

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 **12 to 15%** 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 30 g)

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor (*): ____	Processing Error	Qty. to measure
Betamethasone 1% Stock Solution † §	1.50	mL			
Miconazole Nitrate, USP §	0.600	g			
Mupirocin, USP §	TBD				
Medisca AlpaWash®	TBD				
† Betamethasone 1% Stock Solution					
Betamethasone Valerate, USP §	0.121	g	---	---	
Alcohol (95%), USP §	9.0	mL	---	---	
Alcohol (95%), USP §	q.s. to 10.0	mL	---	---	

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

Preparatory Instruction	
1.	† **Betamethasone 1% Stock Solution preparation:** A. Incrementally add the Betamethasone Valerate (0.121 g) to the Alcohol (95%) (9.0 mL). Specifications: Continuously mix until all solid particles have completely dissolved. End result: Homogeneous liquid-like solution. B. Add additional Alcohol (95%) to the mixture (Step 1A) to fill to the required batch size (10.0 mL). Specifications: Continuously mix. End result: Homogeneous liquid-like solution.

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2. **Ingredient quantification:**

A. Determine the quantity (in g) of Mupirocin required to make a Mupirocin 1% Topical Ointment, batch size (30 g):

Quantity of Mupirocin required for 30 g	300 mg
DIVIDED BY	
Assay result (from certificate of analysis: µg/mg = mg/g)	_____ µg/mg
EQUALS	
i. Quantity of Mupirocin needed for 30 g	_____ **g**
MULTIPLIED BY	
Processing error adjustments (12 to 15%)	1.12 to 1.15
EQUALS	
ii. Quantity of Mupirocin needed *plus* processing error adjustments	_____ **g**

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3. **Ingredient quantification:**

A. Determine the actual quantity of AlpaWash® to weigh for the required batch size (30 g):

Total Weight of the batch	30.00 g
MINUS	
Total amount of other ingredients except Mupirocin	1.821 g
The weight of Mupirocin (Step 2Ai)	_____ g
EQUALS	
i. Quantity of AlpaWash® needed for 30 g	_____ g
MULTIPLIED BY	
Processing error adjustments (12 to 15%)	1.12 to 1.15
EQUALS	
ii. Weight of AlpaWash® required *plus* processing error adjustments	_____ g

4. **Powder-liquid preparation:**

A. Combine and triturate the following ingredients together to form a fine, homogeneous powder blend:

-Miconazole
-Mupirocin (amount determined in Step 2Aii)

B. Levigate the fine homogeneous powder blend (Step 4A) with the Betamethasone 1% Stock Solution 1.50 mL *plus* processing error adjustments).

End result: Homogeneous liquid-like dispersion.

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

A. Incrementally add the homogeneous liquid-like dispersion (Step 4B) to the AlpaWash® (amount determined in Step 3Aii).

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

End result: Homogeneous ointment-like dispersion.

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6.	**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, light-resistant ointment tube/jar.
Auxiliary Labels	1	Keep out of reach of children.		6	Use as directed. Do not exceed prescribed dose.
	2	Cap tightly after use.		7	Protect from light.
	3	Keep at controlled room temperature (20°C – 25°C).		8	For external use only.
	4	Do not take with alcohol, sleep aids, tranquilizers or other CNS depressants.		9	Consult your health care practitioner if any prescription or over-the-counter medications are currently being used or are prescribed for future use.
	5	May produce psychological and/or physical dependence.		10	The site should be cleaned/wiped before nursing.
Pharmacist Instructions	**Note: This non-sterile formulation, as per USP <3>, should not be applied to an open wound or burned area. If this formulation will be applied to an open wound or burned area, it must be prepared within the appropriate facilities under adequate environmental conditions, following the necessary guidelines and procedures as stated within USP <797>. Also, in consideration of the overall formulation make-up and following the manufacturer's specifications, the suggested method of end-stage sterilization is gamma irradiation. The resulting BUD will be 30 days, as per USP <797>, based on a successful sterility test result.** 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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