MEDISCA® NETWORK INC.
TECHNICAL SUPPORT SERVICES
FORMULATION CHEMISTRY DEPARTMENT
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Suggested Formula	Mupirocin 2%, Vancomycin 5% Topical Ointment (Suspension, 100 g)	FIN	F 006 363

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Mupirocin, USP	TBD					
Vancomycin Hydrochloride, USP	TBD					
Polyethylene Glycol 300, NF	4.5	mL				
Medisca AlpaWash™	TBD					

SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Light sensitive *(protect from light whenever possible):* *Vancomycin Hydrochloride*

Hygroscopic *(protect from moisture whenever possible):* *Vancomycin Hydrochloride, Polyethylene Glycol 300*

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, USP	TBD				
Vancomycin Hydrochloride, USP §	TBD				
Polyethylene Glycol 300, NF §	4.5	mL			
Medisca AlpaWash™	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 required to make a Mupirocin 2% Topical Ointment, batch size (100 g):

Quantity of Mupirocin required for 100 g	2 000 mg
DIVIDED BY	
Assay result (from certificate of analysis: µg/mg = mg/g)	_____ µg/mg
EQUALS	
i. Quantity of Mupirocin needed for 100 g	_____ **g**
MULTIPLIED BY	
Processing error adjustments (5 to 9%)	1.05 to 1.09
EQUALS	
ii. Quantity of Mupirocin needed *plus* processing error adjustments	_____ **g**

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2. **Ingredient quantification:**

A. Determine the potency of Vancomycin Hydrochloride based on the certificate of analysis:

	100%
MINUS	
Water Content (from certificate of analysis)	_____ %
DIVIDED BY	100
EQUALS	
Quantity of water free Vancomycin Hydrochloride, in decimal	_____
MULTIPLIED BY	
Assay (base equivalent) on anhydrous basis result (from certificate of analysis)	_____ µg/mg
MULTIPLIED BY (Multiplication factor – µg to grams /mg to grams)	0.001
EQUALS	
i. Potency of Vancomycin Hydrochloride (Base equivalent) in g/g	_____

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3. **Ingredient quantification:**

A. Determine the quantity (in g) of Vancomycin Hydrochloride to make a **Vancomycin (Base)** 5% Topical Ointment, batch size (100 g):

Quantity of **Vancomycin (Base)** required for 100 g	5.000 g
DIVIDED BY	
Potency of Vancomycin Hydrochloride (Base equivalent) in g/g (Step 2Ai)	_____
EQUALS	
i. Quantity of Vancomycin Hydrochloride needed for 100 g	_____ **g**
MULTIPLIED BY	
Processing error adjustments (5 to 9%)	1.05 to 1.09
EQUALS	
ii. Quantity of Vancomycin Hydrochloride needed *plus* processing error adjustments	_____ **g**

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4. **Ingredient quantification:**

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

Total Weight of the batch	100.00 g
MINUS	
Total amount of Polyethylene Glycol 300	5.04 g
MINUS	
The weight of Mupirocin (Step 1Ai)	_____ g
MINUS	
The weight of Vancomycin Hydrochloride (Step 3Ai)	_____ g
EQUALS	
i. Quantity of AlpaWash™ needed for 100 g	_____ g
MULTIPLIED BY	
Processing error adjustments (5 to 9%)	1.05 to 1.09
EQUALS	
ii. Weight of AlpaWash™ required *plus* processing error adjustments	_____ g

5. **Powder-liquid preparation:**

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

-Mupirocin (amount determined in Step 1Aii)
-Vancomycin Hydrochloride (amount determined in Step 3Aii)

B. Levigate the fine, homogeneous powder blend (Step 5A) with the Polyethylene Glycol 300.

End result: Homogeneous paste-like dispersion.

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6.	**Powder-liquid to medium integration:** A. Incrementally add the homogeneous paste-like dispersion (Step 5B) to the AlpaWash™ (amount determined in Step 4Aii). Specifications: Continuously mix, using high-shear mixing techniques. End result: Homogeneous gel-like dispersion. B. If the final result is gritty, pass it through the ointment mill until it becomes smooth and uniform.
7.	**Product transfer:** Transfer the final product into the specified dispensing container (see "Packaging Requirements").

SUGGESTED PRESENTATION

Estimated Beyond-Use Date		6 months, as per USP*.	Packaging Requirements	- Tightly closed, light-resistant container. - 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 external use only.
	4	Keep in a dry place.	8	Keep at room temperature (20°C – 23°C).
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.			

*** The BUD is not later than the time remaining until the earliest expiration date of any API or 6 months, whichever is earlier.**

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REFERENCES

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