MEDISCA® NETWORK INC.
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Suggested Formula	Itraconazole 1%, Levofloxacin 2%, Lidocaine Hydrochloride 5%, Metronidazole 2%, Misoprostol 0.0024%, Phenytoin Sodium 5%, Sucralfate 2%, Vancomycin 5% Topical Ointment (Suspension, 30 g)	FIN	F 006 652

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Misoprostol 0.1% Stock Solution †	0.72	mL				
Itraconazole, USP	0.300	g				
Levofloxacin, USP	0.600	g				
Lidocaine Hydrochloride, USP	TBD					
Metronidazole, USP	0.600	g				
Phenytoin Sodium, USP	1.500	g				
Sucralfate, USP	0.600	g				
Vancomycin Hydrochloride, USP	TBD					
Ethoxy Diglycol	3.0	mL				
Medisca AlpaWash™	TBD					
† **Misoprostol 0.1% Stock Solution**						
Misoprostol, USP	0.100	g				
Alcohol (95%), USP	90.0	mL				
Alcohol (95%), USP	q.s. to 100.0	mL				

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SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Light sensitive *(protect from light whenever possible):*	*Itraconazole, Levofloxacin, Metronidazole, Vancomycin Hydrochloride*
Hygroscopic *(protect from moisture whenever possible):*	*Misoprostol, Phenytoin Sodium, Vancomycin Hydrochloride, Ethoxy Diglycol*
Narrow Therapeutic Index	*Lidocaine Hydrochloride, Phenytoin Sodium, Vancomycin Hydrochloride*
Air sensitive *(protect from air whenever possible):*	*Phenytoin Sodium*

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: Protective apparel, such as a lab coat, disposable gloves, eyewear and face-masks should always be worn.

Lidocaine Hydrochloride, Phenytoin Sodium and Vancomycin Hydrochloride have a Narrow Therapeutic Index.

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
Misoprostol 0.1% Stock Solution † §	0.72	mL			
Itraconazole, USP §	0.300	g			
Levofloxacin, USP §	0.600	g			
Lidocaine Hydrochloride, USP	TBD				
Metronidazole, USP §	0.600	g			
Phenytoin Sodium, USP §	1.500	g			
Sucralfate, USP	0.600	g			
Vancomycin Hydrochloride, USP §	TBD				
Ethoxy Diglycol §	3.0	mL			
Medisca AlpaWash™	TBD				
† **Misoprostol 0.1% Stock Solution**					
Misoprostol, USP §	0.100	g	---	---	
Alcohol (95%), USP	90.0	mL	---	---	
Alcohol (95%), USP	q.s. to 100.0	mL	---	---	

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

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Preparatory Instruction

1. † **Misoprostol 0.1% Stock Solution preparation:**

A. Triturate the Misoprostol (0.100 g) to form a fine, homogeneous powder blend.

B. Incrementally add the fine, homogeneous powder blend (Step 1A) to the Alcohol (95%) (90.0 mL).

Specifications: Continuously mix until all solid particles have completely dissolved.

End result: Homogeneous liquid-like solution.

C. Add additional Alcohol (95%) to the mixture to fill to the required batch size (100.0 mL).

Specifications: Continuously mix.

End result: Homogeneous liquid-like solution.

2. **Ingredient quantification:**

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

	100%
MINUS	
Water Content (from certificate of analysis)	_____ %
DIVIDED BY	100
EQUALS	
Quantity of water free Lidocaine Hydrochloride, in decimal	_____
MULTIPLIED BY	
Assay on anhydrous basis result (from certificate of analysis)	_____ %
DIVIDED BY	100
EQUALS	
i. Potency of Lidocaine Hydrochloride, in decimal	_____

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3. **Ingredient quantification:**

A. Determine the quantity (in g) of Lidocaine Hydrochloride to make a Lidocaine Hydrochloride 5% Topical Ointment, batch size (30 g):

Quantity of Lidocaine Hydrochloride required for 30 g	1.500 g
DIVIDED BY	
Potency of Lidocaine Hydrochloride (Step 2Ai)	_____
EQUALS	
i. Quantity of Lidocaine Hydrochloride needed for 30 g	_____ **g**
MULTIPLIED BY	
Processing error adjustments (12 to 15%)	1.12 to 1.15
EQUALS	
ii. Quantity of Lidocaine Hydrochloride needed *plus* processing error adjustments	_____ **g**

Suggested Formula	Itraconazole 1%, Levofloxacin 2%, Lidocaine Hydrochloride 5%, Metronidazole 2%, Misoprostol 0.0024%, Phenytoin Sodium 5%, Sucralfate 2%, Vancomycin 5% Topical Ointment (Suspension, 30 g)	FIN	F 006 652

4. **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	_____

Suggested Formula	Itraconazole 1%, Levofloxacin 2%, Lidocaine Hydrochloride 5%, Metronidazole 2%, Misoprostol 0.0024%, Phenytoin Sodium 5%, Sucralfate 2%, Vancomycin 5% Topical Ointment (Suspension, 30 g)	FIN	F 006 652

5. **Ingredient quantification:**

A. Determine the quantity (in g) of Vancomycin Hydrochloride to make a **Vancomycin (Base)** 5% Topical Ointment, batch size (30 g):

Quantity of **Vancomycin (Base)** required for 30 g	1.500 g
DIVIDED BY	
Potency of Vancomycin Hydrochloride (Base equivalent) g/g (Step 4Ai)	_____
EQUALS	
i. Quantity of Vancomycin Hydrochloride needed for 30 g	_____ **g**
MULTIPLIED BY	
Processing error adjustments (12 to 15%)	1.12 to 1.15
EQUALS	
ii. Quantity of Vancomycin Hydrochloride needed *plus* processing error adjustments	_____ **g**

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6. **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 Lidocaine Hydrochloride and Vancomycin Hydrochloride	7.15 g
MINUS	
The weight of Lidocaine Hydrochloride (Step 3Ai)	_____ g
MINUS	
The weight of Vancomycin Hydrochloride (Step 5Ai)	_____ g
EQUALS	
i. Quantity of AlpaWash™ 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

Suggested Formula	Itraconazole 1%, Levofloxacin 2%, Lidocaine Hydrochloride 5%, Metronidazole 2%, Misoprostol 0.0024%, Phenytoin Sodium 5%, Sucralfate 2%, Vancomycin 5% Topical Ointment (Suspension, 30 g)	FIN	F 006 652

7. **Powder-liquid preparation:**

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

-Itraconazole
-Levofloxacin
-Lidocaine Hydrochloride (amount determined in Step 3Aii)
-Metronidazole
-Phenytoin Sodium
-Sucralfate
-Vancomycin Hydrochloride (amount determined in Step 5Aii)

B. Combine and mix the following ingredients together to form a homogeneous liquid-like solution:

-Misoprostol 0.1% Stock Solution (0.72 mL *plus* processing error adjustments)
-Ethoxy Diglycol

C. Levigate the fine, homogeneous powder blend (Step 7A) with the homogeneous liquid-like solution (Step 7B).

End result: Homogeneous liquid-like dispersion.

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

A. Incrementally add the homogeneous liquid-like dispersion (Step 7C) to the AlpaWash™ (amount determined in Step 6Aii).

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

End result: Homogeneous ointment-like dispersion.

B If the final result is gritty, pass it through the ointment mill until it becomes smooth and uniform.

9. **Product transfer:**

Transfer the final product into the specified dispensing container (see “Packaging requirements”).

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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.	6		Do not take with alcohol, sleep aids, tranquilizers or other CNS depressants.
	2	Keep out of reach of children.	7		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.	8		May impair mental and/or physical ability. Use care when operating a car or machinery.
	4	Keep at room temperature (20°C – 23°C).	9		Keep in a dry place.
	5	Protect from light.	10		For external use only.

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.

IMPORTANT: - Small batch is prepared due to inherent potential of systemic toxicity.

- Limits as to the total amount of product used should be established by a physician.

- You should not apply this product to open wounds, areas of skin that are damaged or blistered, deep wounds, or large areas.

- Continued application of this product might produce systemic side effects. Advise patient accordingly.

IMPORTANT: DRUG-DRUG INTERACTIONS EXIST BETWEEN DIFFERENT DRUG COMBINATIONS WITHIN THIS FORMULATION. TO BE DISPENSED AND ADMINISTERED ONLY UNDER THE CLOSE SUPERVISION OF THE PRESCRIBING PHYSICIAN.

Patient Instructions

Contact your pharmacist in the event of adverse reactions.

IMPORTANT: - Do not cover the site of application.

- The quantity of API administered is directly dependent on the quantity of product applied.

Suggested Formula	Itraconazole 1%, Levofloxacin 2%, Lidocaine Hydrochloride 5%, Metronidazole 2%, Misoprostol 0.0024%, Phenytoin Sodium 5%, Sucralfate 2%, Vancomycin 5% Topical Ointment (Suspension, 30 g)	FIN	F 006 652

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