



Suggested Formula	Lidocaine Hydrochloride 2%, Metronidazole 2%, Misoprostol 0.0024% Topical Ointment (Suspension, 30 g)	FIN	F 006 358
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SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Lidocaine Hydrochloride, USP	TBD					
Metronidazole, USP	0.600	g				
Misoprostol 1% Dispersion, USP	0.072	g				
Ethoxy Diglycol	3.0	mL				
Medisca AlpaWash™	TBD					

SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Light Sensitive (protect from light whenever possible): *Metronidazole*

Hygroscopic (protect from moisture whenever possible): *Ethoxy Diglycol, Misoprostol*

Narrow Therapeutic Index *Lidocaine Hydrochloride*

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 has 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
Lidocaine Hydrochloride, USP	TBD				
Metronidazole, USP §	0.600	g			
Misoprostol 1% Dispersion, USP §	0.072	g			
Ethoxy Diglycol §	3.0	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 potency of Lidocaine Hydrochloride based on the certificate of analysis:

MINUS	100%
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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2. **Ingredient quantification:**

A. Determine the quantity (in g) of Lidocaine Hydrochloride to make a Lidocaine Hydrochloride 2% Topical Ointment, batch size (30 g):

Quantity of Lidocaine Hydrochloride required for 30 g	0.600 g
DIVIDED BY	
Potency of Lidocaine Hydrochloride, in decimal (Step 1Ai)	_____
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 <i>plus</i> 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 g
MINUS	
The amount of other ingredient except Lidocaine Hydrochloride	3.7539 g
MINUS	
The weight of Lidocaine Hydrochloride (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 <i>plus</i> processing error adjustments	_____ g

4. **Powder-liquid preparation:**

A. By geometrical addition, combine and triturate the following ingredients together to form a fine, homogeneous powder blend:

- Misoprostol 1% Dispersion
- Metronidazole
- Lidocaine Hydrochloride (amount determined from Step 2Aii)

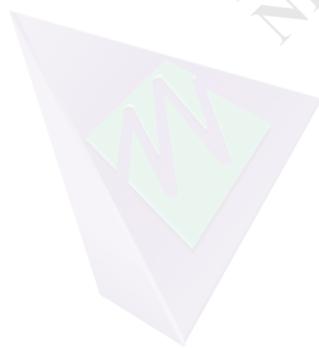
B. Levigate the homogeneous powder blend (Step 4A) with the Ethoxy Diglycol.

End result: Homogeneous liquid-like dispersion.



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5.	<p><u>Powder-liquid to medium integration:</u></p> <p>A. Incrementally add the homogeneous liquid-like dispersion (Step 4B) to the AlpaWash™ (amount determined from Step 3Aii).</p> <p><u>Specifications:</u> Continuously mix, using high-shear mixing techniques.</p> <p><u>End result:</u> Homogeneous gel-like dispersion.</p> <p>B. If the final result is gritty, pass it through the ointment mill until it becomes smooth and uniform.</p>
6.	<p><u>Product transfer:</u></p> <p>Transfer the final product into the specified dispensing container (see “Packaging Requirements”).</p>





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SUGGESTED PRESENTATION

Estimated Beyond-Use Date	6 months, as per USP*.	Packaging Requirements	<ul style="list-style-type: none"> - 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	Protect from light.
	5	For external use only.	10	Keep in a dry place.
Pharmacist Instructions	<p>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.</p> <p>Add any auxiliary labels specific to the API to the dispensing container as deemed necessary.</p> <p>IMPORTANT: - Small batch is prepared due to inherent potential of systemic toxicity.</p> <ul style="list-style-type: none"> - 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. 			
Patient Instructions	<p>Contact your pharmacist in the event of adverse reactions.</p> <p>IMPORTANT: - Do not cover the site of application.</p> <ul style="list-style-type: none"> - 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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