Suggested Formula: Lidocaine 2%, Metronidazole 2%, Misoprostol 0.0024% Topical Ointment (Suspension, 30 g)

**SUGGESTED FORMULATION**

<table>
<thead>
<tr>
<th>Ingredient Listing</th>
<th>Qty.</th>
<th>Unit</th>
<th>NDC #</th>
<th>Supplier</th>
<th>Lot Number</th>
<th>Expiry Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lidocaine, USP</td>
<td>0.600</td>
<td>g</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Metronidazole, USP</td>
<td>0.600</td>
<td>g</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Misoprostol 1% Dispersion, USP</td>
<td>0.072</td>
<td>g</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Polyethylene Glycol 300, NF</td>
<td>3.0</td>
<td>mL</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medisca AlpaWash™</td>
<td>25.37</td>
<td>g</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**SPECIAL PREPARATORY CONSIDERATIONS**

**Ingredient-Specific Information**

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

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

*Narrow Therapeutic Index* Lidocaine

**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.
Suggested Formula

Lidocaine 2%, Metronidazole 2%, Misoprostol 0.0024% Topical Ointment (Suspension, 30 g)

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SUGGESTED PREPARATION (for 30 g)

Weigh and / or measure the following ingredients when appropriate:

<table>
<thead>
<tr>
<th>Ingredient Listing</th>
<th>Qty.</th>
<th>Unit</th>
<th>Multiplication factor: (*)</th>
<th>Processing Error</th>
<th>Qty. to measure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lidocaine, USP</td>
<td>0.600</td>
<td>g</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Metronidazole, USP §</td>
<td>0.600</td>
<td>g</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Misoprostol 1% Dispersion, USP §</td>
<td>0.072</td>
<td>g</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Polyethylene Glycol 300, NF §</td>
<td>3.0</td>
<td>mL</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medisca AlpaWash™</td>
<td>25.37</td>
<td>g</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

Preparatory Instruction

1. **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
   B. Levigate the homogeneous powder blend (Step 1A) with the Polyethylene Glycol 300.
      End result: Homogeneous liquid-like dispersion.

2. **Powder-liquid to medium integration:**
   A. Incrementally add the homogeneous liquid-like dispersion (Step 1B) to the AlpaWash™.
      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.

3. **Product transfer:**
   Transfer the final product into the specified dispensing container (see “Packaging Requirements”).
**SUGGESTED PRESENTATION**

<table>
<thead>
<tr>
<th>Estimated Beyond-Use Date</th>
<th>Packaging Requirements</th>
</tr>
</thead>
</table>
| 6 months, as per USP*     | - 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.  
2. Keep out of reach of children.  
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.

Additional instructions:

<table>
<thead>
<tr>
<th>Auxiliary Labels</th>
</tr>
</thead>
<tbody>
<tr>
<td>5. For external use only.</td>
</tr>
<tr>
<td>6. Do not take with alcohol, sleep aids, tranquilizers or other CNS depressants.</td>
</tr>
<tr>
<td>7. Cap tightly after use.</td>
</tr>
<tr>
<td>8. May impair mental and/or physical ability. Use care when operating a car or machinery.</td>
</tr>
<tr>
<td>9. Protect from light.</td>
</tr>
<tr>
<td>10. Keep in a dry place.</td>
</tr>
</tbody>
</table>

### 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.

### 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.

*The BUD is not later than the time remaining until the earliest expiration date of any API or 6 months, whichever is earlier.*
Suggested Formula: Lidocaine 2%, Metronidazole 2%, Misoprostol 0.0024% Topical Ointment (Suspension, 30 g)

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REFERENCES


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