Suggested Formula
Ibuprofen 10% Topical Gel (Solution, 100 mL)

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>Ibuprofen, USP</td>
<td>10.000</td>
<td>g</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hydroxypropyl Cellulose, NF</td>
<td>2.00</td>
<td>g</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Propylene glycol, USP</td>
<td>10.0</td>
<td>mL</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alcohol, USP</td>
<td>75.0</td>
<td>mL</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Purified water, USP</td>
<td>qs to 100.0</td>
<td>mL</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): Ibuprofen, Propylene Glycol
- **Hygroscopic** (protect from moisture whenever possible): Hydroxypropyl Cellulose, Propylene Glycol

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 10 to 12% 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 mL)

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>Ibuprofen, USP (§)</td>
<td>10.000</td>
<td>g</td>
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<td>Purified water, USP</td>
<td>qs to 100.0</td>
<td>mL</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

Preparatory Instruction

1. **Powder preparation (particle size reduction):**

   Combine and triturate the following ingredients together:
   - Ibuprofen
   - Hydroxypropyl Cellulose

   **End result:** Fine homogeneous powder blend

2. **Liquid preparation:**

   Combine the following ingredients together:
   - Propylene glycol
   - Alcohol

   **Specifications:** Continuously mix

   **End result:** Homogeneous liquid-like solution

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3. **Powder-liquid incorporation:**
   With stirring, incrementally add the fine homogeneous powder blend (Step 1) to the homogeneous liquid-like solution (Step 2).
   
   **Specifications:** Continuously mix until all solid particles have completely dissolved
   
   **End result:** Homogeneous liquid-like solution

4. **Product finishing (filling to volume):**
   Add Purified water to the homogeneous liquid-like solution (Step 3) to fill to the required batch size (100.0 mL plus processing error adjustments). Stir until homogeneous.

5. **Gelling procedure:**
   Cover the mixture (Step 4), and allow to set for about 2 hours to allow for complete hydration and gelification to occur.
   
   **End result:** Homogeneous gel-like solution

6. **Product transfer (semi-solid-to-dispensing container filling):**
   Transfer the final product into the specified dispensing container (see “Packaging Requirements”).

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SUGGESTED PRESENTATION

<table>
<thead>
<tr>
<th>Estimated Beyond-Use Date</th>
<th>Packaging Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>14 days, refrigerated.</td>
<td>Light resistant metered dose dispensing syringe.</td>
</tr>
</tbody>
</table>

1. Use as directed. Do not exceed prescribed dose.
2. Keep out of reach of children.
3. Consult your health care practitioner if any prescription or over-the-counter medications are currently being used or are prescribed for future use.
5. Protect from light.
6. Equilibrate to room temperature before use.
7. For external use only.

**Auxiliary Labels**

**Pharmacist Instructions**

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.

**REFERENCES**


**IMPORTANT**: The quantity of API administered is directly dependent on the quantity of product applied.