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>Progesterone (Micronized), USP</td>
<td>20.000</td>
<td>g</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ethoxy Diglycol</td>
<td>10.0</td>
<td>mL</td>
<td></td>
<td>Medisca VersaPro™ Lotion Base</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medisca VersaPro™ Lotion Base</td>
<td>60.0</td>
<td>mL</td>
<td></td>
<td>Medisca VersaPro™ Lotion Base</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medisca VersaPro™ Lotion Base q.s.</td>
<td>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):* Progesterone

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

**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.
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>Progesterone (Micronized), USP §</td>
<td>20.000</td>
<td>g</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ethoxy Diglycol §</td>
<td>10.0</td>
<td>mL</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medisca VersaPro™ Lotion Base</td>
<td>60.0</td>
<td>mL</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medisca VersaPro™ Lotion Base</td>
<td>q.s. to 100.0</td>
<td>mL</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. Levigate the Progesterone (Micronized) with the Ethoxy Diglycol.
      
      End result: Homogeneous paste-like dispersion.

2. **Powder-liquid to medium integration:**
   A. Incrementally add the homogeneous paste-like dispersion (Step 1A) to the VersaPro™ Lotion Base (60.0 mL plus processing error adjustments).
      
      Specifications: Continuously mix, using high-shear mixing techniques.
      
      End result: Homogeneous lotion-like dispersion.

3. **Filling to volume:**
   A. Add additional VersaPro™ Lotion Base to the mixture (Step 2A) to fill to the required batch size (100.0 mL plus processing error adjustments).
      
      Specifications: Continuously mix, using high-shear mixing techniques.
      
      End result: Homogeneous lotion-like dispersion.

4. **Product transfer:**
   A. Transfer the final product into the specified dispensing container (see “Packaging requirements”).
      
      Note: Continuously mix the final product during the transfer process in order to maintain homogeneity.
**Suggested Formula**

<table>
<thead>
<tr>
<th>Suggested Formula</th>
<th>Progesterone 20% Topical Lotion (Emulsion, 100 mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>FIN</strong></td>
<td>F 006 418</td>
</tr>
</tbody>
</table>

**SUGGESTED PRESENTATION**

<table>
<thead>
<tr>
<th>Estimated Beyond-Use Date</th>
<th>Packaging Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>30 days, as per USP.</td>
<td>- Tightly closed, light-resistant dispensing bottle.</td>
</tr>
<tr>
<td></td>
<td>- To be administered with a metered-dose measuring device.</td>
</tr>
</tbody>
</table>

**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.
4. Protect from light.
5. May impair mental and/or physical ability. Use care when operating a car or machinery.

**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.

**IMPORTANT:** The quantity of API administered is directly dependent on the quantity of product applied.
Suggested Formula | Progesterone 20% Topical Lotion (Emulsion, 100 mL)
--- | ---
FIN | F 006 418

REFERENCES


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