Suggested Formula
Ascorbic Acid 2%, Caffeine 1%, Epigallocatechin Gallate 1%, Methylsulfonylmethane 5% Topical Gel (Suspension, 30 g)

<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>Ascorbic Acid, USP</td>
<td>0.600</td>
<td>g</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Caffeine (Anhydrous), USP</td>
<td>0.300</td>
<td>g</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(-)-Epigallocatechin 3-O-Gallate (EGCG)</td>
<td>0.300</td>
<td>g</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Methylsulfonylmethane (Dimethyl Sulfone, MSM), USP</td>
<td>1.500</td>
<td>g</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ethoxy Diglycol</td>
<td>1.8</td>
<td>mL</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medisca CopaSil™</td>
<td>25.45</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)*: Ascorbic Acid, (-)-Epigallocatechin 3-O-Gallate, Methylsulfonylmethane
- **Hygroscopic** *(protect from moisture whenever possible)*: Methylsulfonylmethane, Ethoxy Diglycol
- **Oxygen sensitive** *(protect from oxygen whenever possible)*: Ascorbic Acid

**Suggested Preparatory Guidelines**

- [ ] Non-Sterile Preparation
- [ ] Sterile Preparation

**Processing Error / Testing Considerations**: To account for processing error 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.

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 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>Ascorbic Acid, USP §</td>
<td>0.600</td>
<td>g</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Caffeine (Anhydrous), USP</td>
<td>0.300</td>
<td>g</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(-)-Epigallocatechin 3-O-Gallate (EGCG) §</td>
<td>0.300</td>
<td>g</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Methylsulfonylmethane (Dimethyl Sulfone, MSM), USP §</td>
<td>1.500</td>
<td>g</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ethoxy Diglycol §</td>
<td>1.8</td>
<td>mL</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medisca CopaSil™</td>
<td>25.45</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 geometric addition, combine and triturate the following ingredients together to form a fine homogeneous powder blend:
      
      - Ascorbic Acid
      - Caffeine (Anhydrous)
      - (-)-Epigallocatechin 3-O-Gallate (EGCG)
      - Methylsulfonylmethane (Dimethyl Sulfone, MSM)

   B. Levigate the fine homogeneous powder blend (Step 1A) with the Ethoxy Diglycol.

      **End result:** Homogeneous liquid-like dispersion.

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

      **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.
### Suggested Formula

<table>
<thead>
<tr>
<th>Suggested Formula</th>
<th>FIN</th>
<th>F 006 352</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ascorbic Acid 2%, Caffeine 1%, Epigallocatechin Gallate 1%, Methylsulfonylmethane 5% Topical Gel (Suspension, 30 g)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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>
<tbody>
<tr>
<td>6 months, as per USP*</td>
<td>- Tightly closed, light-resistant ointment tube/jar. - 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. May produce psychological and/or physical dependence.
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. Keep in a dry place.
5. Keep out of reach of children.

#### 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.

* 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
Ascorbic Acid 2%, Caffeine 1%, Epigallocatechin Gallate 1%, Methylsulfonylmethane 5% Topical Gel (Suspension, 30 g)

FIN F 006 352

REFERENCES


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