Suggested Formula

Phytonadione 2.5 mg/0.5 mL Oral Liquid (Solution, 20 mL)

<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>Phytonadione (Vitamin K₁), USP</td>
<td>0.100</td>
<td>g</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Almond Oil (Sweet) (Natural), NF</td>
<td>18.0</td>
<td>mL</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Almond Oil (Sweet) (Natural), NF</td>
<td>q.s. to 20.0</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):* Phytonadione (Vitamin K₁), Almond Oil (Sweet), (Natural)

**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.

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 20 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>Phytonadione (Vitamin K₁), USP §</td>
<td>0.100</td>
<td>g</td>
<td>0</td>
<td></td>
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<td>q.s. to 20.0</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-Liquid preparation:**
   A. Incrementally add the Phytonadione (Vitamin K₁) to the following ingredient:
      - Almond Oil (Sweet) (Natural) (18.0 mL plus processing error adjustments)

      Specifications: Continuously mix.

      End result: Homogeneous liquid-like solution.

2. **Filling to volume:**
   A. Add additional Almond Oil (Sweet) (Natural) to the mixture (Step 1A) to fill to the required batch size (20.0 mL plus processing error adjustments).

      Specifications: Continuously mix.

      End result: Homogeneous liquid-like solution.

3. **Product transfer:**
   Transfer the final product into the specified dispensing container (see “Packaging requirements”).
Suggested Formula
Phytonadione 2.5 mg/0.5 mL Oral Liquid (Solution, 20 mL)

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**SUGGESTED PRESENTATION**

<table>
<thead>
<tr>
<th>Estimated Beyond-Use Date</th>
<th>Packaging Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>30 days, refrigerated, as per USP.</td>
<td>Tightly closed, light-resistant prescription bottle with 0.5 mL metered dosing 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.
4. Do not take with alcohol, sleep aids, tranquilizers or other CNS depressants.
5. Cap tightly after use.
7. Protect from light.
8. 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.

**REFERENCES**


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