Formulation Record

Name: Zinc Oxide and Talc Lotion
Strength: 25% Each Active Ingredients
Dosage Form: Lotion
Route of Administration: Topical

Date of Last Review or Revision: 09/01/04
Person Completing Last Review or Revision: Robert Shrewsbury

Formula to make 240 ml of lotion:

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Quantity</th>
<th>Physical Description</th>
<th>Solubility</th>
<th>Therapeutic Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zinc oxide USP</td>
<td>60.0 g</td>
<td>very fine white amorphous powder</td>
<td>insoluble in water and alcohol</td>
<td>astringent, antiseptic</td>
</tr>
<tr>
<td>Talc USP</td>
<td>60.0 g</td>
<td>very fine white or grayish white crystalline powder</td>
<td>insoluble in water and alcohol</td>
<td>lubricant, suspending agent</td>
</tr>
<tr>
<td>Alcohol USP</td>
<td>50.0 ml</td>
<td>clear, non-viscous liquid</td>
<td>water miscible</td>
<td>vehicle</td>
</tr>
<tr>
<td>Glycerin USP</td>
<td>40.0 ml</td>
<td>clear, viscous liquid</td>
<td>water miscible</td>
<td>emollient</td>
</tr>
<tr>
<td>Purified Water</td>
<td>120 ml</td>
<td>clear, non-viscous liquid</td>
<td>n/a</td>
<td>diluent</td>
</tr>
</tbody>
</table>

Example Calculations:

Equipment Required:
- Class A prescription balance
- mortar and pestle
- hard rubber spatula

Method of Preparation:
1. Using the prescription balance, weigh zinc oxide and talc. Place in a mortar.
2. Add the alcohol and glycerin, and levigate the powders to form a smooth paste.
3. Add a small portion of water to the mortar and mix. Transfer the mixture to an ointment jar. **USE A RUBBER SPATULA WHEN SCRAPPING THE MORTAR AND PESTLE.**
4. Continue rinsing the mortar and pestle until the appropriate volume of water is used.
5. When final transfer is done, shake the ingredients in the ointment jar.

Description of Finished Product:
Creamy white lotion with no visible particles; shakes easily; spreads easily without a gritty texture

Quality Control Procedures:
- Observations for uniform consistency and free water.
- Weight of final product.

Packaging Container:
- Provide container with sufficient room for shaking.
Storage Requirements:
The presence of glycerin and alcohol are sufficient to preserve the volume of purified water. Zinc oxide and talc are not support media for microbial growth.

Beyond-Use Date Assignment:
USP Guidelines:
Water containing formulations:
When prepared from ingredients in solid form, the beyond-use date should be not later than 14 days when stored at cold temperature.
At issue here is the consistency of the lotion if placed in refrigeration which is not practical. However, there is sufficient alcohol and glycerin to preserve the water at room temperature, so a 14 day beyond use date (without refrigeration) would be assigned.

Label Information:
Shake Well

Source of Recipe:
Pharmaceutics Laboratory Web page: pharmlabs.unc.edu
How to levigate a powder: http://pharmlabs.unc.edu/ointments/media.htm

Literature Information:
Applied Pharmaceutics and Contemporary Compounding, Chapter 9, Dermatological Formulations: Ointments and Pastes.