Formulation Record

Name: Calamine Lotion
Strength: NA
Dosage Form: Suspension
Route of Administration: Topical

Date of Last Review or Revision: 01/27/01
Person Completing Last Review or Revision: RPS

Formula:

<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>Calamine</td>
<td>8.0 g</td>
<td>light pink powder</td>
<td>insoluble in water</td>
<td>protectant, astringent</td>
</tr>
<tr>
<td>Zinc Oxide</td>
<td>8.0 g</td>
<td>white powder</td>
<td>insoluble in water</td>
<td>protectant, astringent</td>
</tr>
<tr>
<td>Glycerin</td>
<td>2.0 ml</td>
<td>clear, viscous liquid</td>
<td>miscible with water</td>
<td>humectant</td>
</tr>
<tr>
<td>Avicel RC Gel</td>
<td>2.0 g</td>
<td>white, opaque gel</td>
<td>miscible with water</td>
<td>viscosity, stabilization agent</td>
</tr>
<tr>
<td>Carboxymethyl cellulose, sodium, medium viscosity</td>
<td>2.0 g</td>
<td>light tan powder</td>
<td>soluble in water</td>
<td>viscosity, suspending agent</td>
</tr>
<tr>
<td>Calcium Hydroxide Solution</td>
<td>qs 100 ml</td>
<td>clear liquid</td>
<td>miscible with water</td>
<td>astringent, vehicle</td>
</tr>
</tbody>
</table>

Additional Information:

Avicel is microcrystalline cellulose; Avicel RC is a mixture of microcrystalline cellulose and carboxymethyl cellulose sodium (synonyms include colloidal cellulose and dispersible cellulose).

Avicel RC Gel is 30 g of Avicel RC-591 and 500 g of water created with an electric mixer.

Example Calculations:

Equipment Required:

- prescription balance
- mortar and pestle
- plastic prescription bottle

Method of Preparation:

1. Accurately weigh the powders.
2. Levigate the calamine and zinc oxide with glycerin in a mortar.
3. Add the gel and then the carboxymethyl cellulose sodium with continual triturations until an uniform paste is formed.
4. Add a portion of the calcium hydroxide solution. **DO NOT POUR, OR DECANT. PIPET ONLY.**
5. Transfer the suspension from the mortar to a calibrated plastic prescription bottle.
6. Continuously rinse the mortar with calcium hydroxide solution, adding each rinse to the prescription bottle until the required volume is reached.

Description of Finished Product:

Creamy pink opaque suspension

Quality Control Procedures:
Packaging Container:
Package in plastic prescription bottle with sufficient room to able vigorous shaking.

Storage Requirements:
Can be stored at room temperature, avoid freezing.

Beyond-Use Date Assignment:
USP Guidelines:

**Aqueous solutions:**
When prepared from ingredients in solid form, the beyond-use date should be not later than 14 days when stored at cold temperature.

Formulation can be stored at cold temperature, but is not recommended. There is no preservative present. Assigning a 14 day beyond-use date cannot be justified. A 7 day beyond-use date will be used.

Label Information:
Shake Well

Source of Recipe:
Remington: Science and Practice of Pharmacy, 19th edition, p. 1519. Formula modification by RPS.

Literature Information: