Formulation Record

Name: Calamine-Zinc Oxide ointment
Strength: 12.5% Calamine, 12.5% Zinc oxide
Dosage Form: Ointment
Route of Administration: Topical
Date of Last Review or Revision: 08/01/01
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>8.25 g</td>
<td>Pink powder</td>
<td>Insol in water and alcohol</td>
<td>Protective, astringent, antiseptic</td>
</tr>
<tr>
<td>Zinc oxide</td>
<td>8.25 g</td>
<td>White powder</td>
<td>Insol in water and alcohol</td>
<td>Protective, astringent, antiseptic</td>
</tr>
<tr>
<td>Aquaphor®</td>
<td>49.5 g</td>
<td>Semi-solid (non-aqueous absorption ointment base)</td>
<td>NA</td>
<td>base</td>
</tr>
<tr>
<td>Mineral Oil</td>
<td>Variable (unknown until compounding; see example below)</td>
<td>Clear oil</td>
<td>NA</td>
<td>levigating agent</td>
</tr>
</tbody>
</table>

Calculations (for total weight = 66 g)

Note: students instructed to prepare excess of 10%.

Calamine and Zinc Oxide (of each) 12.5 g / 100 g x 66 g = 8.25 g

Aquaphor: 66 g – 8.25 g calamine – 8.25 g zinc oxide = 49.5 g – weight of levigating agent

e.g., if 5 ml mineral oil used = 5 ml x 0.88 = 4.4 g (sp.gr = 0.86 – 0.905; average = 0.88)

Equipment Required:

- Prescription balance to weigh solid ingredients
- ointment slab for mixing ointment
- 6” metal spatula to mix ointment ingredients; 4” metal or plastic spatula for scraping and packing ointment
- 5 - 10 ml syringe to measure mineral oil

Method of Preparation:

- Weigh the calamine and zinc oxide
- Draw a known quantity of mineral oil into a syringe and used as needed to levigate the powders. Determine final volume used by difference.
- Subtract the weight of levigating agent from weight of Aquaphor
- Weigh Aquaphor
- Incorporate levigated solids into the Aquaphor using geometric dilution
- Transfer completed ointment into ointment jar

Description of Finished Product:

Non-gritty pink ointment

Quality Control Procedures:
- Product should be a well mixed, homogenous product free from palpable or observable particles, but have a stiff, paste-like consistency
- Product should be elegantly packaged in ointment jar with no product on jar lid
- Proper amount of ointment should be in ointment jar

**Packaging Container:**

2 ounce plastic ointment jar

**Storage Requirements:**

Can be stored at room temperature

**Beyond-Use Date Assignment:**

USP Guidelines:

*All other dosage forms:*

The beyond-use date is not later than the intended duration of therapy or 30 days, whichever is earlier.

Assigning a 30 day beyond-use date. It is not possible to predict how much ointment will be used with each application.

**Label Information:**

*For external use only*

**Source of Recipe:**

A Practical Guide to Contemporary Pharmacy Practice, Lippincott Williams & Wilkins, 1998

**Literature Information:**

NA