Formulation Record

Name: Hydrocortisone Ointment
Strength: 2.0%
Dosage Form: ointment
Route of Administration: Topical

Date of Last Review or Revision: 09/12/06
Person Completing Last Review or Revision: Robert Shrewsbury

<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>Hydrocortisone USP, micronized</td>
<td>2%</td>
<td>white, amorphous powder, odorless</td>
<td>0.28 mg/ml in water</td>
<td>anti-inflammatory glucocorticoid</td>
</tr>
<tr>
<td>Glycerin USP</td>
<td>s.a.</td>
<td>clear, very viscous liquid sweetener, solvent</td>
<td>miscible with water</td>
<td>sweetener, solvent, levigating agent</td>
</tr>
<tr>
<td>Calamine USP</td>
<td>4%</td>
<td>pink, amorphous powder, odorless</td>
<td>insoluble in water; almost completely soluble in mineral acids</td>
<td>used as visual aid, topical protectant, astringent</td>
</tr>
<tr>
<td>Emollient Cream PCCA ™</td>
<td>qs 60 gm</td>
<td>white, moist appearing cream, smooth texture, particle-free</td>
<td>NA</td>
<td>cream base</td>
</tr>
</tbody>
</table>

Example Calculations:

Equipment Required:
- Class A prescription balance
- ointment slab
- 2 stainless steel spatulas

Method of Preparation:
1. Using the prescription balance, weigh hydrocortisone and calamine. Place on ointment slab.
2. Levigate the powders with glycerin to form a smooth paste.
3. Using geometric dilution, incorporate the levigated powders into the base. Use two stainless steel spatulas.
4. Package in ointment jar. Provide a professional finish.

Description of Finished Product:
Uniform, lightly pink cream with no visible particles; spreads easily without a gritty texture

Quality Control Procedures:
Observations for uniform consistency
Weight of final product.

Packaging Container:
Package in 2 oz. plastic ointment jar.
How to pack an ointment jar: http://pharmlabs.unc.edu/ointments/media.htm
**Storage Requirements:**
Store at room temperature.

**Beyond-Use Date Assignment:**
**USP Guidelines:**
All other formulations (i.e., not a solid, not a liquid): 30 days or intended duration of therapy, whichever is less.

**Label Information:**
External Use Only

**Source of Recipe:**
Pharmaceutics Laboratory Web page: pharmlabs.unc.edu

**Literature Information:**
Applied Pharmaceutics and Contemporary Compounding, Chapter 9, Dermatological Formulations: Ointments and Pastes.
How to levigate a powder: [http://pharmlabs.unc.edu/ointments/media.htm](http://pharmlabs.unc.edu/ointments/media.htm)
Incorporating a drug into an ointment: [http://pharmlabs.unc.edu/ointments/media.htm](http://pharmlabs.unc.edu/ointments/media.htm)
How to pack an ointment jar: [http://pharmlabs.unc.edu/ointments/media.htm](http://pharmlabs.unc.edu/ointments/media.htm)