# **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

| Ingredient                        | Quantity | Physical Description  | Solubility   | Therapeutic Activity                               |
|-----------------------------------|----------|---|--|--|
| Hydrocortisone<br>USP, micronized | 2%       | white, amorphous powder, odorless                                 | 0.28 mg/ml in water<br>15.0 mg/ml in ethanol                         | anti-inflammatory<br>glucocorticoid                |
| Glycerin USP                      | s.a.     | clear, very viscous liquid sweetener, solvent                     | miscible with water  | sweetener, solvent,<br>levigating agent            |
| Calamine USP                      | 4%       | pink, amorphous<br>powder, odorless                               | insoluble in water; almost<br>completely soluble in mineral<br>acids | used as visual aid, topical protectant, astringent |
| Emollient Cream<br>PCCA ™         | qs 60 gm | white, moist appearing<br>cream, smooth texture,<br>particle-free | NA   | cream base   |

## **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: <u>http://pharmlabs.unc.edu/ointments/media.htm</u>

## 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: <u>http://pharmlabs.unc.edu/ointments/media.htm</u> Incorporating a drug into an ointment: <u>http://pharmlabs.unc.edu/ointments/media.htm</u>

How to pack an ointment jar: http://pharmlabs.unc.edu/ointments/media.htm