

Formulation Record

Name: _____ Hydrocortisone
Strength: _____ 2.5%
Dosage Form: _____ 45 Gm Application Stick
Route of Administration: _____ Topical

Date of Last Review or Revision: _____ 01/03/07
Person Completing Last Review or Revision: Robert Shrewsbury

Formula:

Ingredient	Quantity	Physical Description	Solubility	Therapeutic Activity
Hydrocortisone USP, micronized	2.5%	white powder	0.28 mg/ml in water 15.0 mg/ml in ethanol	anti-inflammatory
White Beeswax	28%	slightly yellow wax	insoluble in water; soluble in fixed oils: mp 62-65°C	vehicle, stiffening agent
Cetyl Esters Wax	28%	white, translucent flakes	insoluble in water; soluble in fixed oils: mp 43-47°C	vehicle, imparts consistency
Mineral Oil	39%	clear, viscous solution	insoluble in water; miscible with fixed oils	vehicle, humectant
Acacia	5%	off-white amorphous powder	insoluble in alcohol; forms a colloidal dispersion as twice its weight in water	suspending agent

Additional Information:

- Mineral Oil is available as both Heavy Mineral Oil and Light Mineral Oil. If the "type" is not specified on the commercial package, it is Heavy Mineral Oil. Light Mineral Oil must be specifically specified as such. Density of Heavy Mineral Oil = 0.88
- Cetyl Esters Wax is the new name for Spermaceti Wax.

Example Calculations:

- It is prudent to prepare 10% extra to allow for formulation loss (i.e., 45 g + 10% = 49.5 g).
- 49.5 g application stick x 0.025 = 1.24 g of hydrocortisone; (49.50 – 1.24) g = 48.26 g of base

Equipment Required:

- prescription balance
- 100 ml beaker
- hotplate
- stirring rod

Method of Preparation:

1. Accurately weigh the powders in a weigh boat.
2. Heat to melt the beeswax.
3. When the beeswax is melted, **reduce the heat** and melt the cetyl esters wax. Use a stirring rod, not a stirring bar.
4. When the cetyl esters wax is melted, **remove from heat**, add the hydrocortisone, acacia, and use the mineral oil to rinse the weigh boats.
5. When the hydrocortisone and acacia have dispersed in the waxes, cool the mixture until it is just warm to the back of the hand. **Stir one final time** just before filling the package.
6. Fill the application stick or package in an ointment jar.

Description of Finished Product:

Opaque ointment, very slight tan color, very slight greasy feeling

Quality Control Procedures:

- Product weight
- Analysis by spectrophotometry at $UV_{\max} \lambda = 242$ (to be conducted by PCL staff).

Packaging Container:

If package in application stick.

Step 1: Turn the base of the application stick 2 full turns upward to raise the bale.

Step 2: Overfill the tube slightly.

Step 3: If a hole forms around the spindle as the base cools in the application stick, use a warm spatula to melt the overfilled material and fill in the hole.

Storage Requirements:

Store at refrigerator or room temperature; avoid heating.

Beyond-Use Date Assignment:

USP Guidelines:

Nonaqueous liquids and solid formulations:

If the source of the ingredient(s) is a manufactured drug product, the beyond-use date is not later than 25% of the time remaining until the original product's expiration date, or 6 months, whichever is earlier.

If the source of the ingredient(s) is a USP or NF substance, the beyond-use date is not later than 6 months. Assign 6 months.

Label Information:

External Use Only

Avoid Heating

Source of Recipe:

Modified from Compounding Compendium, Apothecary Products, Inc., 1999

Literature Information:

Mineral Oil: Remington: The Science and Practice of Pharmacy, 19th edition, 1995, pp. 899-900

Cetyl Esters Wax: Remington: The Science and Practice of Pharmacy, 19th edition, 1995, p. 1400

White Beeswax: Remington's Pharmaceutical Sciences, 18th edition, 1990, p. 1310-1311

Acacia: Remington: The Science and Practice of Pharmacy, 19th edition, 1995, pp. 1395