

Formulation Record

Name: _____ Hydrocortisone _____

Strength: _____ 2.5% _____

Dosage Form: _____ Ointment/Application Stick _____

Route of Administration: _____ Topical _____

Date of Last Review or Revision: _____ Today _____

Person Completing Last Review or Revision: _____ RPS _____

Formula:

Ingredient	Quantity	Physical Description	Solubility	Therapeutic Activity
Hydrocortisone	2.5%	white powder	0.28 mg/ml in water 15.0 mg/ml in ethanol	anti-inflammatory
White Beeswax	30%	slightly yellow wax	insoluble in water; soluble in fixed oils mp 62-65°C	vehicle, stiffening agent
Cetyl Esters Wax	30%	white, translucent flakes	insoluble in water; soluble in fixed oils mp 43-47°C	vehicle, imparts consistency
Mineral Oil	40%	clear, viscous solution	insoluble in water; miscible with fixed oils	vehicle, humectant

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.
- 5.5 g application stick x 0.025 = 0.14 g of hydrocortisone; (5.50 – 0.14) g = 5.36 g of base

Equipment Required:

- prescription balance

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 and use the mineral oil to rinse the weigh boat.
5. When the hydrocortisone has dispersed in the waxes, cool the mixture until it is just warm to the back of the hand.
6. Fill the application stick or package in an ointment jar.

Description of Finished Product:

Opaque ointment, slight greasy feeling

Quality Control Procedures:

UV $\lambda = 242$

Packaging Container:

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:

Can be stored 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