

Formulation Record

Name: Triamcinolone Acetonide Medicated Stick
Strength: 0.1%
Dosage Form: 45 Gm Application Stick
Route of Administration: Topical

Date of Last Review or Revision: 01/03/05
Person Completing Last Review or Revision: Robert Shrewsbury

Formula:

Ingredient	Quantity	Physical Description	Solubility	Therapeutic Activity
Triamcinolone Acetonide	0.1%	white amorphous powder	practically insoluble in water; slightly soluble in alcohol melting point 292-294°C	anti-inflammatory glucocorticoid
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 in 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 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 0.001 = 0.0495 g of triamcinolone acetonide; (49.5 - 0.0495) g = 49.45 g of base

Equipment Required:

- prescription balance
- small (50 ml) beaker
- hotplate
- stirring rod

Method of Preparation:

- Accurately weigh the powders in individual weigh boats.
- Turn on the hotplate to melt the beeswax in a small beaker.
- When the beeswax is melted, **reduce the heat** and melt the cetyl esters wax. Use a stirring rod, not a stirring bar to blend the waxes.
- Turn the hotplate off**, and add the acacia. Mix well.
- Add the triamcinolone acetonide and use the mineral oil to rinse the weigh boat.
- When the triamcinolone acetonide has been dispersed in the waxes, cool the mixture until it is just warm to the back of the hand.

7. Fill the application stick or package in an ointment jar.

Description of Finished Product:

Opaque ointment, might have a very slight tan color, very slight greasy feeling

Quality Control Procedures:

Content analysis required. $UV_{\max} \lambda = 238$ (to be conducted by Skills Lab 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 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