

Formulation Record

Name: _____ Calamine Lotion _____

Strength: _____ NA _____

Dosage Form: _____ Suspension _____

Route of Administration: _____ Topical _____

Date of Last Review or Revision: _____ 01/27/01 _____

Person Completing Last Review or Revision: _____ RPS _____

Formula:

Ingredient	Quantity	Physical Description	Solubility	Therapeutic Activity
Calamine	8.0 g	light pink powder	insoluble in water	protectant, astringent
Zinc Oxide	8.0 g	white powder	insoluble in water	protectant, astringent
Glycerin	2.0 ml	clear, viscous liquid	miscible with water	humectant
Avicel RC Gel	2.0 g	white, opaque gel	miscible with water	viscosity, stabilization agent
Carboxymethyl cellulose, sodium, medium viscosity	2.0 g	light tan powder	soluble in water	viscosity, suspending agent
Calcium Hydroxide Solution	qs 100 ml	clear liquid	miscible with water	astringent, vehicle

Additional Information:

Avicel is microcrystalline cellulose; Avicel RC is a mixture of microcrystalline cellulose and carboxymethyl cellulose sodium (synonyms include colloidal cellulose and dispersible cellulose).

Avicel RC Gel is 30 g of Avicel RC-591 and 500 g of water created with an electric mixer.

Example Calculations:

Equipment Required:

- prescription balance
- mortar and pestle
- plastic prescription bottle

Method of Preparation:

1. Accurately weigh the powders.
2. Levigate the calamine and zinc oxide with glycerin in a mortar.
3. Add the gel and then the carboxymethyl cellulose sodium with continual triturations until an uniform paste is formed.
4. Add a portion of the calcium hydroxide solution. **DO NOT POUR, OR DECANT. PIPET ONLY.**
5. Transfer the suspension from the mortar to a calibrated plastic prescription bottle.
6. Continuously rinse the mortar with calcium hydroxide solution, adding each rinse to the prescription bottle until the required volume is reached.

Description of Finished Product:

Creamy pink opaque suspension

Quality Control Procedures:

Packaging Container:

Package in plastic prescription bottle with sufficient room to allow vigorous shaking.

Storage Requirements:

Can be stored at room temperature, avoid freezing.

Beyond-Use Date Assignment:

USP Guidelines:

Aqueous solutions:

When prepared from ingredients in solid form, the beyond-use date should be not later than 14 days when stored at cold temperature.

Formulation can be stored at cold temperature, but is not recommended. There is no preservative present. Assigning a 14 day beyond-use date cannot be justified. A 7 day beyond-use date will be used.

Label Information:

Shake Well

Source of Recipe:

Remington: Science and Practice of Pharmacy, 19th edition, p. 1519. Formula modification by RPS.

Literature Information: