

Formulation Record

Name: Calamine

Strength: 15%

Dosage Form: Dusting Powder

Route of Administration: Topical

Date of Last Review or Revision: 02/23/01

Person Completing Last Review or Revision: RPS

Formula:

Ingredient	Quantity	Physical Description	Solubility	Therapeutic Activity
Calamine	15%	light pink powder	insoluble in most solvents	protectant, astringent
Magnesium stearate	1%	white powder	insoluble in water and ethanol	lubricating agent
Talc	q.s. 50 g	white powder	insoluble in most solvents	vehicle

Additional Information:

Caution: Talc will aerosolize easily

Example Calculations:

Equipment Required:

- prescription balance
- sieve, 40 mesh, 5"

Method of Preparation:

1. Accurately weigh the powders.
2. Combine the powders using geometric dilution.
3. Sieve through a 40 mesh, 5" sieve.
4. Package in appropriate container.

Description of Finished Product:

Very light pink powder with easy flow properties

Quality Control Procedures:

Inspect the product to ensure a uniform blend of the calamine.

Packaging Container:

Sift powder can

Important: Remove hole plug in lid before assembling the powder can.

Storage Requirements:

Can be stored at refrigerator or room temperature.

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

Source of Recipe:

Pharmaceutical Laboratory Web Site, <http://www.unc.edu/courses/phar0511>.

Literature Information:

Handbook of Pharmaceutical Excipients, 3rd edition, APhA Publications, © 2000