

Formulation Record

Name: Calamine-Zinc Oxide ointment
 Strength: 12.5% Calamine, 12.5% Zinc oxide
 Dosage Form: Ointment
 Route of Administration: Topical
 Date of Last Review or Revision: 08/01/01
 Person Completing Last Review or Revision: RPS

Formula:

Ingredient	Quantity	Physical Description	Solubility	Therapeutic Activity
Calamine	8.25 g	Pink powder	Insol in water and alcohol	Protective, astringent, antiseptic
Zinc oxide	8.25 g	White powder	Insol in water and alcohol	Protective, astringent, antiseptic
Aquaphor®	49.5 g less wt of levigating agent	Semi-solid (non-aqueous absorption ointment base)	NA	base
Mineral Oil	Variable (<i>unknown until compounding; see example below</i>)	Clear oil	NA	levigating agent

Calculations (for total weight = **66 g**)

Note: students instructed to prepare excess of 10%.

$$\text{Calamine and Zinc Oxide (of each)} \quad 12.5 \text{ g} / 100 \text{ g} \times 66 \text{ g} = 8.25 \text{ g}$$

$$\text{Aquaphor: } 66\text{g} - 8.25 \text{ g calamine} - 8.25 \text{ g zinc oxide} = 49.5 \text{ g} - \text{weight of levigating agent}$$

$$\text{e.g., if 5 ml mineral oil used} = 5 \text{ ml} \times 0.88 = 4.4 \text{ g (sp.gr} = 0.86 - 0.905; \text{ average} = 0.88)$$

Equipment Required:

- Prescription balance to weigh solid ingredients
- ointment slab for mixing ointment
- 6" metal spatula to mix ointment ingredients; 4" metal or plastic spatula for scraping and packing ointment
- 5 - 10 ml syringe to measure mineral oil

Method of Preparation:

- Weigh the calamine and zinc oxide
- Draw a known quantity of mineral oil into a syringe and used as needed to levigate the powders. Determine final volume used by difference.
- Subtract the weight of levigating agent from weight of Aquaphor
- Weigh Aquaphor
- Incorporate levigated solids into the Aquaphor using geometric dilution
- Transfer completed ointment into ointment jar

Description of Finished Product:

Non-gritty pink ointment

Quality Control Procedures:

- Product should be a well mixed, homogenous product free from palpable or observable particles, but have a stiff, paste-like consistency
- Product should be elegantly packaged in ointment jar with no product on jar lid
- Proper amount of ointment should be in ointment jar

Packaging Container:

2 ounce plastic ointment jar

Storage Requirements:

Can be stored at room temperature

Beyond-Use Date Assignment:

USP Guidelines:

All other dosage forms:

The beyond-use date is not later than the intended duration of therapy or 30 days, whichever is earlier.

Assigning a 30 day beyond-use date. It is not possible to predict how much ointment will be used with each application.

Label Information:

For external use only

Source of Recipe:

A Practical Guide to Contemporary Pharmacy Practice, Lippincott Williams & Wilkins, 1998

Literature Information:

NA

