

Note: This lab will explore the relationship between emulsion stability and the amount of energy put into compounding an emulsion formulation. You will make two batches of the coal tar ointment, but by different methods. The first batch will be made by the ointment slab method. The second batch will be prepared using the Unguator.

Formulation Record

Name: Coal Tar Ointment

Strength: 10% v/w Coal Tar Solution, 2% w/w Salicylic Acid

Dosage Form: Ointment

Route of Administration: Topical

Date of Last Review or Revision: 08/26/09

Person Completing Last Review or Revision: Robert Shrewsbury

Formula:

| Ingredient | Quantity | Physical Description | Solubility | Therapeutic Activity |
|-----------------------|----------|--|---|---|
| Coal Tar Solution USP | 163.4 ml | almost black non-viscous liquid with strong naphthalene odor | 81-86% alcohol content; miscible with alcohol; coal tar compounds will precipitate out in water | local irritant, some keratolytic activity |
| Salicylic Acid USP | 32.7 g | white, crystalline powder | 1 g/460 ml water; 1 g/2.7 ml alcohol | topical keratolytic |
| Polysorbate 80 NF | 81.7 ml | amber colored, oily, viscous liquid | very soluble in water; sp. gr. = 1.08; soluble in alcohol | emulsifying agent |
| Ethyl Alcohol USP | 32.7 ml | Clear nonviscous liquid | sp. gr = 0.82; miscible with water | solvent |
| Emollient Cream | 1357.7 g | Unctuous, smooth, white cream | miscible with aqueous solutions and some oil based substances | ointment base |
| Total Batch Size | 1634.0 g | NA | NA | NA |

Addition Information:

Calculations:

Equipment Required:

- Electronic prescription balance
- small and large stainless steel spatulas
- ointment slab or mortar and pestle or unguator
- 50 ml beaker or 20 ml scintillation vial

Method of Preparation:

Ointment Slab Method:

1. Weigh the salicylic acid and emollient cream.
2. Add alcohol to the coal tar solution in a scintillation vial or small beaker.
3. Add salicylic acid and dissolve in the coal tar solution – alcohol mixture.
4. Incorporate the Polysorbate 80 into the mixture from step 3.
5. Incorporate the liquid mixture from step 4 into a portion of the emollient cream.
6. Using geometric dilution, incorporate the remaining emollient cream.
7. Package in a plastic ointment jar.

Unguator Method:

1. Weigh the salicylic acid and emollient cream.
2. Add alcohol to the coal tar solution in a scintillation vial or small beaker.
3. Add salicylic acid and dissolve in the coal tar solution – alcohol mixture.

Formulation Record

Coal Tar Ointment

4. Incorporate the Polysorbate 80 into the mixture from step 3.
5. Add the emollient cream to the unguator jar, and then the liquid mixture from step 4. Slightly blend the mixture with a hard rubber spatula.
6. Complete blending using an Unguator. Blend for 1.5 minutes and a rotation speed of 6. The Unguator clock will read 1.30 (1 minute, 30 seconds).
7. Cap the mixing jar.

Description of Finished Product:

gold to golden smooth, opaque cream with naphthalene odor

Quality Control Procedures:

- product weight
- no signs of emulsion separation or breaking
- no change in physical appearance

Packaging Container:

- plastic ointment jar or unguator mixing jar

Storage Requirements:

- room temperature; keep away from heat

Beyond-Use Date Assignment:

USP Guidelines:

For all other formulations (not liquid, not solid): The beyond-use date is not later than the intended duration of therapy or 30 days, whichever is earlier.

Assign a beyond-use date of either intended duration of therapy or 30 days, whichever is earlier.

Label Information:

- External Use Only

Source of Recipe:

- Pharmaceutical Care Skills Lab (RPS)

Literature Information:

Solubility Information:

- The Merck Index, 12th ed., © 1996.
- Remington's Pharmaceutical Sciences, 16th edition, p. 724