

Note: The purpose of this lab is to use contemporary compounding equipment for dermatologicals and investigate the influence of the equipment on the particle size and texture of a formulation. You will make a large batch of a urea 20% formulation (200 gm) on a pile tile, then use part of it in the unguator (50 gm) and part in an ointment mill (120 gm). You will then evaluate the urea particle size in each formulation using microscopic techniques. You will also package 20 gm of the ointment in an ointment tube and use a heat sealer to seal the tube.

Formulation Record

Name: _____ Urea Ointment _____
Strength: _____ 20% _____
Dosage Form: _____ Ointment _____
Route of Administration: _____ Topical _____

Date of Last Review or Revision: _____ 09/01/06 _____

Person Completing Last Review or Revision: Robert Shrewsbury

| Ingredient | Quantity | Physical Description | Solubility | Therapeutic Activity |
|----------------------|----------|--|---|-----------------------------|
| Urea USP | 20 g | tetragonal prism crystals, with odor of ammonia; salty taste | 1 gm/ml water, 1 gm /10 ml alcohol | astringent, antiseptic |
| White Petrolatum USP | 80 g | yellowish, unctuous ointment, slightly odorous | insoluble in water and alcohol; freely soluble in chloroform, ether | lubricant, suspending agent |

Example Calculations:

Equipment Required:

- Class A prescription balance
- ointment slab
- 2 stainless steel spatulas

Method of Preparation:

1. Using the prescription balance, weigh urea and petrolatum. Place on pill tile.
2. Use a small portion of the petrolatum as a levigating agent, and levigate the urea to form a smooth paste.
3. Using geometric dilution, incorporate the levigated urea into the remaining petrolatum.
4. Package 20 gm of the finished product in an ointment tube.
5. Use 50 gm of the finished product for the unguator.
6. Use the remainder of the finished product for the ointment mill.

Description of Finished Product:

Thick, unctuous ointment with a gritty appearance (pile tile).

Quality Control Procedures:

Weight of final product.

Packaging Container:

An ointment tube (pile tile).

Storage Requirements:

Can be stored at room temperature.

Beyond-Use Date Assignment:

USP Guidelines:

All other formulations (i.e., not a solid, not a liquid): Thirty days or intended duration of therapy, whichever is less.

Label Information:

For External Use Only

Source of Recipe:

Pharmaceutics Laboratory Web page: pharmlabs.unc.edu

How to levigate a powder: <http://pharmlabs.unc.edu/ointments/media.htm>

How to fill an ointment tube: <http://pharmlabs.unc.edu/ointments/media.htm>

How to seal an ointment tube: <http://pharmlabs.unc.edu/ointments/media.htm>

Literature Information:

Applied Pharmaceutics and Contemporary Compounding, Chapter 9, Dermatological Formulations: Ointments and Pastes.