

Formulation Record

Name: Zinc Oxide and Talc Lotion
Strength: 25% Each Active Ingredients
Dosage Form: Lotion
Route of Administration: Topical

Date of Last Review or Revision: 09/01/04
Person Completing Last Review or Revision: Robert Shrewsbury

Formula to make 240 ml of lotion:

Ingredient	Quantity	Physical Description	Solubility	Therapeutic Activity
Zinc oxide USP	60.0 g	very fine white amorphous powder	insoluble in water and alcohol	astringent, antiseptic
Talc USP	60.0 g	very fine white or grayish white crystalline powder	insoluble in water and alcohol	lubricant, suspending agent
Alcohol USP	50.0 ml	clear, non-viscous liquid	water miscible	vehicle
Glycerin USP	40.0 ml	clear, viscous liquid	water miscible	emollient
Purified Water	120 ml	clear, non-viscous liquid	n/a	diluent

Example Calculations:

Equipment Required:

- Class A prescription balance
- mortar and pestle
- hard rubber spatula

Method of Preparation:

1. Using the prescription balance, weigh zinc oxide and talc. Place in a mortar.
2. Add the alcohol and glycerin, and levigate the powders to form a smooth paste.
3. Add a small portion of water to the mortar and mix. Transfer the mixture to an ointment jar. **USE A RUBBER SPATULA WHEN SCRAPPING THE MORTAR AND PESTLE.**
4. Continue rinsing the mortar and pestle until the appropriate volume of water is used.
5. When final transfer is done, shake the ingredients in the ointment jar.

Description of Finished Product:

Creamy white lotion with no visible particles; shakes easily; spreads easily without a gritty texture

Quality Control Procedures:

Observations for uniform consistency and free water.
Weight of final product.

Packaging Container:

Provide container with sufficient room for shaking.

Storage Requirements:

The presence of glycerin and alcohol are sufficient to preserve the volume of purified water. Zinc oxide and talc are not support media for microbial growth.

Beyond-Use Date Assignment:

USP Guidelines:

Water containing formulations:

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

At issue here is the consistency of the lotion if placed in refrigeration which is not practical. However, there is sufficient alcohol and glycerin to preserve the water at room temperature, so a 14 day beyond use date (without refrigeration) would be assigned.

Label Information:

Shake Well

Source of Recipe:

Pharmaceutics Laboratory Web page: pharmlabs.unc.edu

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

Literature Information:

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