

Formulation Record

Name: Urea Cream
Strength: 40%
Dosage Form: Cream
Route of Administration: Topical

Date of Last Review or Revision: 08/15/03
Person Completing Last Review or Revision: RPS

Formula:

Ingredient	Quantity	Physical Description	Solubility	Therapeutic Activity
Urea	40 g	transparent crystals	1 g/1 ml water, 1 g/10 ml of alcohol	keratolytic agent
Propylene Glycol	20 ml	clear, viscous liquid	miscible with water	solvent, mold growth inhibitor, humectant
Emollient Cream	40 g	white, moderate semisolid cream	NA	base

Additional Information:

Density of propylene glycol = 1.036 g/ml.

Example Calculations:

Equipment Required:

- Class A prescription balance
- mortar and pestle
- hard rubber spatula
- stainless steel spatulas

Method of Preparation:

1. Reduce the urea particle size using the method of intervention and trituration in a mortar.
2. Use propylene glycol to transfer urea from mortar.
3. Make a small "well" in a portion of the base. Place part of the urea into the well. Incorporate the urea into the ointment base.
4. Continue incorporating urea into the base using the technique in step 3.

Alternate Method of Preparation

1. Reduce the urea particle size by triturating four portions of the powder. Transfer each triturated portion into a weigh boat.
2. Wet the urea with propylene glycol (use about 5 ml of propylene glycol per weigh boat).
3. Place all of the base on the pill tile.
4. Incorporate one weigh boat of material into the base, reducing particles clumps.
5. Incorporate each remaining weigh boat of material into the base one at a time.

Description of Finished Product:

white, slightly stiff ointment with no visible particles

Quality Control Procedures:

- weight of final product
- visual observation of ointment spread

Packaging Container:

tight, opaque ointment jar

Storage Requirements:

Beyond-Use Date Assignment:

USP Guidelines:

For all other formulations (i.e., not solid or liquid):

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:

Source of Recipe:

Literature Information: