

Formulation Record

Name: Urea, hydrocortisone, lactic acid cream
 Strength: 10% Urea, 0.5% hydrocortisone, 5% lactic acid
 Dosage Form: cream
 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
Urea	3.3 g	Crystal	1 g /1.5 ml water; 10 ml alcohol	keratolytic agent, skin hydration, humectant
Hydrocortisone (as 1% cream)	16.5 g	1% hydrocortisone cream (commercial product)	Insol in water or alcohol	Anti-pruritic agent
Lactic acid	1.9 g or 1.6 ml	Clear to yellow liquid viscous liquid. 85 - 90% w/w, sp.gr. = 1.2	Miscible in water or alcohol	keratolytic agent, skin hydration, formulation stabilizer
Water	5 g or 5 ml	Clear liquid	NA	solvent
Eucerin	6.3 g	Semi-solid, w/o emulsion base	NA	base

Calculations (for total weight = 33 g)

Note: students instructed to prepare excess of 10%.

Urea: $33\text{ g} \times 10\text{ g}/100\text{ g} = 3.3\text{ g}$

Hydrocortisone: $(33\text{ g})(0.5\%) = (x\text{ g})(1\%) \quad x = 16.5\text{ g of 1\% cream}$

Lactic acid: If based on 5% w/w : $(33\text{ g})(5\text{ g}/100\text{ g}) = 1.65\text{ g}$

Lactic acid USP supplied as 85% w/w

$1.65\text{ g} \div 0.85\text{ g pure lactic acid} / 1\text{ g product} = 1.94\text{ g} \div 1.2\text{ sp. gr.} = 1.62\text{ ml}$

Water (based on solubility of urea 1 g/1.5 ml):

$3.3\text{ g urea} \times 1.5\text{ ml water/g urea} = 5\text{ g water} = 5\text{ ml}$

Eucerin: $33\text{ g} - 16.5\text{ g 1\% hydrocortisone} - 3.3\text{ g urea} - 1.9\text{ g lactic acid} - 5\text{ g water} = 6.3\text{ g}$

Equipment Required:

- Prescription balance
- mortar and pestle
- ointment slab (**Make sure students understand pad not acceptable; may lose liquid ingredients into the parchment paper**)
- 6" metal spatula to mix ointment ingredients; 4" metal or plastic spatula for scraping
- 5 - 10 ml graduated cylinder
- 3 - 5 ml syringe

Method of Preparation:

- Using the prescription balance weigh urea, hydrocortisone 1% cream, and Eucerin
- Mix hydrocortisone ointment and Eucerin by geometric dilution on an ointment slab

- Measure water in a 5 - 10 ml graduated cylinder
- Using a mortar and pestle, triturate urea crystals to a fine powder; add water to dissolve
- Measure lactic acid in 3 ml syringe
- Add lactic acid to the aqueous solution
- Very gradually incorporate the urea and lactic acid solution into the ointment base using a spatula taking care not to lose any of the solution
- Transfer completed ointment onto glassine paper. Roll to fit ointment tube opening and insert into end of ointment tube. Using a spatula, block the end of the tube and slowly pull the paper out of the tube leaving the ointment inside the tube.
- Crimp or seal end of ointment tube

Description of Finished Product:

smooth white to yellow-white cream

Quality Control Procedures:

- Product should be well mixed / homogenous creamy to slightly gritty product
- Product should not be of fluid, lotion consistency
- Product should be elegantly packaged in ointment tube with tube properly sealed

Packaging Container:

1 ounce ointment tube

Storage Requirements:

Should be stored in cool environment

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:

Dr. Fellows, Dermatology Clinic.

Literature Information:

No stability information found in the literature

