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:

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Quantity</th>
<th>Physical Description</th>
<th>Solubility</th>
<th>Therapeutic Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Urea</td>
<td>3.3 g</td>
<td>Crystal</td>
<td>1 g /1.5 ml water; 10 ml alcohol</td>
<td>keratolytic agent, skin hydration, humectant</td>
</tr>
<tr>
<td>Hydrocortisone</td>
<td>16.5 g</td>
<td>1% hydrocortisone cream</td>
<td>Insol in water or alcohol</td>
<td>Anti-pruritic agent</td>
</tr>
<tr>
<td>Lactic acid</td>
<td>1.9 g or 1.6 ml</td>
<td>Clear to yellow liquid viscous liquid</td>
<td>Miscible in water or alcohol</td>
<td>keratolytic agent, skin hydration, formulation stabilizer</td>
</tr>
<tr>
<td>Water</td>
<td>5 g or 5 ml</td>
<td>Clear liquid</td>
<td>NA</td>
<td>solvent</td>
</tr>
<tr>
<td>Eucerin</td>
<td>6.3 g</td>
<td>Semi-solid, w/o emulsion base</td>
<td>NA</td>
<td>base</td>
</tr>
</tbody>
</table>

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

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

\( \text{Lactic acid USP supplied as 85\% w/w} \)
\( 1.65 \text{ g} \div 0.85 \text{ g pure lactic acid / 1 g product} = 1.94 \text{ g} \div 1.2 \text{ sp. gr.} = 1.62 \text{ ml} \)

**Water** (based on solubility of urea 1 g/1.5 ml):
3.3 g urea x 1.5 ml water/g urea = 5 g water = 5 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