Formulation Record

Name: ___________________________ Diclofenac Sodium Gel
Strength: ___________________________ 1%
Dosage Form: ___________________________ Gel
Route of Administration: ___________________________ topical
Date of Last Review or Revision: ___________________________ 11/01/12
Person Completing Last Review or Revision: ___________________________ Robert Shrewsbury

Formula for 100 ml:

<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>Diclofenac sodium</td>
<td>1 g</td>
<td>white, off-white, hygroscopic, crystalline powder</td>
<td>sparingly soluble in water, soluble in alcohol</td>
<td>NSAID with antipyretic activity</td>
</tr>
<tr>
<td>Ethoxy diglycol</td>
<td>20 g</td>
<td>colorless, hygroscopic liquid with mild pleasant odor.</td>
<td>miscible with water, alcohol. density = 1.03.</td>
<td>solvent, solubilizer</td>
</tr>
<tr>
<td>Labrasol</td>
<td>10 g</td>
<td>colorless, oily liquid with faint odor.</td>
<td>soluble in water, vegetable oils, propylene glycol, very soluble in ethanol. sp. gr. = 1.06.</td>
<td>solvent, solubilizer, penetration enhancer</td>
</tr>
<tr>
<td>Benzyl alcohol</td>
<td>1 g</td>
<td>clear, colorless, oily liquid with faint aromatic odor.</td>
<td>soluble in water 1g/25ml; miscible with alcohol; sp. gr. = 1.04</td>
<td>antimicrobial preservative</td>
</tr>
<tr>
<td>Hydroxyethyl cellulose</td>
<td>2 g</td>
<td>light tan or cream colored, odorless, tasteless powder</td>
<td>soluble in hot or cold water, insoluble in ethanol</td>
<td>suspending, thickening, viscosity-increasing agent</td>
</tr>
<tr>
<td>Purified water</td>
<td>qs 100 ml</td>
<td>clear, nonviscous liquid</td>
<td>NA</td>
<td>diluent</td>
</tr>
</tbody>
</table>

Additional Information:
Ethoxy diglycol has several synonyms: diethylene glycol monoethyl ether, Carbitol, Transcutol.

Labrasol (caprylic/capric triglycerides) is esterified glycerol with mixtures of caprylic (C:8) and capric (C:10) fatty acids from coconut or palm kernel oils.

Example Calculations:

Equipment Required:
- Class A torsion prescription balance
- Stirring plate and small stir bar, stirring rod
- 150 ml beaker (Note: change size of beaker as needed for the prescription)

Method of Preparation:
1. Calibrate a 150 ml beaker to 100 ml with the stir bar in the beaker.
2. Weigh or measure the ingredients.
3. In the calibrated beaker, dissolve the diclofenac sodium in the ethoxy diglycol, benzyl alcohol, and about 50 ml of purified water. Begin vigorous stirring with a stir bar.
4. Add the hydroxyethyl cellulose to the Labrasol in a scintillation vial and mix well.
5. Slowly add the mixture in the scintillation vial to the stirring mixture in the beaker. If the stir bar cannot stir the mixture, stir with a glass rod.
6. Use purified water to rinse through the scintillation vial and bring the product to the calibration mark. Stir until a smooth, homogenous gel is formed.
Description of Finished Product:
Cloudy, viscous gel

Quality Control Procedures:
Product should be cloudy with no visible particles.
Analysis of diclofenac concentration.

Packaging Container:
1 ml oral syringe with cap (or other appropriate container)

Storage Requirements:
Store at room temperature

Beyond-Use Date Assignment:
USP <795> Guidelines: Water containing topical/dermal/mucosal liquid or semisolid formulation. The beyond use date is not later than 30 days.

Label Information:
For Topical Use Only

Source of Recipe:

Literature Information:
Merck Index, 12th Edition, 1996 for solubility information