

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:

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

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
Handbook of Pharmaceutical Excipients, 4th edition, 2003, pp. 89-92 (carbomers)
Modified from International Journal of Pharmaceutical Compounding 8(5):387, 2004.