

Formulation Record

Name: _____ Diclofenac Gel
Strength: _____ 1%
Dosage Form: _____ Gel
Route of Administration: _____ topical

Date of Last Review or Revision: _____ 10/30/12
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
Propylene glycol	10 ml	clear, colorless, viscous, practically odorless liquid	miscible with water, alcohol, glycerin	inhibitor of mold growth; solubilization agent
Carbomer 940	1.25 g	white, very fluffy, hygroscopic powder	soluble in water; soluble in alcohol after neutralization	gelling agent
Ethanol 95%	50 ml	clear, nonviscous, volatile liquid	miscible with water, glycerin	diluent
Trolamine NF	20 gtts	clear, hygroscopic, colorless to pale yellow, viscous liquid with ammoniacal odor.	sp. gr.=1.12. pH 10.5 (0.1N aq. soln). Miscible with water, alcohol, methanol	alkalizing and emulsifying agent
Purified water	qs 100 ml	clear, nonviscous liquid	NA	diluent

Additional Information:

Carbomer is the generic name for the Carbopol® family of resins. Carbomer is acrylic acid cross-linked with either allyl sucrose or allyl ethers of pentaerythritol.

Trolamine is triethanolamine.

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 the diclofenac sodium and carbomer, and place in a mortar. Triturate with a pestle.
3. Add the propylene glycol to the mortar, and triturate to a smooth paste.
4. Using the alcohol, transfer the mortar contents to the calibrated beaker. Begin vigorous stirring.
5. Add purified water to the calibration mark.
6. Add the trolamine to the stirring mixture after the purified water has been incorporated. Stir bar should not be able to stir the mixture; therefore, stir with a glass rod until a smooth, homogenous gel is formed.

Description of Finished Product:

Cloudy, viscous gel with slight alcohol odor.

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.