

## Formulation Record

Name: Ketoprofen in PLO  
Strength: 10%  
Dosage Form: Emulsion/cream  
Route of Administration: Topical

Date of Last Review or Revision: Today  
Person Completing Last Review or Revision: RPS

### Formula:

Ingredient	Quantity	Physical Description	Solubility	Therapeutic Activity
Ketoprofen	10% w/v	white powder	soluble in alcohol, acetone, chloroform	anti-inflammatory
Ethoxy Diglycol	20% v/v	clear, unctuous liquid	NA	solvent
Lecithin Isopropyl Palmitate Solution	22% v/v	viscous, tan solution	NA	vehicle, surfactant
Pluronic F-127 Gel 20%	qs 100%	clear solution at cold temperature; gels at room temperature	NA	vehicle, surfactant

### Additional Information:

Lecithin can be derived from eggs, but is derived mostly from soybeans. Soybean lecithin contains palmitic, stearic, palmitoleic, oleic, linoleic, linolenic, and arachidonic acids. It is used as a natural surfactant and emulsifier. **Lecithin Isopropyl Palmitate Solution** contains soybean lecithin 10 g, isopropyl palmitate 10 g, and sorbic acid 0.2 g.

Pluronic F-127 is one of a series of polymers known as Poloxamers. They are used as nonionic surfactants. Pluronic F-127 is more soluble in cold temperatures. Solutions should be refrigerated until use since it will gel at room temperature. **Pluronic F-127 Gel 20%** is Pluronic F-127 20 g, potassium sorbate 0.2 g, qs to 100 ml with Purified Water.

### Example Calculations:

### Equipment Required:

- prescription balance
- plastic 10 ml luer-lok™ syringes
- luer-to-luer syringe connector
- luer-to-oral syringe adapter

### Method of Preparation:

1. Accurately weigh the ketoprofen in a weigh boat.
2. Add the Ethoxy Diglycol to the ketoprofen in the weigh boat and dissolve the powder.
3. Transfer the mixture into a 10 ml syringe. Use lecithin isopropyl palmitate solution to rinse the weigh boat and help quantitatively transfer the ketoprofen into the syringe. Mix the solutions in the syringe.
4. **Carefully remove air from the syringe and determine the volume of Pluronic gel needed.**
5. Transfer the appropriate volume of Pluronic gel into another 10 ml syringe using the luer-to-oral adapter. **Remove all air from the syringe.**
6. Attach the luer-to-luer syringe connector to the two syringes, and transfer the emulsion back-and-forth between the syringes until well mixed.
7. Package in an appropriate container.

**Description of Finished Product:**

White to yellow-white emulsion with lotion or cream properties.

**Quality Control Procedures:**

**Packaging Container:**

Package in appropriate container.

**Storage Requirements:**

Can be stored at room temperature, avoid freezing.

**Beyond-Use Date Assignment:**

USP Guidelines:

***Aqueous solutions:***

When prepared from ingredients in solid form, the beyond-use date should be not later than 14 days when stored at cold temperature.

Formulation cannot be stored at cold temperature, because the Pluronic Gel will liquefy. Potassium sorbate and sorbic acids are mold and yeast inhibitors, so a 14 day beyond-use date can be justified.

**Label Information:**

External Use Only

**Source of Recipe:**

Professional Compounding Centers of America Training Course, 1998. Modified for PCL Labs, Spring 2002

**Literature Information:**