

Formulation Record

Name: Artificial Tears

Strength: _____

Dosage Form: Solution

Route of Administration: Ophthalmic

Date of Last Review or Revision: 10/16/02

Person Completing Last Review or Revision: RPS

Formula:

Ingredient	Quantity	Physical Description	Solubility	Therapeutic Activity
Polyvinyl alcohol	1.4%	White to cream granular powder	Soluble in water	Viscosity, lubrication
Povidone	0.6%	White to cream hygroscopic powder	Freely soluble in water	Viscosity, dispersion
Cetylpyridinium chloride	0.01%	White powder	Freely soluble in water	Preservative
Sterile Sodium Chloride for Injection	qs	Clear, non-viscous liquid	N/A	Solvent

Additional Information:

Prepare sterile stock solution of: (see Formulation Record #FR 3491)

Polyvinyl alcohol 2.8%

Povidone 1.2%

Cetylpyridinium chloride 0.02%

In Sterile Sodium Chloride for Injection

Dilute stock solution with equal volume of Sterile Sodium Chloride for Injection using **Aseptic Technique**

Example Calculations:

Equipment Required:

- Class 100 laminar flow hood
- Necessary syringes, needles, alcohol swabs, containers

Method of Preparation:

1. Use **aseptic technique** throughout the preparation.
2. Inject the sterile stock solution into the droptainer.
3. Inject an equal volume of Sterile Sodium Chloride for Injection into the droptainer.
4. Assemble the droptainer components and mix well.
5. Inspect the product for clarity, particulates, or color changes. Inspect the product container for leaks.

Description of Finished Product:

Clear, colorless, non-viscous solution

Quality Control Procedures:

Perform Valiteq™ Aseptic Technique Validation System

Packaging Container:

Package in sterile droptainer. Package droptainer in 16 dr. capsule vial.

Storage Requirements:

Can be stored at room temperature.

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.

Assign 14 days. Storage in cold temperature is not required due to presence of preservative.

Label Information:

Ophthalmic Use Only

Source of Recipe:

International Journal of Pharmaceutical Compounding 4:376, 2000

Literature Information:

pharmlabs.unc.edu

Applied Pharmaceutics in Contemporary Compounding, Chapters 15, 16, and 17