

Formulation Record

Name: Artificial Tears

Strength: _____

Dosage Form: Solution

Route of Administration: Ophthalmic

Date of Last Review or Revision: Today

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 0.9% sodium chloride solution	qs	Clear, non-viscous liquid		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 0.9% sodium chloride solution

Dilute stock solution with equal volume of Sterile 0.9% sodium chloride solution 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. Assemble the droptainer.
3. Inject the sterile stock solution into the droptainer.
4. Inject an equal volume of 0.9% sodium chloride solution into the droptainer.
5. Mix well.
6. 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 **not** in solid form, the beyond-use date is 30 days or intended duration of therapy, whichever is less.

Label Information:

Ophthalmic Use Only

Source of Recipe:

International Journal of Pharmaceutical Compounding 4:376, 2000

Literature Information: