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:

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

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:

Literature Information:
pharmlabs.unc.edu
Applied Pharmaceutics in Contemporary Compounding, Chapters 15, 16, and 17