Tonicity Agents

It was previously thought that tonicity was very important for ophthalmic preparations and that solutions should be isotonic with the body’s natural fluids. Lacrimal fluid has an isotonicity value similar to 0.9% sodium chloride solution or normal saline. However, the eye can tolerate a range from 0.6% to 1.8%. The ideal osmolality value is 300 mOsm/L. Serum osmolality is approximately 285 mOsm/L. Most patients can tolerate solutions with an osmolality range of 200 to 600 mOsm/L.

Pain and irritation can occur with hypertonic solutions. From a practical point of view, hypertonic solutions are well tolerated and cause few or no problems for the patient. Generally, problems are encountered only with hypertonic solutions that cannot be adjusted toward isotonicity because they contain active drugs that make the solutions hypertonic. Vehicles and lubricating solutions, such as artificial tear solutions, are the only solutions that need to be isotonic. Three ingredients are generally used to adjust the tonicity of these solutions: dextrose, glycerin, and sodium chloride. Table 4-4 provides information for preparing isotonic solutions using these ingredients.

If the patient is intolerant of pain and discomfort, the compounding developer can try to determine the sodium chloride equivalent of the active ingredient and then use water with one of the tonicity agents to adjust the solution closer to isotonicity or within the range mentioned previously. Appendix I contains sodium chloride equivalents for drugs commonly used in ophthalmic preparations. If it is simply not possible to prepare the ophthalmic solution within an acceptable range of tonicity, using a viscosity agent may help to reduce some of the pain and discomfort.

Clarity

All ophthalmic solutions should be clear and free from any particulate matter. Particles in an ophthalmic solution can cause damage to the eye by causing abrasions to the cornea or the membranes of the eyelids. Filtering the solutions with a 0.4-micron filter should remove all harmful particulate matter. The use of HPMC over other viscosity agents can improve the clarity of ophthalmic solutions.

Adding Polysorbate 20 and Polysorbate 80, in a maximum concentration of 1%, can also improve the clarity of ophthalmic solutions. Polysorbates, also known as polyoxyethylene sorbitan fatty acid esters, are solubilizing agents that help dissolve poorly soluble ingredients.
**Interferon Alfa-2b Ophthalmic Solution**

**Ophthalmic Vehicle, Sterile, Preserved**

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzalkonium chloride 0.5% solution*</td>
<td>2 mL</td>
</tr>
<tr>
<td>EDTA disodium</td>
<td>0.1 gm</td>
</tr>
<tr>
<td>0.9% Sodium chloride for Injection</td>
<td>99 mL</td>
</tr>
</tbody>
</table>

*See formula for Benzalkonium chloride 0.5% solution on p. 253*

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interferon alfa-2b 10 × 10⁶ IU/mL injectable, albumin free</td>
<td>0.6 mL</td>
</tr>
<tr>
<td>Ophthalmic Vehicle, Sterile, Preserved</td>
<td>9.4 mL</td>
</tr>
</tbody>
</table>

**Method of Preparation**

1. Prepare the *Ophthalmic Vehicle* by measuring or weighing each ingredient and mixing together in a beaker until dissolved.
2. Under a laminar airflow hood, using aseptic technique, filter the vehicle solution through a 0.22 micron filter into sterile vial(s), seal, and label. Discard unused remaining solution.
3. Under a vertical flow hood, using antineoplastic precautions and aseptic technique, withdraw interferon injectable with a sterile syringe and add to a sterile ophthalmic dropper bottle.
4. Withdraw *Ophthalmic Vehicle* with a sterile syringe and add to the same dropper bottle.
5. Replace the tip and cap on the ophthalmic dropper bottle and shake gently to mix.
6. Seal and label bottle.

**Packaging**

- Sterile ophthalmic dropper bottle

**Labeling**

- Store in Refrigerator
- For the Eye
- Cytotoxic

**Beyond-Use Date**

- 15 days Refrigerated
- 7 days Room Temperature

**Use**

FDA-indicated to treat chronic hepatitis B and C, condyloma acuminate, hairy cell leukemia, malignant melanoma, AIDS-related Kaposi’s sarcoma, and follicular non-Hodgkin’s lymphoma. It is used off-label to treat acute hemorrhagic conjunctivitis (AHC), which is a rapidly progressive and contagious viral infection.

**Quality Control**

- Volume, physical observation, pH, osmolality, assay, color, clarity, particulate matter, sterility

**Special Note**

- Discard solution if there are any particulates or precipitants in the solution.
Discussion
Interferon alfa-2b (in ter FEER on Al fa too bee) is genetically engineered recombinant human interferon with antiviral properties. This compounded formulation is colorless and has a pH range of 6.7-7.3. It is nearly isotonic (315 mOsmol/kg).

Information Source
Acetylcysteine 100 mg/mL Ophthalmic Solution

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetylcysteine 20% oral inhalation solution</td>
<td>5 mL</td>
</tr>
<tr>
<td>Chlorobutanol</td>
<td>50 mg</td>
</tr>
<tr>
<td>Edetate disodium</td>
<td>2.5 mg</td>
</tr>
<tr>
<td>Artificial tear solution (LiquiFilm® brand or equivalent preservative-free product)</td>
<td>5 mL</td>
</tr>
</tbody>
</table>

Method of Preparation
1. Accurately weigh or measure each ingredient.
2. Place chlorobutanol in a clean beaker, add artificial tear solution, and mix well on a magnetic stirrer until dissolved.
3. Add edetate disodium and mix well to dissolve.
4. Add acetylcysteine solution and mix well.
5. Under a laminar flow hood, aseptically filter solution through a 0.22-micron filter needle into a sterile ophthalmic dropper bottle.
6. Replace the tip and cap on the ophthalmic dropper bottle, and seal, and label bottle.

Packaging
- Sterile dropper bottle (plastic or glass)

Labeling
- Store in Refrigerator
- For Eye
- Protect from Light

Beyond-Use Date
- 60 days refrigerated

Use
This drug is FDA approved as an antidote to acetaminophen poisoning and as an adjunctive mucolytic therapy in patients with abnormal or viscid mucus secretions in bronchopulmonary diseases. It is not FDA approved for ophthalmic use, although such use is well documented in the medical literature. Common off-label uses include treatment of alkali burns and corneal melting, and decreasing the viscosity and quantity of mucus in the precorneal film in patients with keratoconjunctivitis sicca (dry eye syndrome). It can be applied hourly for acute conditions and four times daily for maintenance therapy.

Quality Control
- Volume, physical observation, pH, osmolality, assay, color, clarity, particulate matter, sterility

Special Notes
- Discard solution if it contains any particulates or precipitants.
- Acetylcysteine is physically incompatible with oxidizing agents, amphotericin B, tetracycline, erythromycin lactobionate, and ampicillin.
- Do not shake solution in bottle.
- Other brands of artificial tear solutions cannot be substituted because of incompatibilities with other preservatives (benzalkonium chloride) and excipients.
Acetylcysteine 200 mg/mL Ophthalmic Solution

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetylcysteine 20% oral inhalation solution</td>
<td>10 mL</td>
</tr>
</tbody>
</table>

**Method of Preparation**
1. Under a laminar flow hood, aseptically withdraw solution from the vial using a sterile 5-micron filter needle affixed to a sterile syringe.
2. Remove filter needle and add solution to a sterile ophthalmic dropper bottle.
3. Replace the tip and cap on the ophthalmic dropper bottle, and seal, and label bottle.

**Packaging**
- Sterile dropper bottle (plastic or glass)

**Labeling**
- Store in Refrigerator
- For Eye
- Protect from Light

**Beyond-Use Date**
- 96 hours refrigerated

**Use**
This drug is FDA approved as an antidote to treat acetaminophen poisoning and as an adjunctive mucolytic therapy in patients with abnormal or viscid mucus secretions in bronchopulmonary diseases. It is not FDA approved for ophthalmic use, although such use is well documented in the medical literature. Common off-label uses include treatment of alkali burns and corneal melting, and decreasing the viscosity and quantity of mucus in the precorneal film in patients with keratoconjunctivitis sicca (dry eye syndrome). It can be applied hourly for acute conditions and four times daily for maintenance therapy.

**Quality Control**
- Volume, physical observation, pH, osmolality, assay, color, clarity, particulate matter, sterility

**Special Notes**
- Discard solution if it contains any particulates or precipitants, or it has congealed.
- Acetylcysteine is physically incompatible with oxidizing agents, amphotericin B, tetracycline, erythromycin lactobionate, and ampicillin.

**Discussion**
Acetylcysteine (a se teel SIS teen) is a mucolytic and collagenase inhibitor. The commercial acetylcysteine solution has a pH range of 6 to 7.5, with peak activity occurring at pH 7 to 9. It has an aqueous solubility of 200 mg/mL. The commercial inhalation solution is extremely hypertonic and has an osmolality of 2259 mOsm/kg.

**Information Source**
Alcohol 20% Ophthalmic Solution

**Ingredients**

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alcohol 100%, dehydrated, sterile, injection</td>
<td>2 mL</td>
</tr>
<tr>
<td>Sterile water for injection</td>
<td>qs 10 mL</td>
</tr>
</tbody>
</table>

**Method of Preparation**

1. Using aseptic technique, withdraw alcohol injection into a sterile syringe, and add to a sterile, ophthalmic dropper bottle.
2. Using a sterile syringe, withdraw a sufficient amount of sterile water for injection to final volume, allowing for the contraction that occurs when alcohol and water are mixed. Add to the same dropper bottle.
3. Replace the tip and cap on the ophthalmic dropper bottle, and shake gently to mix.
4. Seal and label bottle.

**Packaging**

- Sterile dropper bottle (plastic or glass)

**Labeling**

- Store at Room Temperature
- Office Use Only
- For the Eye

**Beyond-Use Date**

- 30 days room temperature

**Use**

Dehydrated alcohol is FDA approved for nerve blocks. Off-label uses of sterile alcohol 20% ophthalmic solution include alcohol delamination of the corneal epithelium (ADCE) to treat corneal erosions.

**Quality Control**

- Volume, physical observation, pH, osmolality, assay, color, clarity, particulate matter, sterility

**Special Notes**

- Discard solution if it contains any particulates or precipitants.
- ADCE is done in a clean procedure room by an ophthalmologist, with the patient under topical anesthesia.

**Discussion**

Alcohol (AL koe hol) is an antidote, anti-infective, and pharmaceutical aid. It is freely soluble in water.

**Information Source**

**Amphotericin B 5 mg/mL Ophthalmic Solution**

### Ingredients

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>Quantities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amphotericin B 50 mg vial for injection</td>
<td>1 vial</td>
</tr>
<tr>
<td>Dextrose 5% in water injection</td>
<td>10 mL</td>
</tr>
</tbody>
</table>

### Method of Preparation

1. Aseptically reconstitute amphotericin B vial with dextrose 5% in water injection to prepare a 5 mg/mL concentration.
2. Withdraw the desired quantity of amphotericin B into a sterile syringe, and add to a sterile, plastic, ophthalmic dropper bottle.
3. Replace the tip and cap on the ophthalmic dropper bottle, and shake gently to mix.
4. Seal and label bottle.

### Packaging

- Sterile dropper bottle (low-density polyethylene plastic or amber glass)

### Labeling

- Store in Refrigerator
- Protect from Light
- For the Eye

### Beyond-Use Date

- 12 days refrigerated

### Use

This drug is FDA approved for parenteral treatment of patients with susceptible fungal infections. It is not FDA approved for ophthalmic use, although such use is well documented in the medical literature. Common off-label uses include treatment of ocular fungal infections caused by *Candida albicans*.

### Quality Control

- Volume, physical observation, pH, osmolality, assay, color, clarity, particulate matter, sterility

### Special Notes

- Do not substitute sodium chloride solutions for 5% dextrose injection because amphotericin B is incompatible with sodium chloride-containing solutions.
- Amphotericin is a colloidal dispersion and should not be filtered.

### Discussion

Amphotericin B (am foe TER i sin bee) is a parenteral antifungal agent that is most stable and soluble in a pH range of at least 4.2% in a 5% dextrose injection. It is insoluble in water but is dispersed by micelle formation in the conventional injection dosage form. Solutions may be yellow to orange in color.

### Information Source

Amphotericin B Liposomal 5 mg/mL Ophthalmic Solution

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>Quantities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amphotericin B liposomal 50 mg vial for injection</td>
<td>1 vial</td>
</tr>
<tr>
<td>Sterile water for injection, preservative free</td>
<td>10 mL</td>
</tr>
</tbody>
</table>

**Method of Preparation**
1. Aseptically reconstitute amphotericin B vial with sufficient sterile water for injection to prepare a 5 mg/mL concentration.
2. Withdraw the desired quantity of amphotericin B with a sterile syringe, and add to a sterile, plastic, ophthalmic dropper bottle.
3. Replace the tip and cap on the ophthalmic dropper bottle.
4. Seal and label bottle.

**Packaging**
- Sterile dropper bottle (amber glass)

**Labeling**
- Store in Refrigerator (preferred) or Room Temperature
- Protect from Light
- For the Eye

**Beyond-Use Date**
- 180 days refrigerated or room temperature

**Use**
This drug is FDA approved for parenteral treatment of patients with susceptible fungal infections that are resistant to conventional amphotericin B. It is not FDA approved for ophthalmic use, although such use is well documented in the medical literature. Common off-label uses include treatment of ocular fungal infections caused by *Candida albicans*.

**Quality Control**
- Volume, physical observation, pH, osmolality, assay, color, clarity, particulate matter, sterility

**Special Notes**
- Do not substitute sodium chloride solutions for sterile water for injection because amphotericin B is incompatible with sodium chloride-containing solutions.
- Amphotericin B liposomal should not be filtered through a filter with a porosity of less than 1 µm.

**Discussion**
Amphotericin B liposomal (am foe TER i sin bee lye po SO mal) is a parenteral antifungal agent that is most stable and soluble at a pH of 5.6. It has an osmolality of 350 mOsm/kg. Solutions may be yellow to orange in color.

**Information Source**
# Amphotericin B Ophthalmic Solutions

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>Quantities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amphotericin B 5 mg/mL (reconstituted)</td>
<td>0.5 mg/mL</td>
</tr>
<tr>
<td></td>
<td>1 mL</td>
</tr>
<tr>
<td></td>
<td>1.5 mg/mL</td>
</tr>
<tr>
<td></td>
<td>3 mL</td>
</tr>
<tr>
<td></td>
<td>2 mg/mL</td>
</tr>
<tr>
<td></td>
<td>4 mL</td>
</tr>
<tr>
<td>Sterile water for injection, preservative free</td>
<td>9 mL</td>
</tr>
<tr>
<td></td>
<td>7 mL</td>
</tr>
<tr>
<td></td>
<td>6 mL</td>
</tr>
</tbody>
</table>

## Method of Preparation
1. Aseptically reconstitute amphotericin B vial with 10 mL of sterile water for injection to prepare a 5 mg/mL concentration.
2. Withdraw the desired quantity of amphotericin B into a sterile syringe, and add to a sterile, plastic, ophthalmic dropper bottle.
3. Withdraw the desired quantity of sterile water for injection, and add to the same ophthalmic dropper bottle.
4. Replace the tip and cap on the ophthalmic dropper bottle, and shake gently to mix.
5. Seal and label bottle.

## Packaging
- Sterile dropper bottle (low-density polyethylene plastic or amber glass)

## Labeling
- Store in Refrigerator
- Protect from Light
- For the Eye

## Beyond-Use Date
- 7 days refrigerated

## Use
This drug is FDA approved for parenteral treatment of patients with susceptible fungal infections. It is not FDA approved for ophthalmic use, although such use is well documented in the medical literature. Common off-label uses include treatment of ocular fungal infections caused by *Candida albicans*.

## Quality Control
- Volume, physical observation, pH, osmolality, assay, color, clarity, particulate matter, sterility

## Special Notes
- Do not substitute sodium chloride solutions for sterile water for injection because amphotericin B is incompatible with sodium chloride-containing solutions.
- Amphotericin is a colloidal dispersion and should not be filtered.

## Discussion
Amphotericin B (am forte TER i sin bee) is a parenteral antifungal agent that is most stable and soluble at a pH range of 6 to 8 in an aqueous solution. Solutions may be yellow to orange in color. Although insoluble in water, amphotericin B is dispersed by micelle formation in the conventional injection dosage form. Less concentrated solutions (below 1.5 mg/mL) are more comfortable and less toxic to the cornea.

## Information Sources
Ceftriaxone Ophthalmic Solutions

**Ingredients**

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>50 mg/mL</th>
<th>100 mg/mL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ceftriaxone 1 g vial for injection</td>
<td>—</td>
<td>1 vial</td>
</tr>
<tr>
<td>Ceftriaxone 500 mg vial for injection</td>
<td>1 vial</td>
<td>—</td>
</tr>
<tr>
<td>0.9% Sodium chloride injection</td>
<td>9.8 mL</td>
<td>9.6 mL</td>
</tr>
</tbody>
</table>

**Method of Preparation**

1. Aseptically reconstitute ceftriaxone vial with 0.9% sodium chloride injection to prepare the desired ceftriaxone concentration.
2. Withdraw the desired quantity of ceftriaxone solution into a sterile syringe, and add to a sterile, plastic, ophthalmic dropper bottle.
3. Replace the tip and cap on the ophthalmic dropper bottle.
4. Seal and label bottle.

**Packaging**

- Sterile dropper bottle

**Labeling**

- Store in Freezer (long-term storage)
- Store in Refrigerator (immediate use)
- For the Eye

**Beyond-Use Date**

- 180 days frozen
- 10 days refrigerated
- 2 days room temperature

**Use**

This drug is FDA approved to treat infections due to susceptible organisms. It is used in the treatment of eye infections and corneal ulcerations with activity against most gram-positive aerobic cocci and gram-negative aerobes.

**Quality Control**

- Volume, physical observation, pH, osmolality, assay, color, clarity, particulate matter, sterility

**Special Notes**

- Discard solution if it contains any particulates or precipitants.
- Ceftriaxone powder displacement is 0.4 mL/g.

**Discussion**

Ceftriaxone (sef trye AKS one) is a third-generation cephalosporin antibiotic that has a pH of approximately 6.7 and an osmolality value of 364 mOsm/kg.

**Information Source**

Chloramphenicol Ophthalmic Solutions, Preservative Free

Ingredients

<table>
<thead>
<tr>
<th></th>
<th>Quantity (to make 10 mL)</th>
<th>5 mg/mL</th>
<th>20 mg/mL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chloramphenicol sodium succinate 100 mg/ml injection</td>
<td>0.5 mL</td>
<td>2 mL</td>
<td></td>
</tr>
<tr>
<td>Sterile water for injection, preservative free</td>
<td>10 mL</td>
<td>10 mL</td>
<td></td>
</tr>
<tr>
<td>0.9% Sodium chloride injection</td>
<td>9.5 mL</td>
<td>8 mL</td>
<td></td>
</tr>
</tbody>
</table>

Method of Preparation
1. Aseptically reconstitute chloramphenicol injection with sterile water for injection to prepare a 100 mg/mL concentration.
2. Withdraw the desired quantity of chloramphenicol into a sterile syringe, and add to a sterile, plastic, ophthalmic dropper bottle.
3. Withdraw the desired quantity of 0.9% sodium chloride injection, and add to the same sterile, plastic, ophthalmic dropper bottle.
4. Replace the tip and cap on the ophthalmic dropper bottle, and shake gently to mix.
5. Seal and label bottle.

Packaging
- Sterile dropper bottle (low-density polyethylene plastic or amber glass)

Labeling
- Store in Freezer (if storing for future use)
- Store at Room Temperature (for immediate use)
- Protect from Light
- For the Eye

Beyond-Use Date
- 180 days frozen
- 30 days room temperature

Use
This drug is a broad-spectrum antibiotic used to treat ophthalmic infections and ulcerations caused by susceptible gram-positive and gram-negative aerobic bacteria (Streptococcus pneumoniae, Haemophilus influenza, Neisseria sp.), some anaerobic bacteria (Bacteroides fragilis), Chlamydia sp., and Mycoplasma sp.

Quality Control
- Volume, physical observation, pH, osmolality, assay, color, clarity, particulate matter, sterility

Special Notes
- Discard solution if it is cloudy or contains any particulates or precipitants.
- Blood dyscrasias have been reported with use of topical chloramphenicol. Use only for resistant cases.

Discussion
Chloramphenicol (klor am FEN i kole) is an antibiotic that is most stable in a pH range of 6 to 7 as a reconstituted solution. A 20 mg/mL solution has an osmolality range of 344 to 368 mOs/kg. The sodium succinate salt is freely soluble in water.

(continued on next page)
Colistimethate 10 mg/mL Ophthalmic Solution

**Ingredients**

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colistimethate sodium 150 mg for injection</td>
<td>1 vial</td>
</tr>
<tr>
<td>Sterile water for injection, preservative free</td>
<td>15 mL</td>
</tr>
</tbody>
</table>

**Method of Preparation**

1. Aseptically reconstitute 150 mg vial of colistimethate with 15 mL sterile water for injection to prepare a 10 mg/mL concentration. Shake well to dissolve powder.
2. Withdraw colistimethate solution into a sterile syringe, and add to a sterile, plastic, ophthalmic dropper bottle.
3. Replace the tip and cap on the ophthalmic dropper bottle, and gently shake to mix.
4. Seal and label bottle.

**Packaging**

- Sterile dropper bottle

**Labeling**

- Store in Refrigerator
- Protect from Light
- For the Eye

**Beyond-Use Date**

- 7 days refrigerated

**Use**

This drug is FDA approved to treat susceptible infections caused by gram-negative bacilli (especially *Pseudomonas aeruginosa*). It is typically reserved for resistant cases when less toxic agents have failed.

**Quality Control**

- Volume, physical observation, pH, osmolality, assay, color, clarity, particulate matter, sterility

**Special Note**

- Discard solution if it contains any particulates or precipitants.

**Discussion**

Colistimethate (koe lis ti METH ate) is an antibiotic related to polymyxin B and a sulfamethyl derivative of colistin. It has a pH range of 7 to 8. Colistimethate is measured in milligrams of colistin (colistimethate 1 mg = colistin 390 mg = 12,700 units). Lower concentrations of colistimethate (<75 mg/mL) can break down to colistin, which is more toxic.

**Information Source**

Cysteamine 0.5% Ophthalmic Solution

Ingredients | Quantity
--- | ---
Cysteamine hydrochloride | 0.1 g
0.9% Sodium chloride injection, preservative free | qsad 20 mL

Method of Preparation
1. Weigh cysteamine granules and place in a beaker.
2. Add a portion of the 0.9% sodium chloride injection, and mix until cysteamine is dissolved.
3. Pour solution into a graduated cylinder, and add sufficient 0.9% sodium chloride injection to the desired volume.
4. Under a laminar/vertical flow hood, aseptically filter solution through a 0.22-micron filter into a sterile, ophthalmic dropper bottle.
5. Cap, seal, and label bottle.

Packaging
- Sterile dropper bottle (plastic or glass)

Labeling
- Store in Freezer (if storing for future use)
- Store in Refrigerator (for immediate use)
- For the Eye

Beyond-Use Date
- 180 days frozen
- 14 days refrigerated
- 7 days room temperature

Use
This drug is FDA approved for the treatment of nephropathic cystinosis. It is not FDA approved for ophthalmic use, although such use is well documented in the medical literature for the treatment of crystal formation in the cornea of patients with nephropathic cystinosis.

Quality Control
- Volume, physical observation, pH, osmolality, assay, color, clarity, particulate matter, sterility

Special Note
- Discard solution if it contains any particulates or precipitants, or its color darkens.

Discussion
Cysteamine (sis TEE a meen) is an anticystine agent that is soluble in water and ethanol. It has a pH range of 3.5 to 5. The crystals are hygroscopic and subject to oxidation upon standing. The crystals must be refrigerated.

Information Sources
Edetate Disodium Ophthalmic Solutions, Made from Active Pharmaceutical Ingredient

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>Quantity (to make 100 mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0.37% (0.01 M)</td>
</tr>
<tr>
<td>Edetate disodium dihydrate</td>
<td>0.41 g</td>
</tr>
<tr>
<td>Sodium hydroxide 1 N solution</td>
<td>qs to pH 7</td>
</tr>
<tr>
<td>Sterile water for injection, preservative free</td>
<td>qsad 100 mL</td>
</tr>
<tr>
<td></td>
<td>1.7% (0.05 M)</td>
</tr>
<tr>
<td>Edetate disodium dihydrate</td>
<td>1.887 g</td>
</tr>
<tr>
<td>Sodium hydroxide 1 N solution</td>
<td>qs to pH 7</td>
</tr>
<tr>
<td>Sterile water for injection, preservative free</td>
<td>qsad 100 mL</td>
</tr>
</tbody>
</table>

**Method of Preparation**
1. Weigh edetate disodium dihydrate and place in a beaker.
2. Add approximately 60% of the total volume sterile water for injection, and mix until powder is dissolved.
3. Adjust to pH 7 using the sodium hydroxide 1 N solution.
4. Pour solution into a graduated cylinder, and add sterile water for injection to desired volume.
5. Under a laminar/vertical flow hood, aseptically filter solution through a 0.22-micron filter into a sterile container.
6. Cap, seal, and label container.

**Packaging**
- Sterile plastic or glass container (irrigation bottle or evacuated container)

**Labeling**
- Store in Refrigerator
- For the Eye
- Topical or Irrigation Use Only

**Beyond-Use Date**
- 14 days refrigerated

**Use**
This drug is FDA approved for emergency lowering of serum calcium in hypercalcemia. Injectable edetate sodium products were voluntarily removed from the market because of concerns that they might be interchanged with edetate calcium injectables, causing serious injury or death. Off-label uses include treatment of corneal calcific band keratopathy and calcium deposits in the cornea.

**Quality Control**
- Volume, physical observation, pH, osmolality, assay, color, clarity, particulate matter, sterility

**Special Notes**
- Edetate disodium 1 mg is equivalent to edetate disodium dihydrate 1.11 mg.
- Discard solution if it contains any particulates or precipitants, or it darkens.
- These preparations are NOT edetate calcium.
- These preparations are administered or applied under anesthesia.
**Tobramycin 13.5 mg/mL Ophthalmic Solution, Fortified**

**Ingredients**

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tobramycin ophthalmic solution 3 mg/mL</td>
<td>5 mL</td>
</tr>
<tr>
<td>Tobramycin sulfate for injection 40 mg/mL, lyophilized, preservative free</td>
<td>2 mL</td>
</tr>
<tr>
<td>Sterile water for injection, preservative free</td>
<td>qs</td>
</tr>
</tbody>
</table>

**Method of Preparation**

1. Under a laminar flow hood, aseptically reconstitute tobramycin for injection with sterile water for injection according to manufacturer’s instructions to prepare a 40 mg/mL concentration.
2. Withdraw tobramycin injection into a sterile syringe, and add to a sterile, plastic, ophthalmic dropper bottle.
3. Uncap and remove the tip of the tobramycin ophthalmic solution bottle, withdraw the solution into a sterile syringe and needle, and add to the sterile plastic ophthalmic dropper bottle containing the injection.
4. Replace the tip and cap on the ophthalmic dropper bottle, and gently shake to mix.
5. Seal and label bottle.

**Packaging**

- Sterile dropper bottle (plastic or glass)

**Labeling**

- Store in Refrigerator
- For the Eye

**Beyond-Use Date**

- 90 days refrigerated

**Use**

This drug is FDA approved to treat superficial ophthalmic infections caused by *Staphylococcus aureus* and *Pseudomonas aeruginosa*. It is the drug of choice to treat conjunctivitis, endophthalmitis (bacterial and fungal), and infectious keratitis.

**Quality Control**

- Volume, physical observation, pH, osmolality, assay, color, clarity, particulate matter, sterility

**Special Note**

- Discard solution if it contains any particulates or precipitants.

**Discussion**

Tobramycin (toe bra MYE sin) is an aminoglycoside antibiotic that has a pH range of 6 to 8 as a 4% aqueous solution. The injection has a pH range of 3 to 6.5. The aqueous solubility is about 667 mg/mL. The powder volume displacement is specific to each manufacturer’s product; check the directions for reconstitution to prepare the desired concentration.

**Information Source**

Tobramycin 15 mg/mL Ophthalmic Solution

Ingredients

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tobramycin sulfate injection 40 mg/mL</td>
<td>3.75 mL</td>
</tr>
<tr>
<td>Sterile water for injection, USP</td>
<td>qs</td>
</tr>
<tr>
<td>Artificial tear solution</td>
<td>6.25 mL</td>
</tr>
</tbody>
</table>

Method of Preparation

1. Under a laminar flow hood, aseptically reconstitute tobramycin injection with sterile water according to manufacturer’s instructions to prepare a 40 mg/mL concentration.
2. Withdraw tobramycin injection into a sterile syringe, and add to a sterile, plastic, ophthalmic dropper bottle.
3. Uncap and remove the tip of the artificial tear solution bottle, withdraw the solution into a sterile syringe and needle, and add to the sterile plastic ophthalmic dropper bottle containing the injection.
4. Replace the tip and cap on the ophthalmic dropper bottle, and gently shake to mix.
5. Seal and label bottle.

Packaging

- Sterile dropper bottle (plastic or glass)

Labeling

- Store in Refrigerator
- For the Eye

Beyond-Use Date

- 28 days refrigerated or room temperature

Use

This drug is FDA approved to treat superficial ophthalmic infections caused by *Staphylococcus aureus* and *Pseudomonas aeruginosa*. It is also the drug of choice to treat conjunctivitis, endophthalmitis (bacterial and fungal), and infectious keratitis.

Quality Control

- Volume, physical observation, pH, osmolality, assay, color, clarity, particulate matter, sterility

Special Note

- Discard solution if it contains any particulates or precipitants.

Discussion

Tobramycin (toe bra MYE sin) is an aminoglycoside antibiotic that has a pH range of 6 to 8 as a 4% aqueous solution. The injection has a pH range of 3 to 6.5. The aqueous solubility is about 667 mg/mL. The powder volume displacement is specific to each manufacturer’s product; check the directions for reconstitution to prepare the desired concentration.

Information Source

Vancomycin 14mg/mL with BAK Ophthalmic Solution

**Ingredients**

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vancomycin 500 mg for injection</td>
<td>1 vial</td>
</tr>
<tr>
<td>Benzalkonium chloride 0.5% solution*</td>
<td>0.27 mL</td>
</tr>
<tr>
<td>0.9% Sodium chloride injection</td>
<td>qs ad 35.5 mL</td>
</tr>
</tbody>
</table>

*See Benzalkonium chloride 0.5% solution formulation on p. 253

**Method of Preparation**

1. Under a laminar flow hood, using aseptic technique, reconstitute vancomycin for injection with 0.9% sodium chloride injection to prepare a 50 mg/ml concentration.
2. Withdraw 10ml of vancomycin with a sterile syringe and add to a container.
3. Measure BAK and remaining 0.9% sodium chloride injection, add to same container, and mix well.
4. Withdraw solution with a sterile syringe, attach a 0.22 micron filter, and add solution to sterile, ophthalmic dropper bottle(s).
5. Cap, seal and label bottle(s).

**Packaging**

- Sterile dropper bottle (plastic or glass)

**Labeling**

- Store at Room Temperature
- For the Eye

**Beyond-Use Date**

- 180 days Frozen
- 60 days Room Temperature

**Use**

FDA-approved to treat patients with infections caused by *staphylococcal* and *streptococcal* species. It is not FDA-approved for ophthalmic use, although such use is well documented in the medical literature. Common unlabeled use for prophylactic use to prevent bacterial endophthalmitis for patients with a keratoprosthesis.

**Quality Control**

- Volume, physical observation, pH, osmolality, assay, color, clarity, particulate matter, sterility

**Special Notes**

- Discard solution if there are any particulates or precipitants in the solution.
- Longer beyond-use date is used to improve patient compliance since use will be daily for life.
Discussion
Vancomycin (van koe MYE sin) is a broad-spectrum glycopeptide antibiotic that is most stable in a pH range of 3 to 5 as a reconstituted solution. The powder volume displacement is specific to each manufacturer’s product; check the directions for reconstitution to prepare the desired concentration. It has an aqueous solubility of greater than 100 mg/mL.

Information Sources

Amikacin Intravitreal Injections

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>Quantity</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Amikacin 250 mg/mL injection</td>
<td>0.04 mL</td>
<td>0.16 mL</td>
</tr>
<tr>
<td>0.9% Sodium chloride for injection</td>
<td>9.96 mL</td>
<td>9.84 mL</td>
</tr>
</tbody>
</table>

**Method of Preparation**

1. Under a laminar airflow workbench, aseptically withdraw each ingredient into a separate sterile syringe.
2. Add contents of each syringe to a sterile empty vial, and shake gently to mix.
3. Add a dispensing pin to the vial.
4. Withdraw 0.5 mL into a sterile Luer-Lock® tuberculin syringe, and cap with a tamper-resistant sterile cap.
5. Label each syringe.
6. Using some of the remaining solution, check pH and send a sample for sterility testing.

**Packaging**
- Sterile syringe with a sterile tamper-resistant cap

**Labeling**
- Store in Refrigerator
- For Eye

**Beyond-Use Date**
- 60 days refrigerated

**Use**
This drug is FDA approved to treat documented infection with mycobacterial organisms susceptible to amikacin, as well as serious infections (bone infections, respiratory tract infections, endocarditis, and septicemia) due to organisms resistant to gentamicin and tobramycin, including *Pseudomonas, Proteus, Serratia*, and other gram-negative bacilli. Off-label uses include intravitreal amikacin as the drug of choice to treat bacterial endophthalmitis. Endophthalmitis is a medical emergency and can lead to severe visual impairment, blindness, or loss of eye if left untreated.

**Quality Control**
- Volume, physical observation, pH, osmolality, assay, color, clarity, particulate matter, sterility

**Special Notes**
- Discard solution if it contains any particulates or precipitants.
- Intravitreal doses are usually 0.1 mL; however, the syringes should be overfilled to account for the dead space in the syringe and needle.

**Discussion**
Amikacin [am i KAY sin] is an aminoglycoside antibiotic that has a pH range of 3.5 to 5.5. It is freely soluble in water and has an osmolality of 349 mOsm/kg in 0.9% sodium chloride at a concentration of 5 mg/mL. Amikacin has a vitreous half-life of 24 hours.
### Amikacin Subconjunctival Injections

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>Quantity</th>
<th>25 mg/0.5 mL</th>
<th>125 mg/0.5 mL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amikacin 50mg/mL Injection</td>
<td>1 mL</td>
<td>—</td>
<td></td>
</tr>
<tr>
<td>Amikacin 250mg/mL Injection</td>
<td>—</td>
<td>1 mL</td>
<td></td>
</tr>
</tbody>
</table>

**Method of Preparation**

1. Under a laminar airflow workbench, using aseptic technique, withdraw 1 mL of the appropriate strength of amikacin injection into a sterile Luer-Lock® syringe and cap with a tamper-resistant sterile cap.
2. Label each syringe.
3. Use some of the remaining solution check pH and send a sample for sterility testing.

**Packaging**

- Sterile syringe with a sterile tamper-resistant cap

**Labeling**

- Store in Refrigerator
- For the Eye

**Beyond-Use Date**

- 48 hours

**Use**

FDA-approved to treat serious infections (bone infections, respiratory tract infections, endocarditis, and septicemia) due to organisms resistant to gentamicin and tobramycin, including *Pseudomonas*, *Proteus*, *Serratia*, and other gram-negative bacilli; documented infection of mycobacterial organisms susceptible to amikacin.

**Quality Control**

- Volume, physical observation, pH, osmolality, assay, color, clarity, particulate matter, sterility

**Special Notes**

- Discard solution if there are any particulates or precipitants in the solution.
- Subconjunctival doses are usually 0.5 mL; however, the syringes should be overfilled to account for the dead space in the syringe and needle.

**Discussion**

Amikacin (am i KAY sin) is an aminoglycoside antibiotic that has a pH range of 3.5-5.5. It is freely soluble in water. The 50 mg/mL has an osmolality of 186 mOsm/kg and the 250 mg/mL has an osmolality of 913 mOsm/kg. It has a vitreous half-life of 24 hours.

**Information Sources**


Amphotericin B Intravitreal Injection 5µg/0.1 mL

**Ingredients**

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amphotericin B (colloidal)</td>
<td>50 mg for injection</td>
</tr>
<tr>
<td>Dextrose 5% in water for injection</td>
<td>19.9 mL</td>
</tr>
</tbody>
</table>

**Method of Preparation**

1. Under a laminar airflow workbench, aseptically withdraw 10 mL of dextrose 5% in water for injection into a sterile syringe.
2. Add contents of syringe to amphotericin B vial, and shake gently to mix. Vial may need to sit for a few minutes to allow dissolution of lyophilized amphotericin B. This is vial #1 and contains amphotericin B 5 mg/mL.
3. From vial #1, withdraw 0.1 mL (500µg) and transfer to another empty sterile vial labeled vial #2.
4. Add 9.9 mL of dextrose 5% in water for injection and shake gently to mix. This contains amphotericin B 50 µg/mL.
5. Add a dispensing pin to vial #2.
6. Withdraw 0.5 mL into a sterile Luer-Lock® tuberculin syringe, and cap with a tamper-resistant sterile cap. Label each syringe and place in an amber bag.
7. Using some of the remaining solution, check pH and send a sample for sterility testing.

**Packaging**

- Sterile syringe with sterile tamper-evident cap, placed in an amber bag

**Labeling**

- Store in Refrigerator
- Protect from Light
- For Eye

**Beyond-Use Date**

- 7 days refrigerated

**Use**

This preparation is FDA approved to treat severe systemic and central nervous system infections caused by susceptible fungi such as *Candida* species, *Histoplasma capsulatum*, *Cryptococcus neoformans*, *Aspergillus* species, *Blastomyces dermatitidis*, *Torulopsis glabrata*, and *Coccidioides immitis*; fungal peritonitis; bladder fungal infections (irrigant); and fungal infection in patients with bone marrow transplantation, amebic meningoencephalitis, ocular aspergillosis (intraocular injection), candidal cystitis (bladder irrigation), chem prophylaxis (low-dose IV), immunocompromised patients at risk of aspergillosis (intranasal/nebulized), refractory meningitis (intrathecal), coccidioidal arthritis (intra-articular/IM). Off-label uses include intravitreal amphotericin B as the drug of choice to treat fungal endophthalmitis. Endophthalmitis is a medical emergency and can lead to severe visual impairment, blindness, or loss of eye if left untreated.

**Quality Control**

- Volume, physical observation, pH, osmolality, assay, color, clarity, particulate matter, sterility

*(continued on next page)*
Amphotericin B Intravitreal Injection 5µg/0.1 mL (Continued)

Special Notes
- Discard solution if it contains any particulates or precipitants.
- Intravitreal doses are usually 0.1 mL; however, the syringes should be overfilled to account for the dead space in the syringe and needle.
- Amphotericin B is incompatible with sodium chloride solutions.

Discussion
Amphotericin B (am foe TER i sin bee) is an antifungal agent that is insoluble in water. Sodium desoxycholate is added to the parenteral form of amphotericin B as a solubilizing agent to create colloidal dispersion of the drug. The pH of the admixture must be at least 4.2.

Information Sources
Amphotericin B Subconjunctival Injection 1 mg/0.5 mL

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amphotericin B (colloidal) 50 mg for injection</td>
<td>1 vial</td>
</tr>
<tr>
<td>Sterile water for injection</td>
<td>11.2 mL</td>
</tr>
</tbody>
</table>

**Method of Preparation**
1. Under a laminar airflow workbench, aseptically withdraw 10 mL of sterile water for injection into a sterile syringe.
2. Add contents of syringe to amphotericin B vial, and shake gently to mix. Vial may need to sit for a few minutes to allow dissolution of lyophilized amphotericin B. This makes a 5 mg/mL solution.
3. Withdraw 0.8 mL (4 mg) from amphotericin B vial and transfer to the empty sterile vial.
4. Withdraw 1.2 mL of sterile water for injection and add to vial with the 0.8 mL amphotericin B solution. Shake to mix. This is a 2 mg/mL solution.
5. Add a dispensing pin to another empty sterile vial.
6. Withdraw 1 mL into a sterile Luer-Lock® syringe, and cap with a tamper-resistant sterile cap.
7. Label each syringe and place in an amber bag.
8. Using some of the remaining solution, check pH and send a sample for sterility testing.

**Packaging**
- Sterile syringe with sterile tamper-evident cap, placed in an amber bag

**Labeling**
- Store in Refrigerator
- Protect from Light
- For Eye

**Beyond-Use Date**
- 7 days refrigerated

**Use**
This drug is FDA approved to treat severe systemic and central nervous system infections caused by susceptible fungi such as Candida species, Histoplasma capsulatum, Cryptococcus neoformans, Aspergillus species, Blastomyces dermatitidis, Torulopsis glabrata, and Coccidioides immitis; fungal peritonitis; bladder fungal infections (irrigant); and fungal infection in patients with bone marrow transplantation, amebic meningoencephalitis, ocular aspergillosis (intraocular injection), candidal cystitis (bladder irrigation), chemoprophylaxis (low-dose IV), immunocompromised patients at risk of aspergillosis (intranasal/nebulized), refractory meningitis (intrathecal), coccidioidal arthritis (intra-articular/IM). Off-label uses include intravitreal amphotericin B as the drug of choice to treat fungal endophthalmitis. Endophthalmitis is a medical emergency and can lead to severe visual impairment, blindness, or loss of eye if left untreated.

**Quality Control**
- Volume, physical observation, pH, osmolality, assay, color, clarity, particulate matter, sterility

*(continued on next page)*
**Special Notes**
- Discard solution if it contains any particulates or precipitants.
- Subconjunctival doses are usually 0.5 mL; however the syringes should be overfilled to account for the dead space in the syringe and needle.
- Amphotericin B is incompatible with sodium chloride solutions.

**Discussion**

**Amphotericin B** (am foe TER i sin bee) is an antifungal agent that is insoluble in water. Sodium desoxycholate is added to the parenteral form of amphotericin B as a solubilizing agent to create colloidal dispersion of the drug. The pH of the admixture must be at least 4.2.

**Information Sources**


Ampicillin 100 mg/0.5 mL Subconjunctival Injection

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ampicillin 1 g for injection</td>
<td>1 vial</td>
</tr>
<tr>
<td>0.9% Sodium chloride for injection</td>
<td>4.5 mL</td>
</tr>
</tbody>
</table>

**Method of Preparation**
1. Under a laminar airflow workbench, aseptically withdraw 5 mL of 0.9% sodium chloride for injection, and add to a vented vial of ampicillin 1 g for injection to prepare a 200 mg/mL concentration.
2. Shake vial gently to mix. Vial may need to sit for a few minutes to allow dissolution of the lyophilized ampicillin powder.
3. Withdraw 0.5 mL into a sterile Luer-Lock® tuberculin syringe, and cap with a tamper-resistant sterile cap.
4. Label each syringe.
5. Using some of the remaining solution, check pH and send a sample for sterility testing.

**Packaging**
- Sterile syringe with a sterile tamper-resistant cap

**Labeling**
- Store in Refrigerator (recommended)
- For Eye

**Beyond-Use Date**
- 4 hours refrigerated
- 1 hour room temperature

**Use**
This drug is FDA approved as treatment for susceptible bacterial infections (non–beta-lactamase-producing organisms); treatment or prophylaxis for infective endocarditis; treatment for susceptible bacterial infections caused by streptococci, pneumococci, non–penicillinase-producing staphylococci, *Listeria*, meningococci, and some strains of *Haemophilus influenzae*, *Salmonella*, *Shigella*, *Escherichia coli*, *Enterobacter*, and *Klebsiella*.

**Quality Control**
- Volume, physical observation, pH, osmolality, assay, color, clarity, particulate matter, sterility

**Special Notes**
- Discard solution if it contains any particulates or precipitants.
- Subconjunctival doses are usually 0.5 mL; however, the syringes should be overfilled to account for the dead space in the syringe and needle.

**Discussion**
Ampicillin (am pi SIL in) is a penicillinase-resistant penicillin that has a pH range of 8 to 10. A 100 mg/mL solution has an osmolality range of 602 mOsm/kg. Ampicillin is sensitive to concentration, pH, and temperature. The ideal stable conditions are a pH range of 5 to 6, refrigerated temperature, and concentrations below 30 mg/mL.
Bacitracin 5,000 units/0.5 mL Subconjunctival Injection

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bacitracin 50,000 units for injection</td>
<td>1 vial</td>
</tr>
<tr>
<td>Sterile water for injection</td>
<td>4.8 mL</td>
</tr>
</tbody>
</table>

Method of Preparation
1. Under a laminar airflow workbench, aseptically withdraw 4.8 mL of sterile water for injection, and add to a vented vial of bacitracin 50,000 units for injection to prepare a 10,000 units/mL concentration.
2. Swirl gently to mix, but do not shake. Vial may need to sit for a few minutes to allow dissolution of the lyophilized powder and to allow the foam to subside.
3. Withdraw 1 mL into a sterile Luer-Lock® tuberculin syringe, and cap with a tamper-resistant sterile cap.
4. Label each syringe.
5. Using some of the remaining solution, check pH and send a sample for sterility testing.

Packaging
- Sterile syringe with a sterile tamper-resistant cap

Labeling
- Store in Freezer
- For the Eye

Beyond-Use Date
- 20 weeks frozen
- 7 days refrigerated

Use
This drug is FDA approved to treat susceptible bacterial infections (primary activity is against gram-positive bacilli) and blepharitis.

Quality Control
- Volume, physical observation, pH, osmolality, assay, color, clarity, particulate matter, sterility

Special Notes
- Discard solution if it contains any particulates or precipitants.
- Subconjunctival doses are usually 0.5 mL; however, the syringes should be overfilled to account for the dead space in the syringe and needle.
- Use should be limited to alternative treatments that are less toxic.

Information Sources
Chloramphenicol Intravitreal Injections

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>Quantity (to make 10 mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chloramphenicol sodium succinate 1 g for injection</td>
<td>1 mL 2 mL</td>
</tr>
<tr>
<td>Sterile water for injection, preservative free</td>
<td>10 mL 10 mL</td>
</tr>
<tr>
<td>0.9% Sodium chloride injection</td>
<td>9 mL 8 mL</td>
</tr>
</tbody>
</table>

**Method of Preparation**

1. Under a laminar airflow workbench, aseptically withdraw 10 mL of sterile water for injection, and add to a vented vial of chloramphenicol 1 g for injection to prepare a 100 mg/mL concentration.
2. Shake vial gently to mix. Vial may need to sit for a few minutes to allow dissolution of the lyophilized chloramphenicol powder.
3. Withdraw desired quantity of the reconstituted chloramphenicol, and add to a sterile empty vial.
4. Withdraw desired quantity of 0.9% sodium chloride injection, add to the same vial, and gently swirl to mix.
5. Add a sterile dispensing pin to the vial.
6. Withdraw 0.5 mL of the final solution into a sterile Luer-Lock® 1-mL syringe, and cap with a sterile tamper-resistant cap.
7. Label each syringe.
8. Using some of the remaining solution, check pH and send a sample for sterility testing.

**Packaging**

- Sterile syringe with a sterile tamper-resistant cap

**Labeling**

- Store in Freezer (long-term storage)
- Store at Room Temperature (immediate use)
- Protect from Light
- For the Eye

**Beyond-Use Date**

- 180 days frozen
- 30 days room temperature

**Use**

This drug is a broad-spectrum antibiotic used to treat ophthalmic infections and ulcerations caused by susceptible gram-positive and gram-negative aerobic bacteria (*Streptococcus pneumoniae, Haemophilus influenza, Neisseria* sp.), some anaerobic bacteria (*Bacteroides fragilis*), *Chlamydia* sp., and *Mycoplasma* sp.

**Quality Control**

- Volume, physical observation, pH, osmolality, assay, color, clarity, particulate matter, sterility (continued on next page)
Corrected Monograph

Chloramphenicol Subconjunctival Injections

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>Quantity (to make 10 mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chloramphenicol sodium succinate 1 gm for injection</td>
<td>50 mg/0.5 mL</td>
</tr>
<tr>
<td>Sterile Water for Injection (preservative free)</td>
<td>1 vial</td>
</tr>
<tr>
<td></td>
<td>10 mL</td>
</tr>
</tbody>
</table>

Method of Preparation
1. Under a laminar airflow workbench, using aseptic technique, withdraw sterile water for injection and add to a vented vial of chloramphenicol 1gm for injection to prepare the desired concentration.
2. Shake gently to mix. May need to let vial set for a few minutes to allow dissolution of the lyophilized chloramphenicol powder.
3. Add a sterile dispensing pin to the vial.
4. Withdraw 1 mL of the final solution with a sterile Luer Lock® 1mL syringe and cap.
5. Label each syringe.
6. Use some of the remaining solution check pH and send a sample for sterility testing.

Packaging
- Sterile syringe with a sterile tamper-resistant cap

Labeling
- Store in Freezer (long term storage)
- Store at Room Temperature (immediate use)
- Protect from light
- For the Eye

Beyond-Use Date
- 180 days Frozen
- 30 days Room Temperature

Use
Chloramphenicol is a broad spectrum antibiotic used to treat ophthalmic infections and ulcerations caused by susceptible gram-positive and gram-negative aerobic bacteria (Strep pneumoniae, Hae-mophilus influenza, Neisseria sp.), some anaerobic bacteria (Bacteriodes fragilis), Chlamydia sp., and Mycoplasma sp.

Quality Control
- Volume, physical observation, pH, osmolality, assay, color, clarity, particulate matter, sterility

Special Notes
- Discard solution if it is cloudy or there are any particulates or precipitants in the solution.
- There have been reported blood dyscrasias with use of ophthalmic chloramphenicol. Only use for resistant cases.
- Subconjunctival doses are usually 0.5mL; however, the syringes should be overfilled to account for the dead space in the syringe and needle.

(continued on next page)
Chloramphenicol Subconjunctival Injections (Continued)

Discussion
Chloramphenicol (klor am FEN i kole) is an antibiotic that is most stable in a pH range of 6 to 7 as a reconstituted solution. A 20 mg/mL solution has an osmolality range of 344–368 mOsm/kg. The sodium succinate salt is freely soluble in water.

Information Sources
Penicillin G Potassium 300 units/0.1 mL Intravitreal Injection

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Penicillin 1 Mu vial for injection</td>
<td>1 vial</td>
</tr>
<tr>
<td>Sterile water for injection</td>
<td>19.3 mL</td>
</tr>
</tbody>
</table>

Method of Preparation
1. Under a laminar airflow workbench, aseptically withdraw 9.6 mL of sterile water for injection into a sterile syringe, and add to a vial of penicillin G potassium 1 Mu for injection to prepare a 100,000 units/mL concentration.
2. Shake vial gently to mix. Vial may need to sit a few minutes to allow dissolution of the penicillin powder.
3. Withdraw 0.3 mL of the reconstituted penicillin G potassium into a sterile syringe, and add to an empty sterile vial.
4. Withdraw 9.7 mL sterile water for injection into a sterile syringe, add to same vial, and shake well to mix.
5. Add a sterile dispensing pin to same vial, withdraw 0.5 mL into a sterile Luer-Lock® tuberculin syringe, and cap with a tamper-resistant sterile cap.
6. Label each syringe.
7. Using some of the remaining solution, check pH and send a sample for sterility testing.

Packaging
- Sterile syringe with a sterile tamper-resistant cap

Labeling
- Store in Refrigerator
- For the Eye

Beyond-Use Date
- 7 days Refrigerated

Use
This drug is FDA approved to treat infections (including sepsis, pneumonia, pericarditis, endocarditis, meningitis, and anthrax) caused by susceptible organisms. It is active against some gram-positive organisms, generally not *Staphylococcus aureus*; some gram-negative organisms such as *Neisseria gonorrhoeae*; and some anaerobes and spirochetes. Off-label uses include treatment of infectious keratitis and corneal ulcerations. Some bacteria may be resistant to this agent, so other agents may be preferred.

Quality Control
- Volume, physical observation, pH, osmolality, assay, color, clarity, particulate matter, sterility

Special Notes
- Discard solution if it contains any particulates or precipitants.
- For every Mu of penicillin G potassium, there is a 0.4 mL displacement in the vial.

(continued on next page)
Benzalkonium Chloride 0.5% Solution

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzalkonium chloride 50% solution</td>
<td>1 mL</td>
</tr>
<tr>
<td>Sterile Water for Injection</td>
<td>99 mL</td>
</tr>
</tbody>
</table>

**Method of Preparation**
1. Accurately measure each ingredient, add to a beaker, and mix well.
2. Withdraw the quantity needed for compounding and discard the remaining solution.

**Packaging**
- None

**Labeling**
- None

**Beyond-Use Date**
- 1 day

**Use**
Add during compounding process for topical ophthalmic preparations.

**Quality Control**
- Volume, physical observation.

**Special Notes**
- This compounded preparation is not sterile and is added as a component in a compounded topical ophthalmic preparation prior to sterilization.

**Discussion**
See Chapter 4 in this text for detailed information about benzalkonium chloride.

**Information Source**