In accordance with the Rules and Procedures of the 2015-2020 Council of Experts, the Chemical Medicines Expert Committees 1 to 6 has revised the monographs listed below. The purpose of the revision is to replace the requirement to comply with the entire content of the USP general chapter Ophthalmic Products—Quality Tests <771> with a requirement to comply only with the subsection for Particulate and Foreign Matter in Ophthalmic Products—Quality Tests <771>, and with the section for Container Content for those monographs where the requirement for Minimum Fill was deleted.

- Atropine Sulfate Ophthalmic Ointment
- Bacitracin Ophthalmic Ointment
- Bacitracin Zinc and Polymyxin B Sulfate Ophthalmic Ointment
- Bland Lubricating Ophthalmic Ointment
- Chloramphenicol and Polymyxin B Sulfate Ophthalmic Ointment
- Chloramphenicol Ophthalmic Ointment
- Chlortetracycline Hydrochloride Ophthalmic Ointment
- Ciprofloxacin Ophthalmic Ointment
- Dexamethasone Sodium Phosphate Ophthalmic Ointment
- Erythromycin Ophthalmic Ointment
- Gentamicin and Prednisolone Acetate Ophthalmic Ointment
- Gentamicin Sulfate Ophthalmic Ointment
- Hydrocortisone Acetate Ophthalmic Ointment
- Idoxuridine Ophthalmic Ointment
- Neomycin and Polymyxin B Sulfates, Bacitracin Zinc, and Hydrocortisone Acetate Ophthalmic Ointment
- Neomycin and Polymyxin B Sulfates and Bacitracin Ophthalmic Ointment
- Neomycin and Polymyxin B Sulfates and Dexamethasone Ophthalmic Ointment
- Neomycin and Polymyxin B Sulfates Ophthalmic Ointment
- Neomycin and Polymyxin B Sulfates, Bacitracin Zinc, and Hydrocortisone Ophthalmic Ointment
- Neomycin and Polymyxin B Sulfates, Bacitracin, and Hydrocortisone Acetate Ophthalmic Ointment
- Neomycin Sulfate and Dexamethasone Sodium Phosphate Ophthalmic Ointment
- Neomycin Sulfate Ophthalmic Ointment
- Oxytetracycline Hydrochloride and Polymyxin B Sulfate Ophthalmic Ointment
- Sodium Chloride Ophthalmic Ointment
- Sulfacetamide Sodium and Prednisolone Acetate Ophthalmic Ointment
- Sulfacetamide Sodium Ophthalmic Ointment
- Tetracycline Hydrochloride Ophthalmic Ointment
- Tobramycin and Dexamethasone Ophthalmic Ointment
- Tobramycin Ophthalmic Ointment

The Revision Bulletins for the monographs listed above supersede the currently official version of these monographs. The Revision Bulletin will be incorporated in the First Supplement to USP 40–NF 35.

Should you have any questions, please contact Margareth R. C. Marques, M.Sc., Ph.D. (301-816-8106 or mrm@usp.org).
Tetracycline Hydrochloride Ophthalmic Ointment

**DEFINITION**
Tetracycline Hydrochloride Ophthalmic Ointment contains NLT 90.0% and NMT 125.0% of the labeled amount of tetracycline hydrochloride (C_{22}H_{24}N_{2}O_{8}·HCl).

**IDENTIFICATION**

**Add the following:**

**A.** The retention time of the major peak of the Sample solution corresponds to that of the Standard solution, as obtained in the Assay.

**ASSAY**

**PROCEDURE**

- Solution A: 0.1 M ammonium oxalate
- Solution B: 0.2 M dibasic ammonium phosphate
- Diluent: Dimethylformamide and Solution A (270:680)
- Mobile phase: Dimethylformamide, Solution A, and Solution B (270:680:50). Adjust, if necessary, with 3 N ammonium hydroxide or 3 N phosphoric acid to a pH of 7.6–7.7
- System suitability solution: 100 µg/mL of tetracycline hydrochloride and 25 µg/mL of USP 4-Epianhydrotetracycline Hydrochloride RS in Diluent
- Standard stock solution: 1 mg/mL of USP Tetracycline Hydrochloride RS in methanol
- Standard solution: 0.12 mg/mL of USP Tetracycline Hydrochloride RS from Standard stock solution in Diluent
- Sample stock solution: Nominally 3 mg/mL of tetracycline hydrochloride prepared as follows. Transfer a portion of Ophthalmic Ointment, containing nominally 300 mg of tetracycline hydrochloride, to a glass-stoppered conical flask. Add 20 mL of cyclohexane, and shake. Add 35 mL of methanol, and sonicate for 20 min. Filter this solution into a 100-mL volumetric flask, and rinse the sides of the conical flask with 40 mL of methanol. Dilute with methanol to volume.
- Sample solution: Nominally 0.12 mg/mL of tetracycline hydrochloride in Diluent from Sample stock solution

**Chromatographic system**

(See Chromatography (621), System Suitability.)

- **Mode:** LC
- **Detector:** UV 280 nm
- **Columns**
  - Guard: 4.6-mm × 3-cm; 10-µm packing L7
  - Analytical: 4.6-mm × 25-cm; 5–10-µm packing L7
- **Flow rate:** 2 mL/min
- **Injection volume:** 20 µL

**System suitability**

<table>
<thead>
<tr>
<th>Samples:</th>
<th>System suitability solution and Standard solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOTE:</td>
<td>The relative retention times of 4-epianhydrotetracycline and tetracycline are 0.9 and 1.0, respectively.</td>
</tr>
</tbody>
</table>

**Suitability requirements**

- Resolution: NLT 1.2 between 4-epianhydrotetracycline and tetracycline, System suitability solution
- Relative standard deviation: NMT 2.0%, Standard solution

**Analysis**

**Samples:** Standard solution and Sample solution

Calculate the percentage of the labeled amount of tetracycline hydrochloride (C_{22}H_{24}N_{2}O_{8}·HCl) in the portion of Ophthalmic Ointment taken:

\[
\text{Result} = \left( \frac{r_U}{r_S} \right) \times \left( \frac{C_S}{C_U} \right) \times P \times F \times 100
\]

- \(r_U\) = peak response of tetracycline from the Sample solution
- \(r_S\) = peak response of tetracycline from the Standard solution
- \(C_S\) = concentration of USP Tetracycline Hydrochloride RS in the Standard solution (mg/mL)
- \(C_U\) = nominal concentration of tetracycline hydrochloride in the Sample solution (mg/mL)
- \(P\) = potency of USP Tetracycline Hydrochloride RS (µg/mg)
- \(F\) = conversion factor, 0.001 mg/µg

**Acceptance criteria:** 90.0%–125.0%

**PERFORMANCE TESTS**

**Delete the following:**

**A.** Minimum Fill (755): Meets the requirements

**SPECIFIC TESTS**

**Delete the following:**

**A.** Water Determination (921), Method I

**Analysis:** Use 20 mL of a mixture of toluene and methanol (7:3) in place of methanol in the titration vessel.

**Acceptance criteria:** NMT 0.5%

**B.** Sterility Tests (71): Meets the requirements

**Delete the following:**

**A.** Metal Particles in Ophthalmic Ointments (751): Meets the requirements

**OTHER REQUIREMENTS:** It meets the requirements for Particulate and Foreign Matter and Container Contents.

**ADDITIONAL REQUIREMENTS**

- **Packaging and Storage:** Preserve in collapsible ophthalmic ointment tubes.

**Drug Quality, Universal Tests, Particulate and Foreign Matter, and Container Contents.**

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