Ophthalmic Ointment Monographs: Atropine Sulfate Ophthalmic Ointment

Type of Posting  Revision Bulletin
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Expert Committee  Chemical Medicines Monographs 1 to 6
Reason for Revision  Compliance

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
• Chlorotetracycline 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 Sulfate 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 supersedes 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).
Atropine Sulfate Ophthalmic Ointment

**DEFINITION**
Atropine Sulfate Ophthalmic Ointment is Atropine Sulfate in a suitable ophthalmic ointment base. It contains NLT 90.0% and NMT 110.0% of the labeled amount of atropine sulfate monohydrate \([\text{C}_{17}\text{H}_{23}\text{NO}_3\text{H}_2\text{SO}_4\text{H}_2\text{O}]\). It is sterile.

**IDENTIFICATION**

**Change to read:**

- **A. IDENTIFICATION—ORGANIC NITROGENOUS BASES (181)**

  **Standard solution:** Proceed as directed in the chapter.

  **Sample solution:** Transfer a portion of Ophthalmic Ointment to a separator, dissolve in 50 mL of ether, and extract with 20 mL of water.

  **Acceptance criteria:** Meets the requirements

**ASSAY**

**PROCEDURE**

**Buffer:** 34.8 g of dibasic potassium phosphate in 900 mL of water. Adjust to a pH of 9.0 by the addition of 3 M hydrochloric acid or 1 M sodium hydroxide, as necessary.

**Internal standard solution:** 0.5 mg/mL of homatropine hydrobromide in water. Prepare fresh daily.

**Standard stock solution:** 0.1 mg/mL of USP Atropine Sulfate RS in water.

**Standard solution:** 0.5 mg/mL of atropine sulfate prepared as follows. Pipet 10 mL of Standard stock solution into a separator, add 2.0 mL of Internal standard solution and 5.0 mL of Buffer, and adjust the solution in the separator with 1 M sodium hydroxide to a pH of 9.0. Extract with two 10-mL portions of methylene chloride, filter the methylene chloride extracts through 1 g of anhydrous sodium sulfate, and adjust the solution in the separator with 1 M sulfuric acid or 0.1 M sulfuric acid to volume. Pipet 10 mL of this solution and treat as follows. Add 25 mL of 0.01 N hydrochloric acid, shake vigorously, and allow the layers to separate, and discard the organic phase. Heat the aqueous phase gently on a steam bath while passing nitrogen through the solution to expel any residual ether.

**Instrumental conditions and Analysis:** Proceed as directed in the chapter.

**Acceptance criteria:** Meets the requirements

- **B. IDENTIFICATION TESTS—GENERAL, Sulfate (191)**

  **Sample solution:** Transfer 5 g of Ophthalmic Ointment to a separator, dissolve in 50 mL of ether, and extract with 20 mL of water.

  **Acceptance criteria:** Meets the requirements

**SPECIFIC TESTS**

- **STERILITY TESTS (71):** Meets the requirements

**Delete the following:**

- **METAL PARTICLES IN OPHTHALMIC OINTMENTS (751):** Meets the requirements

**Change to read:**

- **OTHER REQUIREMENTS:** It meets the requirements for Particulate and Foreign Matter in Ophthalmic Products—Quality Tests (771), Drug Product Quality, Universal Tests, Particulate and Foreign Matter.

**ADDITIONAL REQUIREMENTS**

- **PACKAGING AND STORAGE:** Preserve in collapsible ophthalmic ointment tubes.

- **USP REFERENCE STANDARDS (11)**

  - USP Atropine Sulfate RS