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 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).
Neomycin and Polymyxin B Sulfates and Dexamethasone Ophthalmic Ointment

**DEFINITION**
Neomycin and Polymyxin B Sulfates and Dexamethasone Ophthalmic Ointment contains the equivalent of NLT 90.0% and NMT 130.0% of the labeled amounts of neomycin and polymyxin B, and NLT 90.0% and NMT 110.0% of the labeled amount of dexamethasone (C_{22}H_{29}FO_{5}).

**IDENTIFICATION**

- **A. THIN-LAYER CHROMATOGRAPHIC IDENTIFICATION TEST**
  - **(201BNP):** Meets the requirements
- **B.** The retention time of the dexamethasone peak of the Sample solution corresponds to that of the Standard solution, as obtained in the Assay for Dexamethasone.

**ASSAY**

- **NEOMYCIN**
  - (See Antibiotics—Microbial Assays (81).)
  - **Sample solution:** Shake a portion of Ophthalmic Ointment in a separator with 50 mL of ether. Extract with four 20-mL portions of Buffer B.3. Combine the aqueous extracts, and dilute with Buffer B.3 to a suitable volume.
  - **Analysis:** Proceed as directed in the chapter. Dilute the Sample solution with Buffer B.3 to obtain a Test Dilution having a neomycin concentration that is nominally equivalent to the median level of the standard. **Acceptance criteria:** 90.0%–130.0%

- **POLYMIXYN B**
  - (See Antibiotics—Microbial Assays (81).)
  - **Sample solution:** Shake a portion of Ophthalmic Ointment with 50 mL of ether in a separator. Extract with four 25-mL portions of Buffer B.6. Combine the aqueous extracts, and dilute with Buffer B.6 to a suitable volume.
  - **Analysis:** Proceed as directed in the chapter. Dilute the Sample solution with Buffer B.6 to obtain a Test Dilution having a concentration that is nominally equivalent to the median level of the standard (10 polymyxin B units/mL). Add to each Test Dilution of the standard, a quantity of USP Neomycin Sulfate RS, dissolved in Buffer B.6, to obtain the same concentration of neomycin as in the Test Dilution of the sample. **Acceptance criteria:** 90.0%–130.0%

**Change to read:**

- **DEXAMETHASONE**
  - **Mobile phase:** Acetonitrile and water (1 in 3) ▲\text{USP39}
  - **Diluent:** Acetonitrile and methanol (1:1)
  - **Standard solution:** 60 µg/mL of USP Dexamethasone RS in Diluent
  - **Sample solution:** Nominally 60 µg/mL of dexamethasone from Ophthalmic Ointment in Diluent prepared as follows: Transfer a portion of Ophthalmic Ointment containing nominally 3 mg of dexamethasone to a suitable test tube, and add 15 mL of cyclohexane. Heat in a water bath at 75 ± 5° for 10 min. If the Ophthalmic Ointment is not fully dissolved, heat on a steam bath for about 30 s, place a cap on the test tube, and place on a vortex mixer until all solid material is dissolved. Pass with suction through a medium-porosity, sintered-glass filter. Rinse the test tube twice with 10-mL portions of cyclohexane, passing the rinsings through the filter, and discard the filtrate. Wash the filter with about 10 mL of a mixture of Diluent, and collect the filtrate in a 50-mL beaker. Wash the test tube and the filter with several 10-mL portions of Diluent, and combine the washings in the 50-mL beaker. Transfer the contents of the beaker to a 50-mL volumetric flask with the aid of Diluent, and dilute with Diluent to volume.

**Chromatographic system**
(See Chromatography (621), System Suitability.)

- **Mode:** LC
- **Detector:** UV 254 nm
- **Column:** 4.6-mm × 25-cm; 5- to 10-µm packing L1
- **Flow rate:** 2 mL/min
- **Injection volume:** 10 µL

**System suitability**

- **Sample:** Standard solution and Sample solution
- **Calculate the percentage of the labeled amount of dexamethasone (C_{22}H_{29}FO_{5}) in the portion of Ophthalmic Ointment taken:**

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

- **f_U = peak response from the Sample solution**
- **f_S = peak response from the Standard solution**
- **C_S = concentration of USP Dexamethasone RS in the Standard solution (µg/mL)**
- **C_U = nominal concentration of dexamethasone in the Sample solution (µg/mL)**

**Acceptance criteria:** 90.0%–110.0%

**PERFORMANCE TESTS**

- **Delete the following:**
  - **▲ MINIMUM FILL (755):** Meets the requirements ▲\text{USP39}

**SPECIFIC TESTS**

- **Delete the following:**
  - **▲ WATER DETERMINATION, Method Ib (921):** 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% ▲\text{USP39}

**Change to read:**

- **STERILITY TESTS (71):** ▲Meets the requirements ▲\text{USP39}

**Delete the following:**

- **▲ METAL PARTICLES IN OPHTHALMIC OINTMENTS (751):** Meets the requirements ▲\text{USP39}

**Change to read:**

- **OTHER REQUIREMENTS:** It meets the requirements for Particulate and Foreign Matter and Container Contents. ▲\text{USP39}

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ADDITIONAL REQUIREMENTS

- Packaging and Storage: Preserve in collapsible ophthalmic ointment tubes.
- USP Reference Standards (11)
  - USP Dexamethasone RS
  - USP Neomycin Sulfate RS
  - USP Polymyxin B Sulfate RS