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 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).
Chloramphenicol Ophthalmic Ointment

DEFINITION
Chloramphenicol Ophthalmic Ointment contains NLT 90.0% and NMT 130.0% of the labeled amount of chloramphenicol (C11H12Cl2N2O5).

IDENTIFICATION
• 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
Change to read:

• PROCEDURE
Mobile phase: Methanol, glacial acetic acid, and water (450:1:550)
Standard stock solution: 0.25 mg/mL of USP Chloramphenicol RS in methanol
Standard solution: 0.1 mg/mL of USP Chloramphenicol RS from the Standard stock solution in Mobile phase. Pass through a suitable filter, and use the clear filtrate.
Sample stock solution: Nominally 0.25 mg/mL of chloramphenicol prepared as follows. Transfer a portion of Ophthalmic Ointment containing nominally 25 mg of chloramphenicol to a suitable conical flask. Add 20 mL of cyclohexane, mix, and sonicate for 2 min. Add 60 mL of methanol. Filter this mixture, collecting the filtrate in a 100-mL volumetric flask. Wash the filter with methanol, collecting the washings in the volumetric flask. Dilute with methanol to volume. Transfer 50.0 mL of the resulting solution to a suitable round-bottom flask, and evaporate to dryness by rotating the flask under vacuum at 35°C. Dissolve the residue in 50.0 mL of methanol.
Sample solution: Nominally 0.1 mg/mL of chloramphenicol from the Sample stock solution in Mobile phase. Pass through a suitable filter, and use the clear filtrate.

Chromatographic system
(See Chromatography (621), System Suitability.)
Mode: LC
Detector: UV 280 nm
Column: 4.6-mm × 10-cm; 5-µm packing L1
Flow rate: 1 mL/min
Injection volume: 10 µL

System suitability
Sample: Standard solution
Suitability requirements
Tailing factor: NMT 2.0
Relative standard deviation: NMT 1.0%

Analysis
Samples: Standard solution and Sample solution
Calculate the percentage of the labeled amount of chloramphenicol (C11H12Cl2N2O5) in the portion of Ophthalmic Ointment taken:

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