

Ophthalmic Ointment Monographs: Chlortetracycline Hydrochloride Ophthalmic Ointment

Type of Posting	Revision Bulletin
Posting Date	29–Jul–2016
Official Date	01–Aug–2016
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
- 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 Bacitracin Zinc 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).

Chlortetracycline Hydrochloride Ophthalmic Ointment

DEFINITION

Chlortetracycline Hydrochloride Ophthalmic Ointment contains NLT 90.0% and NMT 125.0% of the labeled amount of chlortetracycline hydrochloride ($C_{22}H_{23}ClN_2O_8 \cdot HCl$).

ASSAY

PROCEDURE

(See *Antibiotics—Microbial Assays* (81).)

Sample solution: Shake a portion of Ophthalmic Ointment containing nominally 10 mg of chlortetracycline hydrochloride in a separator with 50 mL of ether, and extract with four 20-mL portions of 0.01 N hydrochloric acid. Combine the aqueous extracts in a 100-mL volumetric flask, and dilute with 0.01 N hydrochloric acid to volume.

Analysis: Proceed as directed in the chapter. Dilute the *Sample solution* with water to obtain a *Test Dilution* having a chlortetracycline hydrochloride concentration that is nominally equivalent to the median level of the standard.

Acceptance criteria: 90.0%–125.0%

PERFORMANCE TESTS

Delete the following:

- ▲ **MINIMUM FILL** (755): Meets the requirements

▲USP39

SPECIFIC TESTS

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

Delete the following:

- ▲ **WATER DETERMINATION, Method I** (921)

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%

▲USP39

Delete the following:

- ▲ **METAL PARTICLES IN OPHTHALMIC OINTMENTS** (751):

Meets the requirements

▲USP39

Change to read:

- ▲ **OTHER REQUIREMENTS:** It meets the requirements for *Particulate and Foreign Matter and Container Contents* (RB 1-Aug-2016) in *Ophthalmic Products—Quality Tests* (771), *Drug Product Quality, Universal Tests, Particulate and Foreign Matter and Container Contents*. (RB 1-Aug-2016)

▲USP39

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in collapsible ophthalmic ointment tubes.
- **USP REFERENCE STANDARDS** (11)
USP Chlortetracycline Hydrochloride RS