

Ophthalmic Ointment Monographs: Oxytetracycline Hydrochloride and Polymyxin B Sulfate 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).

Oxytetracycline Hydrochloride and Polymyxin B Sulfate Ophthalmic Ointment

DEFINITION

Oxytetracycline Hydrochloride and Polymyxin B Sulfate Ophthalmic Ointment is a sterile ointment containing Oxytetracycline Hydrochloride and Polymyxin B Sulfate. It contains the equivalent of NLT 90.0% and NMT 120.0% of the labeled amount of oxytetracycline and NLT 90.0% and NMT 125.0% of the labeled amount of polymyxin B.

ASSAY

• OXYTETRACYCLINE

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

Sample solution: Transfer a suitable, weighed quantity of the Ophthalmic Ointment to a separator, add 50 mL of ether, and shake. Add 20 mL of 0.1 N hydrochloric acid, shake, and allow to separate. Collect the acid layer, and repeat the extraction with three additional 20-mL portions of 0.1 N hydrochloric acid. Combine the acid extracts in a 100-mL volumetric flask, and dilute with 0.1 N hydrochloric acid to volume. Dilute a portion of this solution with 0.1 N hydrochloric acid to obtain a solution containing NLT 150 µg/mL of oxytetracycline.

Analysis: Proceed as directed in the chapter, using a suitable aliquot of the *Sample solution* diluted with water, to yield a *Test Dilution* having an oxytetracycline concentration that is nominally equivalent to the median level of the standard.

Acceptance criteria: 90.0%–120.0%

• POLYMYXIN B

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

Sample solution: Transfer nominally 10,000 USP Polymyxin B Units from the Ophthalmic Ointment to a 15-mL centrifuge tube. Add 10 mL of ether, stir, and centrifuge for 10 min. Decant, and discard the clear ether. Wash the residue with 10 mL of ether, and centrifuge for 10 min, decanting and discarding the clear ether. Wash the residue with several 10-mL portions of acetone, centrifuging, decanting, and discarding each washing until the yellow color is removed from the residue. Take care not to remove any of the residue with the washings. Add 0.2 mL of polysorbate 80 to the residue, and mix. Transfer the mixture to a 100-mL volumetric flask with the aid of *Buffer B.6*, and dilute with the same solvent to volume.

Analysis: Proceed as directed in the chapter, using a suitable aliquot of the *Sample solution* diluted with

Buffer B.6, to yield a *Test Dilution* having a polymyxin B 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:

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

▲*USP39*

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 1.0%

▲*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

Change to read:

- **PACKAGING AND STORAGE:** Preserve in collapsible ophthalmic ointment tubes. ▲Store at controlled room temperature.▲*USP39*
- **USP REFERENCE STANDARDS** (11)
USP Oxytetracycline RS
USP Polymyxin B Sulfate RS