

Ophthalmic Ointment Monographs: Bacitracin Zinc and Polymyxin B Sulfate Ophthalmic Ointment

Type of Posting	Revision Bulletin
Posting Date	29-Jul-2016
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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
- 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).

Bacitracin Zinc and Polymyxin B Sulfate Ophthalmic Ointment

DEFINITION

Bacitracin Zinc and Polymyxin B Sulfate Ophthalmic Ointment contains the equivalent of NLT 90.0% and NMT 130.0% of the labeled amounts of bacitracin and polymyxin B.

IDENTIFICATION

- **A. THIN-LAYER CHROMATOGRAPHIC IDENTIFICATION TEST** (201BNP): Meets the requirements

ASSAY

Change to read:

- **BACITRACIN**

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

Standard solution: Proceed as directed in the chapter. To each *Test Dilution* of the standard add sufficient hydrochloric acid to obtain the same concentration of hydrochloric acid as in the *Test Dilution* of Ophthalmic Ointment.

Sample solution: Use a portion of Ophthalmic Ointment shaken with about 50 mL of ether in a separator and extracted with four 20-mL portions of 0.01 N hydrochloric acid. Combine the acid extracts, and dilute with 0.01 N hydrochloric acid to a suitable volume.

Analysis: Proceed as directed in the chapter. Dilute the *Sample solution* with *Buffer B.1* to obtain a *Test Dilution* having a bacitracin concentration that is nominally equivalent to the median level of the standard. ▲^{USP39}

Acceptance criteria: 90.0%–130.0%

- **POLYMYXIN B**

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

Sample solution: Shake a portion of Ophthalmic Ointment with about 50 mL of ether in a separator, and extract with four 20-mL portions of *Buffer B.6* (see the chapter). Combine the buffer 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 polymyxin B concentration that is nominally equivalent to the median level of the standard.

Acceptance criteria: 90.0%–130.0%

PERFORMANCE TESTS

Delete the following:

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

▲^{USP39}

SPECIFIC TESTS

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:

- **STERILITY TESTS (71):** ▲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

Change to read:

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