

## Ophthalmic Ointment Monographs: Bacitracin Ophthalmic Ointment

<b>Type of Posting</b>	Revision Bulletin
<b>Posting Date</b>	29-Jul-2016
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<b>Expert Committee</b>	Chemical Medicines Monographs 1 to 6
<b>Reason for Revision</b>	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](mailto:mrm@usp.org)).

## Bacitracin Ophthalmic Ointment

### DEFINITION

Bacitracin Ophthalmic Ointment is a sterile preparation of Bacitracin in an anhydrous ointment base. It contains NLT 90.0% and NMT 140.0% of the labeled amount of bacitracin.

### IDENTIFICATION

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

### ASSAY

#### • PROCEDURE

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

**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 *Buffer B.1* (see the chapter). Combine the buffer extracts, and dilute with *Buffer B.1* to a suitable volume.

**Analysis:** Proceed as directed in the chapter. Add sufficient 0.01 N hydrochloric acid to a suitable aliquot of the *Sample solution* so that the amount of hydrochloric acid in the *Test Dilution* is the same as in the median level of the standard. Dilute with *Buffer B.1* to obtain a *Test Dilution* having a bacitracin concentration that is nominally equivalent to the median level of the standard.

**Acceptance criteria:** 90.0%–140.0%

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

#### Change to read:

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