

## Ophthalmic Ointment Monographs: Neomycin and Polymyxin B Sulfates Ophthalmic Ointment

<b>Type of Posting</b>	Revision Bulletin
<b>Posting Date</b>	29–Jul–2016
<b>Official Date</b>	01–Aug–2016
<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)).

## Neomycin and Polymyxin B Sulfates Ophthalmic Ointment

### DEFINITION

Neomycin and Polymyxin B Sulfates Ophthalmic Ointment is a sterile ointment containing Neomycin Sulfate and Polymyxin B Sulfate. It contains the equivalent of NLT 90.0% and NMT 130.0% of the labeled amounts of neomycin and polymyxin B.

### IDENTIFICATION

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

### ASSAY

#### • NEOMYCIN

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

**Sample solution:** Shake a portion of Ophthalmic Ointment in a separator with 50 mL of ether. Extract with four 20-mL portions of *Buffer B.3*. Combine the aqueous extracts, and dilute with *Buffer B.3* to a suitable volume.

**Analysis:** Proceed as directed in the chapter. Dilute the *Sample solution* with *Buffer B.3* to obtain a *Test Dilution* having a neomycin concentration that is nominally equivalent to the median level of the standard.

**Acceptance criteria:** 90.0%–130.0%

#### • POLYMYXIN B

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

**Sample solution:** Shake a portion of Ophthalmic Ointment with 50 mL of ether in a separator. Extract with four 25-mL portions of *Buffer B.6*. Combine the aqueous 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 concentration that is nominally equivalent to the median level of the standard (10 Polymyxin B Units/mL). Add to each *Test Dilution* of the standard, a quantity of USP Neomycin Sulfate RS, dissolved in *Buffer B.6*, to obtain the same concentration of neomycin as in the *Test Dilution* of the sample.

**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

**Change to read:**

- **STERILITY TESTS** (71): ▲Meets the requirements▲USP39

**Delete the following:**

- ▲ **METAL PARTICLES IN OPHTHALMIC OINTMENTS** (751): It 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 Neomycin Sulfate RS  
USP Polymyxin B Sulfate RS