

Ophthalmic Ointment Monographs: Gentamicin 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).

Gentamicin Sulfate Ophthalmic Ointment

DEFINITION

Gentamicin Sulfate Ophthalmic Ointment contains the equivalent of NLT 90.0% and NMT 135.0% of the labeled amount of gentamicin.

IDENTIFICATION

Change to read:

• A. THIN-LAYER CHROMATOGRAPHY

Standard solution: 1 mg/mL of USP Gentamicin Sulfate RS in water

Sample solution: Nominally 1 mg/mL of gentamicin from Ophthalmic Ointment prepared as follows. Shake a quantity of Ophthalmic Ointment, containing nominally 5 mg of gentamicin, with a mixture of 200 mL of chloroform and 5 mL of water. Allow to separate, and filter the aqueous layer.

Chromatographic system

(See *Chromatography* <621>, *Thin-Layer Chromatography*.)

Adsorbent: 0.25-mm layer of chromatographic silica gel ▲^{USP39}

Application volume: 20 µL

Developing solvent system: Mix chloroform, methanol, and ammonium hydroxide (20:13:10). Allow to separate, and use the lower layer.

Analysis

Samples: *Standard solution* and *Sample solution*
Apply the *Standard solution* and the *Sample solution* to the plate. Place the plate in a chromatographic chamber, and develop the chromatogram in the *Developing solvent system* until the solvent front has moved three-fourths of the length of the plate. Remove the plate, air-dry, and expose it to vapors of iodine in a detection jar containing iodine crystals.

Acceptance criteria: The intensities and R_f values of the three principal spots of the *Sample solution* correspond to those of the *Standard solution*.

ASSAY

• PROCEDURE

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

Sample solution: Shake a portion of Ophthalmic Ointment containing nominally 1 mg of gentamicin with about 50 mL of ether in a separator, and extract with four 20-mL portions of *Buffer B.3* (see the chapter). Combine the buffer extracts, and dilute with *Buffer B.3*

to a suitable volume to obtain a *Test Dilution* with a gentamicin concentration that is nominally equivalent to the median level of the standard.

Analysis: Proceed as directed in the chapter.

Acceptance criteria: 90.0%–135.0%

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** <921>, *Method I*
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 Gentamicin Sulfate RS