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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

• **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

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%

SPECIFIC TESTS

• **Sterility Tests ⟨71⟩:** Meets the requirements

• **Other Requirements:** It meets the requirements for *Particulate and Foreign Matter* and *Container Contents* in *Ophthalmic Products—Quality Tests ⟨771⟩, Drug Product Quality, Universal Tests, Particulate and Foreign Matter* and *Container Contents*.

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in collapsible ophthalmic ointment tubes. Store at controlled room temperature.

• **USP Reference Standards ⟨11⟩**

USP Gentamicin Sulfate RS

Topic/Question	Contact	Expert Committee
GENTAMICIN SULFATE OPHTHALMIC OINTMENT	Ying Han Associate Science & Standards Liaison	BIO42020 Biologics Monographs 4 - Antibiotics

Chromatographic Database Information: Chromatographic Database

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