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Neomycin and Polymyxin B Sulfates and Dexamethasone Ophthalmic Ointment

DEFINITION

Neomycin and Polymyxin B Sulfates and Dexamethasone Ophthalmic Ointment contains the equivalent of NLT 90.0% and NMT 130.0% of the labeled amounts of neomycin and polymyxin B, and NLT 90.0% and NMT 110.0% of the labeled amount of dexamethasone ($C_{22}H_{29}FO_5$).

IDENTIFICATION

• **A. Thin-Layer Chromatographic Identification Test ⟨201BNP⟩:** Meets the requirements

• **B.** The retention time of the dexamethasone peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay* for *Dexamethasone*.

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%

• **Dexamethasone**

Mobile phase: Acetonitrile and water (1 in 3)

Diluent: Acetonitrile and methanol (1:1)

Standard solution: 60 µg/mL of USP Dexamethasone RS in *Diluent*

Sample solution: Nominally 60 µg/mL of dexamethasone from Ophthalmic Ointment in *Diluent* prepared as follows. Transfer a portion of Ophthalmic Ointment containing nominally 3 mg of dexamethasone to a suitable test tube, and add 15 mL of cyclohexane. Heat in a water bath at 75 ± 5° for 10 min. If the Ophthalmic Ointment is not fully dissolved, heat on a steam bath for about 30 s, place a cap on the test tube, and place on a vortex mixer until all solid material is dissolved. Pass with suction through a medium-porosity, sintered-glass filter. Rinse the test tube twice with 10-mL portions of cyclohexane, passing the rinsings through the filter, and discard the filtrate. Wash the filter with about 10 mL of a mixture of *Diluent*, and collect the filtrate in a 50-mL beaker. Wash the test tube and the filter with several 10-mL portions of *Diluent*, and combine the washings in the 50-mL beaker. Transfer the contents of the beaker to a 50-mL volumetric flask with the aid of *Diluent*, and dilute with *Diluent* to volume.

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 254 nm

Column: 4.6-mm × 25-cm; 5- to 10-µm packing L1

Flow rate: 2 mL/min

Injection volume: 10 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Relative standard deviation: NMT 1.5%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of dexamethasone ($C_{22}H_{29}FO_5$) in the portion of Ophthalmic Ointment taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

C_S = concentration of USP Dexamethasone RS in the *Standard solution* (µg/mL)

C_U = nominal concentration of dexamethasone in the *Sample solution* (µg/mL)

Acceptance criteria: 90.0%–110.0%

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.

• **USP Reference Standards ⟨11⟩**

USP Dexamethasone RS

USP Neomycin Sulfate RS

USP Polymyxin B Sulfate RS

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
NEOMYCIN AND POLYMYXIN B SULFATES AND DEXAMETHASONE OPHTHALMIC OINTMENT	Julie Zhang Associate Science & Standards Liaison	BIO42020 Biologics Monographs 4 - Antibiotics
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	BIO42020 Biologics Monographs 4 - Antibiotics

Chromatographic Database Information: Chromatographic Database

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