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Neomycin Sulfate and Dexamethasone Sodium Phosphate Ophthalmic Ointment

DEFINITION

Neomycin Sulfate and Dexamethasone Sodium Phosphate Ophthalmic Ointment is a sterile ointment containing Neomycin Sulfate and Dexamethasone Sodium Phosphate. It contains the equivalent of NLT 90.0% and NMT 135.0% of the labeled amount of neomycin, and the equivalent of NLT 90.0% and NMT 110.0% of the labeled amount of dexamethasone phosphate ($C_{22}H_{30}FO_8P$).

[Note—Where Neomycin Sulfate and Dexamethasone Sodium Phosphate Ophthalmic Ointment is prescribed without reference to the quantity of neomycin or dexamethasone phosphate contained therein, a product containing 3.5 mg of neomycin and 0.5 mg of dexamethasone phosphate per g shall be dispensed.]

IDENTIFICATION

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

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

ASSAY

• **Neomycin**

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

Sample solution: Shake a weighed portion of Ophthalmic Ointment in a separator with about 50 mL of ether, and 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%–135.0%

• **Dexamethasone Phosphate**

Buffer: 6.9 g/L of monobasic sodium phosphate

Mobile phase: Methanol and *Buffer* (52:48)

Diluent: Dissolve 0.29 g of dibasic sodium phosphate in 450 mL of water, and add 550 mL of alcohol.

Standard solution: 33 µg/mL of USP Dexamethasone Sodium Phosphate RS in *Diluent*. Prepare this solution freshly.

Sample solution: Nominally 30 µg/mL of dexamethasone phosphate, prepared as follows. Transfer a portion of Ophthalmic Ointment containing nominally 3 mg of dexamethasone phosphate to a suitable beaker. Add 65 mL of *Diluent*, and heat just to boiling. Pour the contents of the beaker into a separator containing 45 mL of isooctane. After shaking for 1 min, decant the lower layer into a 100-mL volumetric flask. Rinse the beaker with two 15-mL portions of *Diluent*, extracting the remaining isooctane in the separator with each portion, and decanting the lower layer from each extraction into the 100-mL volumetric flask. Dilute with *Diluent* to volume, and mix. Pass through a suitable filter.

Chromatographic system

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

Mode: LC

Detector: UV 254 nm

Column: 3.9-mm × 30-cm; 10-µm packing L1

Flow rate: 1.5 mL/min

Injection volume: 20 µL

System suitability

Sample: *Standard solution*

[Note—The retention time for dexamethasone phosphate is about 8.5 min.]

Suitability requirements

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Relative standard deviation: NMT 1.5%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of dexamethasone phosphate ($C_{22}H_{30}FO_8P$) in the portion of Ophthalmic Ointment taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (M_{r1}/M_{r2}) \times 100$$

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

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

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

M_{r1} = molecular weight of dexamethasone phosphate, 472.44

M_{r2} = molecular weight of dexamethasone sodium phosphate, 516.40

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 Sodium Phosphate RS

USP Neomycin Sulfate RS

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

Topic/Question	Contact	Expert Committee
NEOMYCIN SULFATE AND DEXAMETHASONE SODIUM PHOSPHATE 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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