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Neomycin Sulfate and Dexamethasone Sodium Phosphate Ophthalmic Solution

DEFINITION

Neomycin Sulfate and Dexamethasone Sodium Phosphate Ophthalmic Solution is a sterile, aqueous solution of Neomycin Sulfate and Dexamethasone Sodium Phosphate. It contains the equivalent of NLT 90.0% and NMT 130.0% of the labeled amount of neomycin, and the equivalent of NLT 90.0% and NMT 115.0% of the labeled amount of dexamethasone phosphate ($C_{22}H_{30}FO_8P$). It may contain one or more suitable buffers, dispersants, and preservatives.

[NOTE—Where Neomycin Sulfate and Dexamethasone Sodium Phosphate Ophthalmic Solution is prescribed, without reference to the amount of neomycin or dexamethasone phosphate contained therein, a product containing 3.5 mg/mL of neomycin and 1.0 mg/mL of dexamethasone phosphate shall be dispensed.]

IDENTIFICATION

• **A. THIN-LAYER CHROMATOGRAPHIC IDENTIFICATION TEST ⟨201BNP⟩:** Meets the requirements for neomycin

• **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⟩*.)

Analysis: Dilute an aliquot of Ophthalmic Solution with *Buffer B.3* to obtain a *Test Dilution* with a neomycin concentration that is nominally equivalent to the median level of the standard (1.0 µg/mL).

Acceptance criteria: 90.0%–130.0%

• **DEXAMETHASONE PHOSPHATE**

Solution A: 0.29 g/L of dibasic sodium phosphate

Solution B: 13.80 g/L of monobasic sodium phosphate

Mobile phase: Acetonitrile and *Solution B* (31:69)

Standard solution: 27 µg/mL of USP Dexamethasone Sodium Phosphate RS in *Solution A*. Pass through a filter of 1-µm or finer pore size.

Sample solution: Nominally 25 µg/mL of dexamethasone phosphate from Ophthalmic Solution in *Solution A* prepared as follows. Slowly dilute a portion of Ophthalmic Solution with *Solution A* to volume, mix, and pass through a suitable filter of 1-µm or finer pore size.

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: 1.3 mL/min

Injection volume: 50 µL

System suitability

Sample: *Standard solution*

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

Suitability requirements

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

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

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

r_U = peak area from the *Sample solution*

r_S = peak area 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%–115.0%

SPECIFIC TESTS

- **Sterility Tests ⟨71⟩:** Meets the requirements
- **pH ⟨791⟩:** 6.0–8.0

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in tight, light-resistant containers, and avoid exposure to excessive heat.
- **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 SOLUTION	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

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