

Status: Currently Official on 16-Feb-2025
Official Date: Official as of 01-Aug-2017
Document Type: USP Monographs
DocId: GUID-6B30953E-9A75-4F20-B791-EB54222E73B3_1_en-US
DOI: https://doi.org/10.31003/USPNF_M56228_01_01
DOI Ref: 7fg73

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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 $75 \pm 5^\circ$ 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](#)

Most Recently Appeared In:

Pharmacopeial Forum: Volume No. PF 39(5)

Current DocID: GUID-6B30953E-9A75-4F20-B791-EB54222E73B3_1_en-US

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