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Chloramphenicol and Polymyxin B Sulfate Ophthalmic Ointment

DEFINITION

Chloramphenicol and Polymyxin B Sulfate Ophthalmic Ointment contains NLT 90.0% and NMT 120.0% of the labeled amount of chloramphenicol ($C_{11}H_{12}Cl_2N_2O_5$) and NLT 90.0% and NMT 125.0% of the labeled amount of polymyxin B.

IDENTIFICATION

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

ASSAY

• **Chloramphenicol**

Mobile phase: Methanol, glacial acetic acid, and water (450:1:550)

Standard stock solution: 0.25 mg/mL of USP Chloramphenicol RS in methanol

Standard solution: 0.1 mg/mL of USP Chloramphenicol RS from the *Standard stock solution* in *Mobile phase*. Pass through a suitable filter, and use the clear filtrate.

Sample stock solution: Nominally 0.25 mg/mL of chloramphenicol prepared as follows. Transfer a portion of Ophthalmic Ointment containing nominally 25 mg of chloramphenicol to a suitable conical flask. Add 20 mL of cyclohexane, mix, and sonicate for 2 min. Add 60 mL of methanol. Filter this mixture, collecting the filtrate in a 100-mL volumetric flask. Wash the filter with methanol, collecting the washings in the volumetric flask. Dilute with methanol to volume. Transfer 50.0 mL of the resulting solution to a suitable round-bottom flask, and evaporate to dryness by rotating the flask under vacuum in a water bath at 35°. Dissolve the residue in 50.0 mL of methanol.

Sample solution: Nominally 0.1 mg/mL of chloramphenicol from the *Sample stock solution* in *Mobile phase*. Pass through a suitable filter, and use the clear filtrate.

Chromatographic system

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

Mode: LC

Detector: UV 280 nm

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

Flow rate: 1 mL/min

Injection volume: 10 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 1.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of chloramphenicol ($C_{11}H_{12}Cl_2N_2O_5$) in the portion of Ophthalmic Ointment taken:

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

r_U = peak height from the *Sample solution*

r_S = peak height from the *Standard solution*

C_S = concentration of USP Chloramphenicol RS in the *Standard solution* (mg/mL)

C_U = nominal concentration of chloramphenicol in the *Sample solution* (mg/mL)

P = potency of chloramphenicol in USP Chloramphenicol RS (µg/mg)

F = conversion factor, 0.001 mg/µg

Acceptance criteria: 90.0%–120.0%

• **Polymyxin B**

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

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Sample solution: Shake a portion of Ophthalmic Ointment containing nominally 5000 Polymyxin B Units with 50 mL of ether in a separator. Extract with four 20-mL portions of *Buffer B.6*. Combine the aqueous extracts in a 100-mL volumetric flask, and dilute with *Buffer B.6* to 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.

Acceptance criteria: 90.0%–125.0%

SPECIFIC TESTS

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

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

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in collapsible ophthalmic ointment tubes.

• **USP Reference Standards ⟨11⟩**

USP Chloramphenicol RS

USP Polymyxin B Sulfate RS

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

Topic/Question	Contact	Expert Committee
CHLORAMPHENICOL AND POLYMYXIN B SULFATE OPHTHALMIC OINTMENT	Julie Zhang Associate Science & Standards Liaison	BIO42020 Biologics Monographs 4 - Antibiotics

Chromatographic Database Information: Chromatographic Database

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