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Chloramphenicol Ophthalmic Ointment

DEFINITION

Chloramphenicol Ophthalmic Ointment contains NLT 90.0% and NMT 130.0% of the labeled amount of chloramphenicol ($C_{11}H_{12}Cl_2N_2O_5$).

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

PROCEDURE

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%–130.0%

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 Chloramphenicol RS](#)

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
CHLORAMPHENICOL OPHTHALMIC OINTMENT	Documentary Standards Support	SE2020 Simple Excipients
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SE2020 Simple Excipients

Chromatographic Database Information: [Chromatographic Database](#)

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