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Chlortetracycline Hydrochloride Ophthalmic Ointment

DEFINITION
Chlortetracycline Hydrochloride Ophthalmic Ointment contains NLT 90.0% and NMT 125.0% of the labeled amount of chlortetracycline hydrochloride ($C_{22}H_{23}ClN_2O_8 \cdot HCl$).

ASSAY

- **PROCEDURE**
(See [Antibiotics—Microbial Assays \(81\)](#).)
Sample solution: Shake a portion of Ophthalmic Ointment containing nominally 10 mg of chlortetracycline hydrochloride in a separator with 50 mL of [ether](#), and extract with four 20-mL portions of [0.01 N hydrochloric acid](#). Combine the aqueous extracts in a 100-mL volumetric flask, and dilute with [0.01 N hydrochloric acid](#) to volume.
Analysis: Proceed as directed in the chapter. Dilute the *Sample solution* with [water](#) to obtain a *Test Dilution* having a chlortetracycline hydrochloride 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* 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 Chlortetracycline Hydrochloride RS](#)

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

Topic/Question	Contact	Expert Committee
CHLORTETRACYCLINE HYDROCHLORIDE OPHTHALMIC OINTMENT	Ying Han Associate Science & Standards Liaison	BIO42020 Biologics Monographs 4 - Antibiotics

Chromatographic Database Information: [Chromatographic Database](#)

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