

Status: Currently Official on 14-Feb-2025
Official Date: Official as of 01-Dec-2023
Document Type: USP Monographs
DocId: GUID-202E916E-29A0-4F16-B972-21C90CA960AB_2_en-US
DOI: https://doi.org/10.31003/USPNF_M16959_02_01
DOI Ref: ed11v

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Chlortetracycline Hydrochloride Ointment

(This monograph has been updated to the current USP style. No revisions or changes to tests have been made.)

DEFINITION

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

ASSAY

• **PROCEDURE**

Standard: [USP Chlortetracycline Hydrochloride RS](#)

Sample stock solution: Use an accurately weighed quantity of Ointment, equivalent to about 30 mg of chlortetracycline hydrochloride, shaken in a separator with about 50 mL of [ether](#), and extracted with four 20-mL portions of 0.01 N [hydrochloric acid](#). Combine the aqueous extracts in a 100-mL volumetric flask, dilute with 0.01 N [hydrochloric acid](#) to volume, and mix.

Sample solution: Dilute the *Sample stock solution* quantitatively and stepwise with [water](#) to obtain a *Test Dilution* having a concentration assumed to be equal to the medium dose level of the *Standard*.

Analysis: Proceed as directed for chlortetracycline in [Antibiotics—Microbial Assays \(81\)](#).

Acceptance criteria: 90.0%–125.0%

PERFORMANCE TESTS

- **MINIMUM FILL (755):** Meets the requirements

SPECIFIC TESTS

- **WATER DETERMINATION (921), Method I**

Analysis: Use 20 mL of a mixture of [methanol](#) and [toluene](#) (3:7) in place of methanol in the titration vessel.

Acceptance criteria: NMT 0.5%

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in collapsible tubes or in well-closed, light-resistant containers.
- **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 OINTMENT	Jennifer Tong Sun Senior Scientist II	BIO42020 Biologics Monographs 4 - Antibiotics

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

Pharmacopeial Forum: Volume No. Information currently unavailable

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