

Status: Currently Official on 16-Feb-2025
 Official Date: Official as of 01-Aug-2023
 Document Type: USP Monographs
 DocId: GUID-BB946573-43CF-4DF6-B621-F53080A4E6B6_2_en-US
 DOI: https://doi.org/10.31003/USPNF_M81839_02_01
 DOI Ref: a15yd

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Tetracycline Hydrochloride Ointment

DEFINITION

Tetracycline Hydrochloride Ointment contains NLT 90.0% and NMT 125.0% of the labeled amount of tetracycline hydrochloride ($C_{22}H_{24}N_2O_8 \cdot HCl$).

IDENTIFICATION

Change to read:

• **A.** (USP 1-Aug-2023) The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

Add the following:

• **B.** The UV spectrum of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay. (USP 1-Aug-2023)

ASSAY

Change to read:

PROCEDURE

▲ **Diluent:** [Dimethylformamide](#) and 0.1 M [ammonium oxalate](#) (27:68)

Mobile phase: [Dimethylformamide](#), 0.1 M [ammonium oxalate](#), and 0.2 M [ammonium phosphate, dibasic](#) (27:68:5). If necessary, adjust with 3 N [ammonium hydroxide](#) or 3 N [phosphoric acid](#) to a pH of 7.6–7.7.

System suitability solution: 100 µg/mL of [USP Tetracycline Hydrochloride RS](#) and 25 µg/mL of [USP 4-Epianhydrotetracycline Hydrochloride RS](#) in *Diluent* ▲ (USP 1-Aug-2023)

Standard stock solution: 1 mg/mL of [USP Tetracycline Hydrochloride RS](#) in [methanol](#)

Standard solution: 0.12 mg/mL of [USP Tetracycline Hydrochloride RS](#) from *Standard stock solution*, in *Diluent*

Sample stock solution: Nominally 3 mg/mL of tetracycline hydrochloride prepared as follows. Transfer a weighed portion of Ointment, equivalent to 300 mg of tetracycline hydrochloride, to a glass-stoppered conical flask. Add 20 mL of [cyclohexane](#) and shake. Add 35 mL of [methanol](#), and sonicate for about 20 min. Filter this solution into a 100-mL volumetric flask, and rinse the sides of the conical flask with 40 mL of [methanol](#), passing the rinsing through the filter into the volumetric flask. Dilute with [methanol](#) to volume.

Sample solution: Nominally 0.12 mg/mL of tetracycline hydrochloride from the *Sample stock solution*, in *Diluent*

▲ Chromatographic system

(See [Chromatography \(621\)](#), [System Suitability](#).)

Mode: LC

Detector: UV 280 nm. For *Identification B*, use a diode array detector in the range of 200–400 nm.

Columns

Guard: 4.6-mm × 3-cm; 10-µm packing [L7](#)

Analytical: 4.6-mm × 25-cm; 5- to 10-µm packing [L7](#)

Flow rate: 2 mL/min

Injection volume: 20 µL

System suitability

Samples: *System suitability solution* and *Standard solution*

[NOTE—The relative retention times for 4-epianhydrotetracycline and tetracycline are 0.9 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 1.2 between 4-epianhydrotetracycline and tetracycline, *System suitability solution*

Relative standard deviation: NMT 1.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of tetracycline hydrochloride ($C_{22}H_{24}N_2O_8 \cdot HCl$) in the portion of Ointment taken:

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

- r_U = peak response of tetracycline from the *Sample solution*
- r_S = peak response of tetracycline from the *Standard solution*
- C_S = concentration of [USP Tetracycline Hydrochloride RS](#) in the *Standard solution* (mg/mL)
- C_U = nominal concentration of tetracycline hydrochloride in the *Sample solution* (mg/mL)
- P = potency of [USP Tetracycline Hydrochloride RS](#) (µg/mg)
- F = conversion factor, 0.001 mg/µg▲ (USP 1-Aug-2023)

Acceptance criteria: 90.0%–125.0%

PERFORMANCE TESTS

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

SPECIFIC TESTS

- **WATER DETERMINATION (921), Method I**
Analysis: 20 mL of a mixture of [toluene](#) and [methanol](#) (70:30) instead of [methanol](#) in the titration vessel
Acceptance criteria: NMT 1.0%

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in well-closed containers, preferably at controlled room temperature.

Change to read:

- **USP REFERENCE STANDARDS (11).**
[USP 4-Epianhydrotetracycline Hydrochloride RS](#)
▲(4*R*,4*aS*,12*aS*)-4-(Dimethylamino)-3,10,11,12*a*-tetrahydroxy-6-methyl-1,12-dioxo-1,4,4*a*,5,12,12*a*-hexahydrotetracene-2-carboxamide hydrochloride.
 $C_{22}H_{22}N_2O_7 \cdot HCl$ 462.88▲ (USP 1-Aug-2023)
[USP Tetracycline Hydrochloride RS](#)

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

Topic/Question	Contact	Expert Committee
TETRACYCLINE HYDROCHLORIDE OINTMENT	Documentary Standards Support	SM12020 Small Molecules 1
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM12020 Small Molecules 1

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

Pharmacopeial Forum: Volume No. 48(1)

Current DocID: GUID-BB946573-43CF-4DF6-B621-F53080A4E6B6_2_en-US

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