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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

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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*,4a*S*,12a*S*)-4-(Dimethylamino)-3,10,11,12a-tetrahydroxy-6-methyl-1,12-dioxo-1,4,4a,5,12,12a-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

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