

Tetracycline Hydrochloride Capsules

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

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.
- B.** The UV spectrum of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

ASSAY

- PROCEDURE**
Solution A: Dilute 1 mL of [phosphoric acid](#) with [water](#) to 1 L.
Solution B: [Acetonitrile](#)
Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	85	15
7.5	60	40
7.6	85	15
10	85	15

System suitability solution: 25 µg/mL each of [USP Anhydrotetracycline Hydrochloride RS](#), [USP 4-Epianhydrotetracycline Hydrochloride RS](#), [USP Epitetracycline Hydrochloride RS](#), and [USP Tetracycline Hydrochloride RS](#) in *Solution A*

Standard solution: 100 µg/mL of [USP Tetracycline Hydrochloride RS](#) in *Solution A*. [NOTE—If needed, dilute the *Standard solution* concentration for *Identification B*.]

Sample solution: Nominally equivalent to 100 µg/mL of tetracycline hydrochloride in *Solution A* from NLT 20 Capsules prepared as follows. Transfer a portion of Capsule contents, equivalent to 25 mg of tetracycline hydrochloride, to a 250-mL volumetric flask. Dissolve with the aid of sonication, and dilute with *Solution A* to volume. Pass through a syringe filter of 0.22-µm pore size and discard the first 2 mL of the filtrate. [NOTE—If needed, dilute the *Sample solution* concentration for *Identification B*.]

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 220–400 nm.

Column: 4.6-mm × 15-cm; 3-µm packing [L1](#)

Temperatures

- Autosampler:** 4°
- Column:** 50°

Flow rate: 1.0 mL/min

Injection volume: 10 µL

System suitability

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

[NOTE—The relative retention times for epitetracycline, tetracycline, 4-epianhydrotetracycline, and anhydrotetracycline are 0.9, 1.0, 1.6, and 1.8, respectively.]

Suitability requirements

Tailing factor: NMT 1.5, *Standard solution*

Resolution: NLT 2.5 between epitetracycline and tetracycline; NLT 2.5 between anhydrotetracycline and 4-epianhydrotetracycline, *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 Capsules 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* (µg/mL)

C_U = nominal concentration of tetracycline hydrochloride in the *Sample solution* (µg/mL)

P = potency of [USP Tetracycline Hydrochloride RS](#) (µg/mg)

F = correction factor, 0.001 mg/µg

Acceptance criteria: 90.0%–125.0%

PERFORMANCE TESTS

Change to read:

- [DISSOLUTION \(711\)](#)

Test 1

Medium: [Water](#); 900 mL

Apparatus 2: 75 rpm. Maintain a distance of 45 ± 5 mm between the blade and the inside bottom of the vessel.

Times

For Capsules labeled to contain 250 mg: 60 min

For Capsules labeled to contain 500 mg: 90 min

Standard solution: A known concentration of [USP Tetracycline Hydrochloride RS](#) in *Medium*

Sample solution: Pass a portion of the solution under test through a suitable filter. Dilute with *Medium*, if necessary.

Instrumental conditions

▲(See [Ultraviolet-Visible Spectroscopy \(857\)](#).)▲ (IRA 1-May-2022)

Mode: UV

Analytical wavelength: 276 nm

▲**Analysis:**

Samples: *Standard solution* and *Sample solution*

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

$$\text{Result} = (A_U/A_S) \times (C_S/L) \times V \times D \times 100$$

A_U = absorbance of the *Sample solution*

A_S = absorbance of the *Standard solution*

C_S = concentration of [USP Tetracycline Hydrochloride RS](#) in the *Standard solution* (mg/mL)

L = label claim (mg/Capsule)

V = volume of *Medium*, 900 mL

D = dilution factor for the *Sample solution*, if applicable▲ (IRA 1-May-2022)