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Mefloquine Hydrochloride Tablets

DEFINITION
Mefloquine Hydrochloride Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of mefloquine hydrochloride ($C_{17}H_{16}F_6N_2O \cdot HCl$).

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*.

Change to read:

• **B.** ▲**Spectroscopic Identification Tests ⟨197⟩, *Ultraviolet-Visible Spectroscopy*: 197U**▲ (CN 1-May-2020)

Diluent, Standard solution, and **Sample solution:** Proceed as directed in the *Assay*.

Blank: *Diluent*

ASSAY
• **Procedure**

Buffer: 2.7 g/L of monobasic potassium phosphate. Adjust with phosphoric acid to a pH of 3.0 ± 0.1.

Diluent: Methanol and water (23:27)

Mobile phase: Methanol, acetonitrile, and *Buffer* (13:10:27)

Standard solution: 0.05 mg/mL of USP Mefloquine Hydrochloride RS in *Diluent*

Sensitivity solution: 0.025 µg/mL of USP Mefloquine Hydrochloride RS in *Diluent*

Sample stock solution: Transfer a suitable number of Tablets to a volumetric flask, dilute with methanol (approximately 80% of the total volume), shake for 30 min, allow to sit for 1 h, and dilute with methanol to volume to obtain a solution having a concentration of 2.5 mg/mL of mefloquine hydrochloride.

Sample solution: Nominally 0.05 mg/mL of mefloquine hydrochloride in *Diluent* from the *Sample stock solution*

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 222 nm

Column: 4.6-mm × 15-cm; 5-µm packing L68

Flow rate: 1 mL/min

Injection size: 10 µL

System suitability

Samples: *Standard solution* and *Sensitivity solution*

Suitability requirements

Column efficiency: NLT 4000 theoretical plates, *Standard solution*

Tailing factor: NMT 1.5, *Standard solution*

Signal-to-noise ratio: NLT 5, *Sensitivity solution*

Relative standard deviation: NMT 2.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of mefloquine hydrochloride ($C_{17}H_{16}F_6N_2O \cdot HCl$) in the portion of Tablets taken:

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

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

C_S = concentration of USP Mefloquine Hydrochloride RS in the *Standard solution* (mg/mL)

C_U = nominal concentration of mefloquine hydrochloride in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0%

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PERFORMANCE TESTS

• **Dissolution** ⟨711⟩

Test 1

Medium: 0.1 N hydrochloric acid; 900 mL

Apparatus 2: 50 rpm

Time: 30 min

Standard stock solution: 0.2 mg/mL of USP Mefloquine Hydrochloride RS in *Medium*. A small amount of methanol, not exceeding 5% of the final volume, may be used to help solubilize mefloquine.

Standard solution: 0.04 mg/mL of USP Mefloquine Hydrochloride RS in *Medium* from the *Standard stock solution*

Sample solution: Dilute a portion of the solution under test with *Medium* (1:5), and pass a portion through a suitable filter of 0.8-µm pore size.

Instrumental conditions

(See *Ultraviolet-Visible Spectroscopy* ⟨857⟩.)

Mode: UV

Analytical wavelength: 285 nm

Cell length: 1 cm

Blank: *Medium*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of mefloquine hydrochloride ($C_{17}H_{16}F_6N_2O \cdot HCl$) dissolved:

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

A_U = absorbance from the *Sample solution*

A_S = absorbance from the *Standard solution*

C_S = concentration of USP Mefloquine Hydrochloride RS in the *Standard solution* (mg/mL)

L = label claim (mg/Tablet)

D = dilution factor of the *Sample solution*

V = volume of *Medium*, 900 mL

Tolerances: NLT 80% (*Q*) of the labeled amount of mefloquine hydrochloride ($C_{17}H_{16}F_6N_2O \cdot HCl$) is dissolved.

Test 2: If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 2*.

Medium: 0.01 N hydrochloric acid; 900 mL

Apparatus 2: 50 rpm

Time: 30 min

Standard solution: 0.278 mg/mL of USP Mefloquine Hydrochloride RS in *Medium*. A small amount of methanol, not exceeding 2.5% of the final volume, may be used to help solubilize mefloquine.

Sample solution: Pass a portion of the solution under test through a suitable filter.

Instrumental conditions

(See *Ultraviolet-Visible Spectroscopy* ⟨857⟩.)

Mode: UV

Analytical wavelength: 284 nm

Cell length: 0.2 cm

Blank: *Medium*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of mefloquine hydrochloride ($C_{17}H_{16}F_6N_2O \cdot HCl$) dissolved:

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

A_U = absorbance from the *Sample solution*

A_S = absorbance from the *Standard solution*

C_S = concentration of USP Mefloquine Hydrochloride RS in the *Standard solution* (mg/mL)

L = label claim (mg/Tablet)

V = volume of *Medium*, 900 mL

Tolerances: NLT 75% (*Q*) of the labeled amount of mefloquine hydrochloride ($C_{17}H_{16}F_6N_2O \cdot HCl$) is dissolved.

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• **Uniformity of Dosage Units ⟨905⟩:** Meet the requirements

IMPURITIES

• **Organic Impurities**

Buffer, Diluent, Mobile phase, Standard solution, Sensitivity solution, Sample stock solution, Sample solution, Chromatographic system, and **System suitability:** Proceed as directed in the *Assay*.

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of each impurity in the portion of Tablets taken:

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

r_U = peak response of each impurity from the *Sample solution*

r_S = peak response of mefloquine hydrochloride from the *Standard solution*

C_S = concentration of USP Mefloquine Hydrochloride RS in the *Standard solution* (mg/mL)

C_U = nominal concentration of mefloquine hydrochloride in the *Sample solution* (mg/mL)

Acceptance criteria: See *Table 1*.

[Note—Do not include the threo isomer, a process impurity monitored in the drug substance, in the calculation of total impurities. Disregard any peak less than 0.05%.]

Table 1

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Specified (unidentified)	0.67	0.15
Specified (unidentified)	0.70	0.15
threo-Mefloquine (DL-*threo*-α-2-piperidyl-2,8-bis(trifluoromethyl)-4-quinolinemethanol)	0.75	—
Specified (unidentified)	0.84	0.25
Mefloquine hydrochloride	1.0	—
Any other unknown individual impurity	—	0.15
Total impurities	—	0.50

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight, light-resistant containers. Store at controlled room temperature.

• **Labeling:** When more than one *Dissolution* test is given, the labeling states the *Dissolution* test used only if *Test 1* is not used.

• **USP Reference Standards ⟨11⟩**
USP Mefloquine Hydrochloride RS

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
MEFLOQUINE HYDROCHLORIDE TABLETS	Documentary Standards Support	SM12020 Small Molecules 1

Chromatographic Database Information: Chromatographic Database

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