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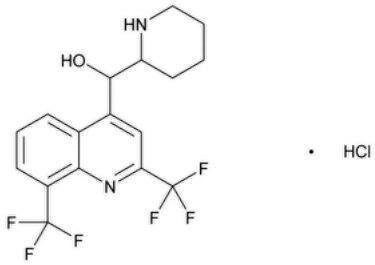
Mefloquine Hydrochloride



• HCl

$C_{17}H_{16}F_6N_2O \cdot HCl$ 414.77

4-Quinolinemethanol, α-2-piperidinyl-2,8-bis(trifluoro methyl)-, monohydrochloride, (*R**,*S**)- (±)-;

DL-*erythro*-α-2-Piperidyl-2,8-bis(trifluoromethyl)-4-quin olinemethanol monohydrochloride CAS RN®: 51773-92-3; UNII: 5Y9L3636O3.

DEFINITION

Mefloquine Hydrochloride contains NLT 98.0% and NMT 102.0% of $C_{17}H_{16}F_6N_2O \cdot HCl$, calculated on the anhydrous basis.

IDENTIFICATION

Change to read:

• **A.** ▲**Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*: 197K**▲ (CN 1-May-2020)

• **B.** **Identification Tests—General, *Chloride*⟨191⟩**

ASSAY

• **Procedure**

Solution A: 1.5 g/L of sodium hydrogen sulfate in water

Mobile phase: Dissolve 1 g of tetraheptylammonium bromide in a 1000-mL mixture of acetonitrile, methanol, and *Solution A* (2:1:2).

System suitability solution: 4 µg/mL each of USP Mefloquine Hydrochloride RS and USP Mefloquine Related Compound A RS in *Mobile phase*

Standard solution: 0.2 mg/mL of USP Mefloquine Hydrochloride RS in *Mobile phase*

Sample solution: 0.2 mg/mL of Mefloquine Hydrochloride in *Mobile phase*

Chromatographic system

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

Mode: LC

Detector: UV 280 nm

Guard column: 4-mm × 3-cm; C18 (recommended)

Column: 4.0-mm × 25-cm; 5-µm packing L1

Column temperature: 25°

Flow rate: 0.8 mL/min

Injection size: 20 µL

System suitability

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

[Note—The relative retention times for mefloquine related compound A and mefloquine are about 0.7 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 2.0 between mefloquine related compound A and mefloquine, *System suitability solution*

Tailing factor: NMT 2.0, *Standard solution*

Relative standard deviation: NMT 1.0%, *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 Mefloquine Hydrochloride taken:

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

r_U = peak response of mefloquine from the *Sample solution*

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

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

C_U = concentration of Mefloquine Hydrochloride in the *Sample solution* (mg/mL)

Acceptance criteria: 98.0%–102.0% on the anhydrous basis

IMPURITIES

• **Residue on Ignition ⟨281⟩:** NMT 0.1%

• **Organic Impurities**

Mobile phase: Dissolve 1 g of tetraheptylammonium bromide in a 1-L mixture of a 1.5-g/L solution of sodium hydrogen sulfate, acetonitrile, and methanol (2:2:1).

System suitability solution: 4 µg/mL each of USP Mefloquine Hydrochloride RS and USP Mefloquine Related Compound A RS in *Mobile phase*. [Note—Mefloquine related compound A is *threo*-mefloquine.]

Sample stock solution: 4 mg/mL of Mefloquine Hydrochloride in *Mobile phase*

Sample solution: 4 µg/mL from the *Sample stock solution* in *Mobile phase*

Chromatographic system

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

Mode: LC

Detector: UV 280 nm

Guard column: 4-mm × 2.5-cm; 5-µm packing L1

Column: 4.0-mm × 25-cm; 5-µm packing L1

Flow rate: 0.8 mL/min

Injection size: 20 µL. [Note—Equilibrate the column with *Mobile phase* at a flow rate of 0.8 mL/min for 30 min.]

System suitability

Sample: *System suitability solution*

[Note—The relative retention times for mefloquine related compound A and mefloquine are about 0.7 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 2.0 between mefloquine related compound A and mefloquine

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Sample stock solution* and *Sample solution*

Record the chromatogram for a time that is 10 times the retention time of the main peak.

Acceptance criteria: The response of the mefloquine related compound A peak in the *Sample stock solution* is NMT twice the area of the main peak of the *Sample solution* (0.2%). The response of any other individual peak, other than the main peak of the *Sample stock solution*, is NMT that of the main peak of the *Sample solution* (0.1%); and the sum of the responses of any such peaks of the *Sample stock solution* is NMT five times the response of the main peak of the *Sample solution* (0.5%). [Note—Exclude the main peak and any other peak producing a response of less than 0.2 times (0.02%) the main peak of the *Sample solution*.]

SPECIFIC TESTS

• **Optical Rotation, *Specific Rotation*⟨781S⟩**

Sample solution: 50 mg/mL in methanol

Acceptance criteria: −0.2° to +0.2°

• **Water Determination, *Method I*⟨921⟩:** NMT 3.0%

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight, light-resistant containers. Store between 15° and 30°.

• **USP Reference Standards ⟨11⟩**

USP Mefloquine Hydrochloride RS

USP Mefloquine Related Compound A RS

threo-Mefloquine.

$C_{17}H_{16}F_6N_2O \cdot HCl$ 414.78

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

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

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 35(5)
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