

BRIEFING

Mefloquine Hydrochloride Tablets. This monograph has been posted on the USP Non-U.S. Standards Web page for review and public comment for more than 90 days. No comments were received. The MD-AA Expert Committee has approved the monograph as an Authorized USP Non-U.S. Standard.

The TLC procedure used in the test for *Organic Impurities* for mefloquine is based on analysis performed with a Silica Gel GF TLC plate. The approximate chromatographic retardation factor for mefloquine is 0.6.

(MD-AA: L. Santos, B. Davani. BPC: M. Marques.) RTS—
C54651

Mefloquine Hydrochloride Tablets

v.1 Authorized September 1, 2009

DEFINITION

Mefloquine Hydrochloride Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of mefloquine (C₁₇H₁₆F₆N₂O).

IDENTIFICATION

• A. ULTRAVIOLET ABSORPTION (197U)

Sample solution: Proceed as directed in the *Assay*.

Medium: Methanol

Acceptance criteria: Absorptivities at 283 nm do not differ by more than 2.0%.

• B. THIN-LAYER CHROMATOGRAPHIC IDENTIFICATION TEST (201)

Standard solution: 11 mg/mL of USP Mefloquine Hydrochloride RS in methanol

Sample solution: Transfer an equivalent to 250 mg from powdered Tablets to a 25-mL volumetric flask. Add 10 mL of methanol, and sonicate with intermittent swirling to obtain uniform dispersion. Dilute with methanol to volume, centrifuge, and use the clear supernatant.

Application volume: 20 µL

Developing solvent: Toluene, dehydrated alcohol, 25% ammonia water (35:15:1)

ASSAY

• PROCEDURE

Standard solution: 0.025 mg/mL of USP Mefloquine Hydrochloride RS in methanol

Sample stock solution: Transfer an equivalent to 50 mg of mefloquine from finely powdered Tablets (NLT 10) to a 100-mL volumetric flask. Add 70 mL of methanol, and sonicate with intermittent swirling to obtain uniform dispersion. Dilute with methanol to volume, and mix. Pass a portion of the solution under test through a suitable 0.45-µm filter.

Sample solution: 0.025 mg/mL of mefloquine in methanol

Spectrometric conditions

(See *Spectrophotometry and Light-Scattering* (851).)

Mode: UV absorption spectroscopy

Analytical wavelength: UV 283 nm

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of C₁₇H₁₆F₆N₂O in the portion of Tablets taken:

$$\text{Result} = (A_U/A_S) \times (C_S/C_U) \times (M_1/M_2) \times 100$$

A_U = absorbance of mefloquine from the *Sample solution*

A_S = absorbance of mefloquine from the *Standard solution*

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

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

M₁ = molecular weight of mefloquine, 378.28

M₂ = molecular weight of mefloquine hydrochloride, 414.78

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

• DISSOLUTION (711)

Medium: Simulated gastric fluid TS, without pepsin; 900 mL

Apparatus 2: 100 rpm

Time: 60 min

Standard solution: USP Mefloquine Hydrochloride RS in *Medium*

Sample solution: Pass a portion of the solution under test through a suitable 0.45-µm filter. Dilute with *Medium* to a concentration similar to that of the *Standard solution*.

Spectrometric conditions

(See *Spectrophotometry and Light-Scattering* (851).)

Mode: UV absorption spectroscopy

Analytical wavelength: UV 283 nm

Analysis

Calculate the percentage of C₁₇H₁₆F₆N₂O dissolved:

$$\text{Result} = (A_U/A_S) \times (C_S/L) \times (M_1/M_2) \times D \times V \times 100$$

A_U = absorbance of mefloquine from the *Sample solution*

A_S = absorbance of mefloquine from the *Standard solution*

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

L = label claim (mg/Tablet)

M₁ = molecular weight of mefloquine, 378.28

M₂ = molecular weight of mefloquine hydrochloride, 414.78

D = dilution factor of the solution under test

V = volume of *Medium*, 900 mL

Tolerances: NLT 80% (Q) of the labeled amount of C₁₇H₁₆F₆N₂O is dissolved.

• **UNIFORMITY OF DOSAGE UNITS (905):** Meet the requirements for *Weight Variation*

IMPURITIES

Organic Impurities

• PROCEDURE

Standard solution: 11 mg/mL USP Mefloquine Hydrochloride RS in methanol

Sample solution: Transfer an equivalent to 250 mg of mefloquine from finely powdered Tablets to a 25-mL volumetric flask. Add about 10 mL of methanol, and sonicate with intermittent swirling to obtain uniform dispersion. Dilute with methanol to volume, and mix.

Chromatographic system

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

Mode: TLC

Adsorbent: 0.25-mm layer of chromatographic silica gel

Application volume: 20 µL

Developing solvent: Toluene, dehydrated alcohol, 25% ammonia water (35:15:1)

Detector: Short-wavelength UV light

Analysis

Samples: *Standard solution* and *Sample solution*
Examine the plate using short-wavelength UV light. Estimate the percentage of all secondary spots observed in the chromatograms from the *Sample solution* by comparing each spot with the principal spots from the chromatograms of the *Standard solution*. The approximate R_f value for mefloquine is 0.6.

Acceptance criteria

Individual impurities: NMT 0.5%

Total impurities: NMT 1.0%

ADDITIONAL REQUIREMENTS

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

• **USP REFERENCE STANDARDS (11)**
USP Mefloquine Hydrochloride RS