Mefloquine Hydrochloride Tablets

DEFINITION
Mefloquine Hydrochloride Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of mefloquine (C_{17}H_{16}F_{6}N_{2}O).

PROCEDURE
• ASSAY

B. THIN-LAYER CHROMATOGRAPHIC IDENTIFICATION TEST

1. Ultraviolet Absorption (197U)
   - Sample solution: Proceed as directed in the Assay.
   - Acceptance criteria: Absorbivities at 283 nm do not differ by more than 2.0%.

2. 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)
   - Analysis
     - Procedure
       - Standard solution: 0.025 mg/mL of USP Mefloquine Hydrochloride RS in methanol
       - Sample stock solution: Transfer an equivalent to 11 mg/mL USP Mefloquine Hydrochloride RS in methanol
       - 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
         - Analytical wavelength: UV 283 nm

   - Analysis
     - Individual impurities: NMT 0.5%
     - Total impurities: NMT 1.0%