bring the Reference Standard into solution prior to dilution with water. Prepare this *Standard stock solution* fresh daily.]

Standard solution—Pipet a 20-mL aliquot of *Standard stock solution* into a 1 L volumetric flask. Add 40 mL of *Sodium lauryl sulfate stock solution*, and dilute with water to volume. This solution is stable for up to 7 days.

Test solution—Withdraw 15 mL of the solution under test, and filter, discarding the first 5 mL of the filtrate.

Mobile phase—Prepare a filtered and degassed solution of acetonitrile and water (60:40). Make adjustments if necessary (see *System Suitability* under *Chromatography* ⟨621⟩).

Chromatographic system (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 254-nm detector and a 4-mm × 8-cm column that contains packing L7. The flow rate is about 1.5 mL per minute. Chromatograph the *Standard solution*, and record the peak responses as directed for *Procedure:* the tailing factor for the analyte peak is not more than 1.2; and the relative standard deviation for replicate injections is not more than 2.0%.

Procedure—Separately inject equal volumes (about 20 µL) of the *Standard solution* and the *Test solution* into the chromatograph, record the chromatograms, and measure the responses for the major peaks. Calculate the percentage of $C_{24}H_{34}O_4$ dissolved from the peak responses so obtained.

Tolerances—Not less than 50% *(Q)* of the labeled amount of $C_{24}H_{34}O_4$ is dissolved in 45 minutes.

Uniformity of dosage units ⟨905⟩: meet the requirements.

Procedure for content uniformity—Dissolve an accurately weighed portion of USP Medroxyprogesterone Acetate RS in a mixture of alcohol and water (3:1) to obtain a solution having a known concentration of about 15 µg per mL. Transfer 1 Tablet to a volumetric flask, add a mixture of alcohol and water (3:1) to volume, and shake for about 15 minutes. Filter, and quantitatively dilute a portion of the filtrate as required to obtain a final solution containing about 15 µg per mL. Concomitantly determine the absorbances of this solution and the Standard solution in 1-cm cells at the wavelength of maximum absorbance at about 242 nm. Calculate the quantity, in mg, of $C_{24}H_{34}O_4$ in the Tablet taken by the formula:

$$(T/D)C(A_U / A_S)$$

in which T is the labeled quantity, in mg, of medroxyprogesterone acetate in the Tablet; D is the concentration, in µg per mL, of medroxyprogesterone acetate in the solution from the Tablet; C is the concentration, in µg per mL; of USP Medroxyprogesterone Acetate RS in the Standard solution, and A_U and A_S are the absorbances of the solution from the Tablet and the Standard solution, respectively.

Assay—

Mobile phase, *Standard preparation*, and *Chromatographic system*—Prepare as directed in the *Assay* under *Medroxyprogesterone Acetate*.

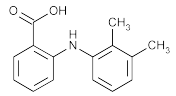
Assay preparation—Weigh and finely powder not fewer than 20 Tablets. Weigh accurately a portion of the powder, equivalent to about 25 mg of medroxyprogesterone acetate, into a 50-mL glass centrifuge tube. Pipet 25 mL of acetonitrile into the tube, shake to wet the powder thoroughly, and sonicate for not less than 10 minutes, and centrifuge. Use the clear supernatant as the *Assay preparation*.

Procedure—Proceed as directed for *Procedure* in the *Assay* under *Medroxyprogesterone Acetate*. Calculate the quantity, in mg, of medroxyprogesterone acetate ($C_{24}H_{34}O_4$) in the portion of Tablets taken by the formula:

$$25C(r_U / r_S)$$

in which C is the concentration, in mg per mL, of USP Medroxyprogesterone Acetate RS in the *Standard preparation*; and r_U and r_S are the peak responses obtained from the *Assay preparation* and the *Standard preparation,* respectively.

Mefenamic Acid



$C_{15}H_{15}NO_2$ 241.29
Benzoic acid, 2-(2,3-dimethylphenyl)amino-.
N-2,3-Xylylanthranilic acid [61-68-7].

» Mefenamic Acid contains not less than 98.0 percent and not more than 102.0 percent of $C_{15}H_{15}NO_2$, calculated on the dried basis.

Packaging and storage—Preserve in tight, light-resistant containers.

USP Reference standards ⟨11⟩**—**
USP Mefenamic Acid RS

Identification—

A: *Infrared Absorption* ⟨197K⟩.

B: The retention time of the major peak in the chromatogram of the *Assay preparation* corresponds to that in the chromatogram of the *Standard preparation*, as obtained in the *Assay*.

Loss on drying ⟨731⟩**—**Dry it at 105° for 4 hours: it loses not more than 1.0% of its weight.

Residue on ignition ⟨281⟩: not more than 0.1%.

Heavy metals, *Method II* ⟨231⟩**:** 0.002%.

Chromatographic purity—

Buffer solution, Mobile phase, and *Chromatographic system*—Proceed as directed in the *Assay*.

Standard solution—Dissolve an accurately weighed quantity of USP Mefenamic Acid RS in *Mobile phase* to obtain a solution having a known concentration of about 10 µg per mL.

Test solution—Transfer about 100 mg of Mefenamic Acid, accurately weighed, to a 100-mL volumetric flask, dissolve in and dilute with *Mobile phase* to volume, and mix.

Procedure—Separately inject equal volumes (about 10 µL) of the *Standard solution* and the *Test solution* into the chromatograph, record the chromatograms, and measure the responses for the major peaks. Calculate the percentage of each impurity in the portion of Mefenamic Acid taken by the formula:

$$100(C_S / C_U)(r_i / r_S)$$

in which C_S is the concentration, in µg per mL, of USP Mefenamic Acid RS in the *Standard solution;* C_U is the concentration, in µg per mL, of Mefenamic Acid in the *Test solution;* r_i is the peak response for each impurity obtained from the *Test solution;* and r_S is the peak response for mefenamic acid obtained from the *Standard solution:* not more than 0.1% of any individual impurity is found; and not more than 0.5% of total impurities is found.

Assay—

Buffer solution—Prepare a 50 mM solution of monobasic ammonium phosphate, and adjust with 3 M ammonium hydroxide to a pH of 5.0.

Mobile phase—Prepare a filtered and degassed mixture of acetonitrile, *Buffer solution*, and tetrahydrofuran (23:20:7). Make adjustments if necessary (see *System Suitability* under *Chromatography* ⟨621⟩).

Standard preparation—Dissolve an accurately weighed quantity of USP Mefenamic Acid RS in *Mobile phase*, and dilute quantitatively, and stepwise if necessary, with *Mobile phase* to obtain a solution having a known concentration of about 0.2 mg per mL.

Assay preparation—Transfer about 100 mg of Mefenamic Acid, accurately weighed, to a 500-mL volumetric flask, dissolve in and dilute with *Mobile phase* to volume, and mix.

Chromatographic system (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 254-nm detector and a 4.6-mm × 25-cm column that contains packing L1. The flow rate is about 1 mL per minute. Chromatograph the *Standard preparation*, and record the peak responses as directed for *Procedure:* the column efficiency is not less than 8200 theoretical plates; the tailing factor for the analyte peak is not more than 1.6; and the relative standard deviation for replicate injections is not more than 1.0%.

Procedure—Separately inject equal volumes (about 10 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the responses for the major peaks. Calculate the quantity, in mg, of $C_{15}H_{15}NO_2$ in the portion of Mefenamic Acid taken by the formula:

$$500C(r_U / r_S)$$

in which C is the concentration, in mg per mL, of USP Mefenamic Acid RS in the *Standard preparation;* and r_U and r_S are the mefenamic acid peak responses obtained from the *Assay preparation* and the *Standard preparation*, respectively.

Mefenamic Acid Capsules

» Mefenamic Acid Capsules contain not less than 90.0 percent and not more than 110.0 percent of the labeled amount of mefenamic acid ($C_{15}H_{15}NO_2$).

Packaging and storage—Preserve in tight containers.

USP Reference standards ⟨11⟩**—**
USP Mefenamic Acid RS

Identification—

A: Place a portion of Capsule contents, equivalent to about 250 mg of mefenamic acid, in a 250-mL volumetric flask, add about 100 mL of a mixture of chloroform and methanol (3:1), and shake vigorously. Dilute with a mixture of chloroform and methanol (3:1) to volume, mix, and filter: the filtrate so obtained responds to the *Thin-layer Chromatographic Identification Test* ⟨201⟩, a solvent system consisting of a mixture of chloroform, ethyl acetate, and glacial acetic acid (75:25:1) and the *Ordinary Impurities* ⟨466⟩ visualization technique 17 being used.

B: The retention time of the major peak in the chromatogram of the *Assay preparation* corresponds to that of the *Standard preparation*, obtained as directed in the *Assay*.

Dissolution ⟨711⟩**—**

0.05 M Tris buffer—Dissolve 60.5 g of tris(hydroxymethyl) aminomethane in 6 L of water, and dilute with water to 10 L. Adjust with phosphoric acid to a pH of 9.0 ± 0.05. To a second container, transfer about 6 liters of this solution, add 100 g of sodium lauryl sulfate, and mix to dissolve the solid material. Transfer this solution back into the first container, and mix.

Medium: 0.05 M Tris buffer; 900 mL.

Apparatus 1: 100 rpm.

Time: 45 minutes.

Procedure—Determine the amount of $C_{15}H_{15}NO_2$ dissolved, employing the procedure set forth in the *Assay*, making any necessary volumetric adjustments.

Tolerances—Not less than 75% *(Q)* of the labeled amount of $C_{15}H_{15}NO_2$ is dissolved in 45 minutes.

Uniformity of dosage units ⟨905⟩: meet the requirements.

Assay—

Mobile phase, Standard preparation, and *Chromatographic system*—Proceed as directed in the *Assay* under *Mefenamic Acid*.

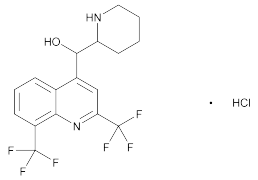
Assay preparation—Remove, as completely as possible, the contents of not fewer than 20 Capsules. Weigh the contents, and determine the average weight per capsule. Mix the combined contents, and transfer an accurately weighed quantity of the powder, equivalent to about 100 mg of mefenamic acid, to a 500-mL volumetric flask. Add 10.0 mL of tetrahydrofuran, and sonicate for about 5 minutes with occasional mixing. Dilute with *Mobile phase* to volume, mix, and filter.

Procedure—Proceed as directed for *Procedure* in the *Assay* under *Mefenamic Acid*. Calculate the quantity, in mg, of $C_{15}H_{15}NO_2$ in the portion of Capsules taken by the formula:

$$500C(r_U / r_S)$$

in which the terms are as defined therein.

Mefloquine Hydrochloride



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

4-Quinolinemethanol, α-2-piperidinyl-2,8-bis(trifluoromethyl)-, monohydrochloride, (*R*,S**)- (±)-;
DL-*erythro*-α-2-Piperidyl-2,8-bis(trifluoromethyl)-4-quinolinemethanol monohydrochloride [51773-92-3].

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

- **A. Infrared Absorption** ⟨**197K**⟩
- **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*