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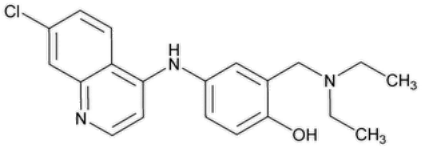
Amodiaquine



$C_{20}H_{22}ClN_3O$ 355.86

Phenol, 4-[(7-chloro-4-quinolinyl)amino]-2-[(diethylamino)-methyl]-;

4-[(7-Chloro-4-quinolyl)amino]-α-(diethylamino)-*o*-cresol CAS RN®: 86-42-0; UNII: 220236ED28.

DEFINITION

Amodiaquine contains NLT 97.0% and NMT 103.0% of amodiaquine ($C_{20}H_{22}ClN_3O$), calculated on the anhydrous basis.

IDENTIFICATION

Change to read:

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

Standard: Dissolve 20 mg of USP Amodiaquine Hydrochloride RS in 10 mL of water in a separator, add 1 mL of ammonium hydroxide, and extract by shaking with 25 mL of chloroform. Draw off and evaporate the chloroform extract, and dry the residue at 105° for 2 h.

Acceptance criteria: Meets the requirements

Change to read:

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

Sample solution: 10 µg/mL in 0.1 N hydrochloric acid

Acceptance criteria: Meets the requirements

ASSAY

• **Procedure**

Standard solution: 15 µg/mL of USP Amodiaquine Hydrochloride RS in 0.1 N hydrochloric acid

Sample solution: 15 µg/mL of Amodiaquine in 0.1 N hydrochloric acid

Instrumental conditions

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

Mode: UV

Analytical wavelength: 342 nm

Cell: 1 cm

Blank: 0.1 N hydrochloric acid

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of amodiaquine ($C_{20}H_{22}ClN_3O$) in the portion of Amodiaquine taken:

$$\text{Result} = (A_U/A_S) \times (C_S/C_U) \times (M_{r1}/M_{r2}) \times 100$$

A_U = absorbance of the *Sample solution*

A_S = absorbance of the *Standard solution*

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

C_U = concentration of Amodiaquine in the *Sample solution* (µg/mL)

M_{r1} = molecular weight of amodiaquine, 355.86

M_{r2} = molecular weight of anhydrous aminodiaquine hydrochloride, 428.79

Acceptance criteria: 97.0%–103.0% on the anhydrous basis

IMPURITIES

• **Residue on Ignition ⟨281⟩:** NMT 0.2%

• **Organic Impurities**

Standard solution A: To 20 mg of USP Amodiaquine Hydrochloride RS in a glass-stoppered test tube add 1.0 mL of chloroform (saturated with ammonium hydroxide), and shake vigorously for 2 min. Allow the solids to settle, and decant the liquid into a second test tube.

Standard solution B: *Standard solution A* and chloroform (saturated with ammonium hydroxide) (1 in 200)

Sample solution: 15 mg/mL of Amodiaquine in chloroform (saturated with ammonium hydroxide)

Chromatographic system

(See *Chromatography ⟨621⟩, Thin-Layer Chromatography*.)

Mode: TLC

Adsorbent: 0.25-mm layer of chromatographic silica gel mixture

Application volume: 10 µL

Developing solvent system: Chloroform (saturated with ammonium hydroxide) and dehydrated alcohol (9:1)

Analysis

Samples: *Standard solution A*, *Standard solution B*, and *Sample solution*

Develop the chromatogram until the solvent front has moved about three-fourths of the length of the plate. Remove the plate from the developing chamber, mark the solvent front, allow the solvent to evaporate, and examine the plate under short-wavelength UV light.

Acceptance criteria: The chromatograms show principal spots at about the same R_F value; and no secondary spot, if present in the chromatogram from the *Sample solution*, is more intense than the principal spot obtained from *Standard solution B*.

SPECIFIC TESTS

• **Water Determination, *Method I*⟨921⟩:** NMT 0.5%

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight containers.

• **USP Reference Standards ⟨11⟩**

USP Amodiaquine Hydrochloride RS

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

Topic/Question	Contact	Expert Committee
AMODIAQUINE	Documentary Standards Support	SM12020 Small Molecules 1
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM12020 Small Molecules 1

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. Information currently unavailable

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