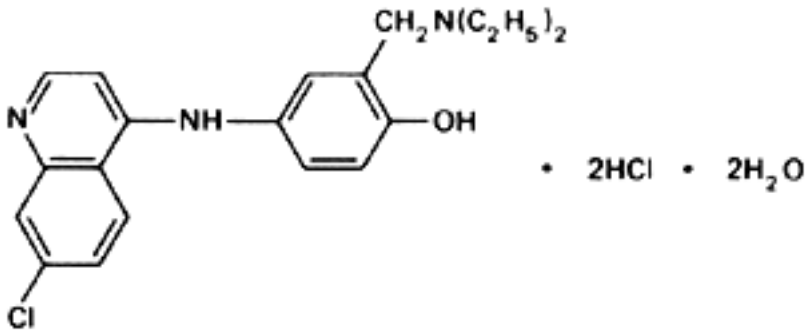
Amodiaquine hydrochloride (Amodiaquini hydrochloridum)

Molecular formula. $C_{20}H_{22}ClN_3O,2HCl,2H_2O$

Relative molecular mass. 464.8

Graphic formula.



Chemical name. 4-[(7-Chloro-4-quinolyl)amino]-*α*-(diethylamino)-*o*-cresol dihydrochloride dihydrate; 4-[(7-chloro-4-quinolinyl)amino]-2-[(diethylamino)-methyl]phenol dihydrochloride dihydrate; CAS Reg. No. 6398-98-7.

Description. A yellow, crystalline powder; odourless.

Solubility. Soluble in about 22 parts of water; sparingly soluble in ethanol (~750 g/l) TS; practically insoluble in ether R.

Category. Antimalarial.

Storage. Amodiaquine hydrochloride should be kept in a tightly closed container.

Requirements

Definition. Amodiaquine hydrochloride contains not less than 98.0% and not more than 101.5% of $C_{20}H_{22}ClN_3O,2HCl$, calculated with reference to the anhydrous substance.

Identity tests

• Either test A alone or all 3 tests B, C, and D may be applied.

A. Carry out the examination as described under 1.7 Spectrophotometry in the infrared region. The infrared absorption spectrum is concordant with the *reference spectrum* of amodiaquine hydrochloride.

B. To 1 mL of a 20 mg/mL solution add 0.5 mL of cobaltous thiocyanate TS; a green precipitate is produced.

C. A 20 mg/mL solution yields reaction B described under 2.1 General identification tests as characteristic of chlorides.

D. Melting temperature, determined without previous drying, about 158°C with decomposition.

Sulfated ash. Not more than 2.0 mg/g.

Water. Determine as described under 2.8 Determination of water by the Karl Fischer method, Method A, using about 0.15 g of the substance; the water content is not less than 70 mg/g and not more than 90 mg/g.

pH value. pH of a 20 mg/mL solution, 4.0-4.8.

Related substances. Carry out the test as described under *1.14.1 Chromatography*, Thin-layer chromatography. Prepare a solution of chloroform saturated with ammonia by shaking chloroform R with ammonia (~260 g/l) TS and separate the chloroform-layer. Use silica gel R2 as the coating substance and a mixture of 9 volumes of chloroform saturated with ammonia, and 1 volume of dehydrated ethanol R as the mobile phase. For the preparation of the test solutions transfer 0.20 g of the substance being examined to a glass-stoppered test-tube, add 10 mL of chloroform saturated with ammonia, shake vigorously for 2 minutes, allow the solids to settle, and decant the solution to a second tube; this constitutes solution A. Dilute 1.0 mL of solution A with sufficient chloroform saturated with ammonia to 200 mL; this constitutes solution B. Apply separately to the plate 10 *µl* of each of solutions A and B. After removing the plate from the chromatographic chamber, allow it to dry in air, and examine the chromatogram in ultraviolet light (254 nm). Any spot obtained with solution A, other than the principal spot, is not more intense than that obtained with solution B.

Assay. Dissolve about 0.3 g, accurately weighed, in 50 mL of water, make the solution alkaline with ammonia (~100 g/l) TS, and allow to stand for 30 minutes. Filter, wash the residue with water until the washings are free from chlorides, and dry to constant weight at 105°C. Each g of residue is equivalent to 1.205 g of $C_{20}H_{22}ClN_3O,2HCl$.