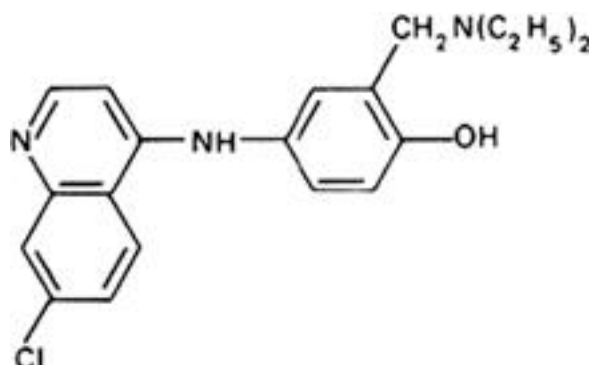


Amodiaquine (Amodiaquinum)**Molecular formula.** $C_{20}H_{22}ClN_3O$ **Relative molecular mass.** 355.9**Graphic formula.****Chemical name.** 4-[(7-Chloro-4-quinolyl)amino]- α -(diethylamino)-*o*-cresol; 4-[(7-chloro-4-quinolyl)amino]-2-[(diethylamino)methyl]phenol; CAS Reg. No. 86-42-0.**Description.** A yellow, crystalline powder; odourless.**Solubility.** Practically insoluble in water.**Category.** Antimalarial drug.**Storage.** Amodiaquine should be kept in a tightly closed container.**Requirements****Definition.** Amodiaquine contains not less than 97.0% and not more than 103.0% of $C_{20}H_{22}ClN_3O$, calculated with reference to the anhydrous substance.**Identity tests**

- Either test A or tests B and C 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 spectrum obtained from the free base of amodiaquine hydrochloride RS or with the *reference spectrum* of amodiaquine.

B. Dissolve 20 mg in 1.0 mL of water and add 0.5 mL of ammonium thiocyanate/cobalt(II) nitrate TS; a green precipitate is produced.

C. See the test described below under "Related substances". The principal spot obtained with solution A corresponds in position, appearance, and intensity with that obtained with solution B.

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 0.8 g of the substance; the water content is not more than 5.0 mg/g.**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 solution dissolve 0.15 g of the substance being examined in 10 mL of chloroform saturated with ammonia (solution A). For the preparation of the reference solutions transfer 40 mg of amodiaquine hydrochloride RS to a glass-stoppered test-tube, add 2.0 mL of chloroform saturated with ammonia, and shake vigorously for 2 minutes. Allow the solids to settle, and decant the solution to a second test-tube (solution B). Dilute 1.0 mL of solution B to 200 mL with chloroform saturated with ammonia (solution C). Apply separately to the plate 10 μ l of each of solutions A, B and C. 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 C.**Assay.** Dissolve about 0.3 g, accurately weighed, in sufficient hydrochloric acid (0.1 mol/l) VS to produce 200 mL; dilute 10.0 mL of this solution to 1000 mL with the same medium. Separately prepare a reference solution containing 15 μ g of amodiaquine

hydrochloride RS per mL of hydrochloric acid (0.1 mol/l) VS. Measure the absorbance of a 1-cm layer of both solutions at the maximum at about 342 nm against a solvent cell containing hydrochloric acid (0.1 mol/l) VS. Calculate the quantity, in mg, of $C_{20}H_{22}ClN_3O$ in the substance being examined using the formula $(355.9/428.8) (20C) (A_U/A_S)$, in which 355.9 and 428.8 are the relative molecular masses of amodiaquine and anhydrous amodiaquine hydrochloride, respectively, C is the concentration, in μg per mL, calculated with reference to the anhydrous substance of amodiaquine hydrochloride RS in the reference solution, and A_U and A_S are the absorbances of the solution of the substance being examined and the reference solution, respectively.