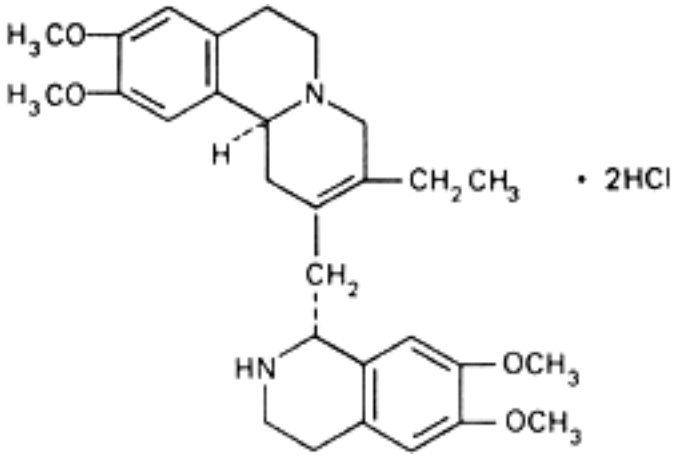
Dehydroemetine dihydrochloride (Dehydroemetini dihydrochloridum)

Molecular formula. $C_{29}H_{38}N_2O_4,2HCl$

Relative molecular mass. 551.6

Graphic formula.



Chemical name. (±)-2,3-Didehydroemetine dihydrochloride; (±)-2,3-didehydro-6',7',10,11-tetramethoxyemetan dihydrochloride; (±)-(11b*R**)-3-ethyl-1,6,7,11b-tetrahydro-9,10-dimethoxy-1-[[(1b*S**)-1,2,3,4-tetrahydro-6,7-dimethoxy-1-isoquinolyl]methyl]-4*H*-benzo[*a*]quinolizine dihydrochloride; CAS Reg. No. 3317-75-7.

Description. A white to yellowish, crystalline powder; odourless.

Solubility. Sparingly soluble in water; soluble in methanol R.

Category. Antiamoebic drug.

Storage. Dehydroemetine dihydrochloride should be kept in a tightly closed container.

Requirements

Definition. Dehydroemetine dihydrochloride contains not less than 98.0% and not more than 101.0% of $C_{29}H_{38}N_2O_4,2HCl$, calculated with reference to the dried substance.

Identity tests

A. The absorption spectrum of a 0.040 mg/mL solution in hydrochloric acid (0.1 mol/l) VS, when observed between 240 nm and 350 nm, exhibits a maximum at about 282 nm. The absorbance of a 1-cm layer at this wavelength is about 0.49.

B. Sprinkle a small quantity of the powdered substance on the surface of 1 mL of sulfuric acid (~1760 g/l) TS containing 5 mg of molybdenum trioxide R; a bright green colour is produced.

C. A 0.1 g/mL solution yields reaction B described under 2.1 General identification tests as characteristic of chlorides.

Clarity and colour of solution. A solution of 0.30 g in 10 mL of water is clear and not more intensely coloured than standard colour solution Yw2 when compared as described under 1.11 Colour of liquids.

Sulfated ash. Not more than 1.0 mg/g.

Loss on drying. Dry to constant weight at 105°C; it loses not more than 70 mg/g.

pH value. pH of a 30 mg/mL solution, 3.5-5.0.

Related substances. Carry out the test as described under 1.14.1 Thin-layer chromatography, using silica gel R4 as the coating substance and a mixture of 9 volumes of ethyl acetate R and 1 volume of diethylamine R as the mobile phase. Apply separately to the plate 5 µl of each of 3 solutions in methanol R containing (A) 20 mg of the test substance per mL, (B) 0.10 mg of the test substance per mL, and (C) 0.10 mg of emetine hydrochloride RS per mL. After removing the plate from the chromatographic chamber, allow it to dry in air, spray it with mercuric acetate/acetic acid TS, heat it at 120 °C for 10 minutes, and examine the chromatogram in ultraviolet light (365 nm). Any spot obtained with solution A, other than the principal spot, is not more intense than that obtained with solution B or solution C, as appropriate.

Assay. Dissolve about 0.4 g, accurately weighed, in 75 mL of glacial acetic acid R1, add 10 mL of mercuric acetate/acetic acid

TS, and titrate with perchloric acid (0.1 mol/l) VS as described under 2.6 Non-aqueous titration, Method A. Each mL of perchloric acid (0.1 mol/l) VS is equivalent to 27.58 mg of $C_{29}H_{38}N_2O_4$,2HCl.