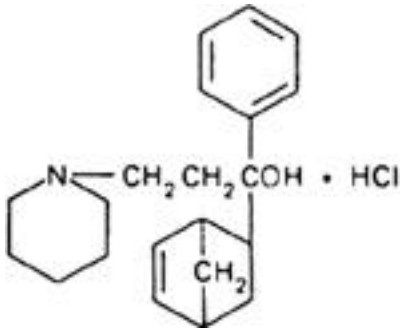
Biperiden hydrochloride (Biperideni hydrochloridum)

2018-01

Molecular formula. $C_{21}H_{29}NO,HCl$

Relative molecular mass. 347.9

Graphic formula.



Chemical name. α-5-Norbornen-2-yl-α-phenyl-1-piperidinepropanol hydrochloride; α-bicyclo[2.2.1]hept-5-en-2-yl-α-phenyl-1-piperidinepropanol hydrochloride; CAS Reg. No. 1235-82-1.

Description. A white, crystalline powder; odourless.

Solubility. Slightly soluble in water, ethanol (~750 g/l) TS and ether R; sparingly soluble in methanol R.

Category. Antiparkinsonism drug.

Storage. Biperiden hydrochloride should be kept in a well-closed container, protected from light.

Requirements

Definition. Biperiden hydrochloride contains not less than 98.0% and not more than 101.0% of $C_{21}H_{29}NO,HCl$, calculated with reference to the dried substance.

Identity tests

• Either tests A and D or 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 spectrum obtained from biperiden hydrochloride RS or with the *reference spectrum* of biperiden hydrochloride.

B. Dissolve 20 mg in 5 mL of phosphoric acid (~1440 g/l) TS and allow to stand; a green colour is produced.

C. Dissolve 0.10 g in 50 mL of water and to 5 mL of this solution add bromine TS1 drop by drop; a yellow precipitate is formed which dissolves on shaking. Upon the addition of more bromine TS1, a permanent precipitate is produced.

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

Sulfated ash. Not more than 1.0 mg/g.

Loss on drying. Dry for 3 hours at 105 °C; it loses not more than 5 mg/g.

Related substances. Carry out the test as described under *1.14.1 Chromatography*, Thin-layer chromatography, using a plate coated with a suspension of silica gel R1 in sodium hydroxide (0.5 mol/l) VS, and as the mobile phase a mixture of 96.5 volumes of toluene R and 3.5 volumes of methanol R. Apply separately to the plate 10 µl of each of 2 solutions in methanol R containing (A) 20 mg of the test substance per mL and (B) 0.10 mg of the test substance per mL. After removing the plate from the chromatographic chamber, allow it to dry in air, spray it with potassium iodobismuthate TS2, and examine the chromatogram in daylight. Any spot obtained with solution A, other than the principal spot, is not more intense than that obtained with solution B.

Assay. Dissolve 0.200 g in 60 mL of dehydrated ethanol R. Carry out a potentiometric titration using potassium hydroxide/ethanol (0.1 mol/L) VS, as described under *2.6 Non-aqueous titration*.

1 mL of potassium hydroxide/ethanol (0.1 mol/L) VS is equivalent to 34.79 mg of $C_{21}H_{29}NO,HCl$.