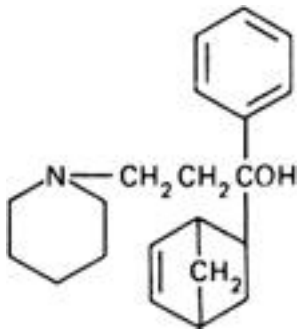
Biperiden (Biperidenum)

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

Relative molecular mass. 311.5

Graphic formula.



Chemical name. α-5-Norbornen-2-yl-α-phenyl-1-piperidinepropanol; α-bicyclo[2.2.1]hept-5-en-2-yl-α-phenyl-1-piperidinepropanol; CAS Reg. No. 514-65-8.

Description. A white or almost white, crystalline powder; odourless.

Solubility. Practically insoluble in water; soluble in ether R; sparingly soluble in ethanol (~750 g/l) TS.

Category. Antiparkinsonism drug.

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

Requirements

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

Identity tests

• Either test A alone 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 RS or with the *reference spectrum* of biperiden.

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

C. To 0.20 g add 80 mL of water, 0.5 mL of hydrochloric acid (~70 g/l) TS, and warm until dissolved. Cool 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. Melting temperature, about 114 °C.

Sulfated ash. Not more than 1.0 mg/g.

Loss on drying. Dry for 3 hours at 105 °C; it loses not more than 10 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 5 µl of each of 2 solutions in chloroform R containing (A) 40 mg of the test substance per mL and (B) 0.20 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 about 0.4 g, accurately weighed, in 30 mL of glacial acetic acid R1, add 0.15 mL of 1-naphtholbenzein/acetic acid TS as indicator 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 31.15 mg of $C_{21}H_{29}NO$.

Additional requirement for Biperiden for parenteral use

Complies with the monograph for "Parenteral preparations".