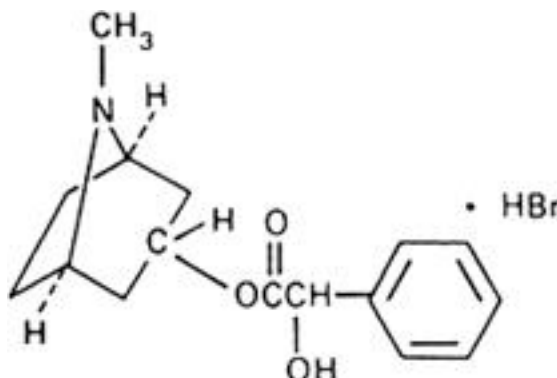


Homatropine hydrobromide (Homatropini hydrobromidum)

2018-01

Molecular formula. $C_{16}H_{21}NO_3 \cdot HBr$ **Relative molecular mass.** 356.3**Graphic formula.****Chemical name.** 1 α H,5 α H-Tropan-3 α -ol mandelate (ester) hydrobromide; (\pm)-*endo*-8-methyl-8-azabicyclo[3.2.1]oct-3-yl α -hydroxybenzeneacetate hydrobromide; CAS Reg. No. 51-56-9.**Description.** Colourless crystals or a white, crystalline powder; odourless.**Solubility.** Freely soluble in water; sparingly soluble in ethanol (~750 g/l) TS; practically insoluble in ether R.**Category.** Mydriatic.**Storage.** Homatropine hydrobromide should be kept in a tightly closed container, protected from light.**Requirements****Definition.** Homatropine hydrobromide contains not less than 98.5% and not more than 101.0% of $C_{16}H_{21}NO_3 \cdot HBr$, calculated with reference to the dried substance.**Identity tests**

A. Dissolve 10 mg in 1 mL of water, add ammonia (~100 g/l) TS to render the solution slightly alkaline, and shake with 5 mL of chloroform R. Evaporate the chloroform layer to dryness on a water-bath and add 1.5 mL of mercuric chloride/ethanol TS to the residue; a yellow colour is produced, which turns red on heating.

B. A 20 mg/mL solution yields reaction A described under [2.1 General identification tests](#) as characteristic of bromides.

C. Melting temperature, about 215°C with decomposition.

Sulfated ash. Not more than 1.0 mg/g.**Loss on drying.** Dry to constant weight at 105°C; it loses not more than 15 mg/g.**pH value.** pH of a 20 mg/mL solution, 5.5-7.0.**Foreign alkaloids.** Dissolve 10 mg in 2 mL of water and add 0.25 mL of tannic acid (50 g/l) TS; no precipitate is produced.**Related alkaloids.** Dissolve 5 mg in 0.25 mL of fuming nitric acid R and evaporate to dryness on a water-bath. Allow to cool, add 0.1 mL of acetone R and 0.1 mL of a mixture of 1 volume of potassium hydroxide/ethanol (0.5 mol/l) VS and 4 volumes of aldehyde-free ethanol (~750 g/l) TS; no violet or reddish violet colour is produced.**Assay.**

Dissolve 0.300 g in a mixture of 5.0 mL of hydrochloric acid (0.01 mol/L) VS and 50 mL of dehydrated ethanol R. Carry out a potentiometric titration using sodium hydroxide (0.1 mol/L) VS, as described under [2.6 Non-aqueous titration](#). Read the volume added between the two points of inflexion.

1 mL of sodium hydroxide (0.1 mol/L) VS is equivalent to 35.63 mg of $C_{16}H_{21}NO_3 \cdot HBr$.