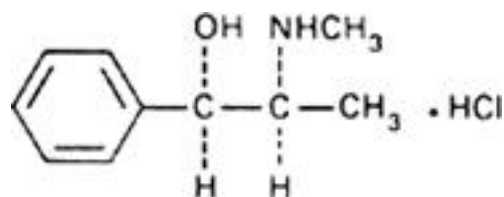


Ephedrine hydrochloride (Ephedrini hydrochloridum)

2018-01

Molecular formula. $C_{10}H_{15}NO, HCl$ **Relative molecular mass.** 201.7**Graphic formula.****Chemical name.** (-)-Ephedrine hydrochloride; [*R*-(*R**,*S**)]- α -[1-(methylamino)ethyl]benzenemethanol hydrochloride; CAS Reg. No. 50-98-6.**Description.** Colourless crystals or a white, crystalline powder; odourless.**Solubility.** Soluble in 4 parts of water; soluble in ethanol (~750 g/l) TS; practically insoluble in ether R.**Category.** Antiasthmatic drug.**Storage.** Ephedrine hydrochloride should be kept in a well-closed container, protected from light.**Additional information.** Ephedrine hydrochloride darkens on exposure to light.**Requirements****Definition.** Ephedrine hydrochloride contains not less than 99.0% and not more than 101.0% of $C_{10}H_{15}NO, HCl$, calculated with reference to the dried substance.**Identity tests**

A. The absorption spectrum of a 0.50 mg/mL solution, when observed between 230 nm and 350 nm, exhibits maxima at about 251 nm, 257 nm, and 263 nm; the absorbances of a 1-cm layer at these wavelengths are about 0.37, 0.48, and 0.36, respectively.

B. Dissolve 10 mg in 1 mL of water and add 0.1 mL of copper(II) sulfate (80 g/l) TS, followed by 2 mL of sodium hydroxide (~80 g/l) TS; a violet colour is produced. Add 1 mL of ether R and shake; a purple colour is produced in the ethereal layer and a blue colour in the aqueous layer.

C. Dissolve 0.05 g in 5 mL of water. Add a few drops of sodium hydroxide (~80 g/l) TS and 4 mL of potassium ferricyanide (50 g/l) TS, and heat; an odour of benzaldehyde is perceptible.

D. A 0.05 g/mL solution yields reaction A described under [2.1 General identification tests](#) as characteristic of chlorides.

Melting range. 217-220°C.

Specific optical rotation. Use a 50 mg/mL solution; $[\alpha]_D^{20} = -33.0^\circ$ to -35.5° .

Sulfates. Dissolve 0.050 g in 40 mL of water and add 1.5 mL of hydrochloric acid (~70 g/l) TS and 1 mL of barium chloride (50 g/l) TS; no turbidity develops within 10 minutes.

Clarity and colour of solution. A solution of 1.0 g in 10 mL of water is clear, or not more opalescent than opalescence standard TS2, and colourless.

Sulfated ash. Not more than 1.0 mg/g.**Loss on drying.** Dry to constant weight at 105°C; it loses not more than 5.0 mg/g.

Acidity and alkalinity. Dissolve 1.0 g in 10 mL of water and add 0.1 mL of methyl red/ethanol TS; not more than 0.1 mL of sodium hydroxide (0.1 mol/l) VS or 0.1 mL of hydrochloric acid (0.1 mol/l) VS is required to obtain the midpoint of the indicator (orange).

Assay. Dissolve 0.150 g in 50 mL of dehydrated ethanol R and add 5.0 mL of hydrochloric acid (0.01 mol/L) VS. 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 20.17 mg of $\text{C}_{10}\text{H}_{15}\text{NO}\cdot\text{HCl}$.