Ephedrine hydrochloride (Ephedrini hydrochloridum)

**Molecular formula.** $C_{10}H_{15}NO\cdot HCl$

**Relative molecular mass.** 201.7

**Graphic formula.**

![Graphic formula of Ephedrine hydrochloride](image)

**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 $C_{10}H_{15}NO\cdot HCl$, 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; $[\alpha]_{D}^{20\,\circ\,C} = -33.0^\circ$ to $-35.5^\circ$.

**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 about 0.2 g, accurately weighed, in 10 mL of warm mercuric acetate/acetic acid TS, add 50 mL of acetone R and 1 mL of methyl orange/acetone 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 20.17 mg of $C_{10}H_{15}NO\cdot HCl$. 

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