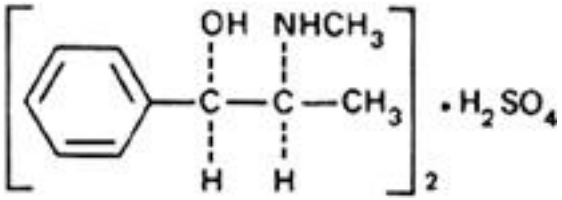
## Ephedrine sulfate (Ephedrini sulfas)

**Molecular formula.** $(C_{10}H_{15}NO)_2,H_2SO_4$

**Relative molecular mass.** 428.5

**Graphic formula.**




**Chemical name.** (-)-Ephedrine sulfate (2:1) (salt); [*R*-(*R**,*S**)]-α-[1-(methylamino)ethyl]benzenemethanol sulfate (2:1) (salt); CAS Reg. No. 134-72-5.

**Description.** Colourless crystals or a white, crystalline powder; odourless.

**Solubility.** Freely soluble in water; sparingly soluble in ethanol (~750 g/l) TS.

**Category.** Antiasthmatic drug.

**Storage.** Ephedrine sulfate should be kept in a well-closed container, protected from light.

**Additional information.** Ephedrine sulfate darkens on exposure to light. Even in the absence of light, it is gradually degraded on exposure to a humid atmosphere, the decomposition being faster at higher temperatures.

### Requirements

**Definition.** Ephedrine sulfate contains not less than 98.0% and not more than 101.0% of $(C_{10}H_{15}NO)_2,H_2SO_4$, calculated with reference to the dried substance.

### Identity tests

A. The absorption spectrum of a 1.0 mg/mL solution, when observed between 230 nm and 350 nm, exhibits maxima at about 251 nm, 257 nm, and 262 nm; the absorbances of a 1-cm layer at these wavelengths are about 0.61, 0.76, and 0.61, 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 20 mg/mL solution yields reaction A described under 2.1 General identification tests as characteristic of sulfates.

E. Melting temperature, about 245 °C with decomposition.

**Specific optical rotation.** Use a 50 mg/mL solution and calculate with reference to the dried substance; $[\alpha]_D^{20\,°C}$ = -30.5° to -32.5°.

**Chlorides.** A quantity of 0.20 g of the test substance shows no more turbidity than 0.40 mL of hydrochloric acid (0.02 mol/l) VS when subjected to the procedure described under 2.2.1 Limit test for chlorides; the chloride content is not more than 1.4 mg/g.

**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 20 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 0.3 g, accurately weighed, in 10 mL of water, add about 3 g of sodium chloride R to saturate the solution, then add 5 mL of sodium hydroxide (1 mol/l) VS and extract with 4 volumes, each of 25 mL, of chloroform R. Wash the combined

chloroform extracts with 10 mL of a saturated solution of sodium chloride R, and filter through purified cotton saturated with chloroform R. Shake the aqueous wash solution with 10 mL of chloroform R and add it to the main chloroform extract. Add 0.25 mL of methyl red/ethanol TS and titrate with perchloric acid/dioxan (0.1 mol/l) VS, as described under 2.6 Non-aqueous titration, Method A. Each mL of perchloric acid/dioxan (0.1 mol/l) VS is equivalent to 21.43 mg of $(C_{10}H_{15}NO)_2,H_2SO_4$.