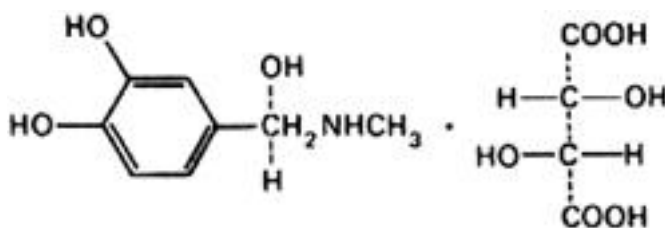


Epinephrine hydrogen tartrate (Epinephrini hydrogenotartras)**Molecular formula.** $C_9H_{13}NO_3$, $C_4H_6O_6$ or $C_{13}H_{19}NO_9$ **Relative molecular mass.** 333.3**Graphic formula.**

Chemical name. (-)-(R)-3,4-Dihydroxy- α [(methylamino)methyl]benzyl alcohol L-(+)-tartrate (1:1) (salt); (-)-(R)-4-[1-hydroxy-2-(methylamino)ethyl]-1,2-benzenediol[R-(R*,R*)]-2,3-dihydroxybutanedioate (1:1) (salt); (-)- α -3,4-dihydroxyphenyl- β -(methylamino)ethanol L-(+)-tartrate; CAS Reg. No. 51-42-3.

Other name. Adrenalin tartrate. (In certain countries the name Adrenalin is a trademark. In those countries this name may be used only when applied to the product issued by the owners of the trademark.)

Description. A white to greyish white, crystalline powder; odourless.

Solubility. Soluble in 3 parts of water; slightly soluble in ethanol (~750 g/l) TS; practically insoluble in ether R.

Category. Sympathomimetic.

Storage. Epinephrine hydrogen tartrate should be kept in a tightly closed container, protected from light.

Additional information. Epinephrine hydrogen tartrate gradually darkens in colour on exposure to air and light. Even in the absence of light, Epinephrine hydrogen tartrate is gradually degraded on exposure to a humid atmosphere, the decomposition being faster at higher temperatures.

Requirements

Definition. Epinephrine hydrogen tartrate contains not less than 98.0% and not more than 101.0% of $C_9H_{13}NO_3$, $C_4H_6O_6$, calculated with reference to the dried substance.

Identity tests

A. The absorption spectrum of a 0.10 mg/mL solution in hydrochloric acid (0.01 mol/l) VS, when observed between 230 nm and 350 nm exhibits a maximum at about 280 nm; the absorbance of a 1-cm layer at this wavelength is about 0.8.

B. Dissolve 10 mg in 10 mL of water and transfer 1 mL to a flask containing 10 mL of buffer phthalate, pH 3.4, TS; another buffer having the same pH may also be used. Add 0.5 mL of iodine (0.1 mol/l) VS, and allow to stand for 5 minutes. Add 2 mL of sodium thiosulfate (0.1 mol/l) VS, and allow to stand for 1 minute; a strong red colour is produced (distinction from levarterenol, which gives a clear solution with a pink tinge).

C. The filtrate obtained when carrying out the determination of specific optical rotation (see below) yields reaction B described under [2.1 General identification tests](#), as characteristic of tartrates.

Specific optical rotation. Dissolve about 0.5 g in 20 mL of water containing about 0.1 g of sodium metabisulfite R, add a slight excess of ammonia (~100 g/l) TS, and allow to stand in the cold for 1 hour. Filter (keep the filtrate for identity test C, see above), wash the precipitate with 3 quantities, each of 2 mL of water, followed by 5 mL of ethanol (~750 g/l) TS and 5 mL of ether R. Dry the precipitate at ambient temperature under reduced pressure (not exceeding 0.6 kPa or about 5 mm of mercury) for 3 hours.

Use a 20 mg/mL solution of epinephrine base in hydrochloric acid (0.5 mol/l) VS; $[\alpha]_D^{20} = -50^\circ$ to -53° .

Clarity and colour of solution. A solution of 1.0 g in 10 mL of water is clear and colourless.

Sulfated ash. Not more than 1.0 mg/g.

Loss on drying. Dry at ambient temperature under reduced pressure (not exceeding 0.6 kPa or about 5 mm of mercury) over silica gel, desiccant, R for 3 hours; it loses not more than 5.0 mg/g.

Adrenalone. The absorbance of a 1-cm layer of a 4.0 mg/mL solution in hydrochloric acid (0.1 mol/l) VS at 310 nm is not more than 0.2 (preferably use 2-cm cells for the measurement and calculate the absorbance of a 1-cm layer).

Levarterenol. Dissolve 10 mg in 1 mL of water, add 4 mL of buffer borate, pH 9.6, TS, or another buffer having the same pH, mix, add 1 mL of a freshly prepared solution of sodium 1,2-naphthoquinone-4-sulfonate (5 g/L) TS, mix, and allow to stand for 30 minutes. Add 0.2 mL of benzalkonium chloride TS1, mix, add 15 mL of toluene R, previously washed with buffer borate, pH 9.6, TS and filtered through a dry filter-paper, shake for 30 minutes and allow to separate, centrifuging if necessary. Any red or purple colour in the toluene-layer is not more intense than that produced by treating a solution of 0.40 mg of levarterenol hydrogen tartrate R and 9.0 mg of epinephrine hydrogen tartrate R in 1 mL of water in a similar manner, when compared as described under [1.11.1 Colour of liquids](#).

Assay. Dissolve about 0.3 g, accurately weighed, in 50 mL of glacial acetic acid R1, warming slightly if necessary, 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 33.33 mg of $C_9H_{13}NO_3 \cdot C_4H_6O_6$.

Additional requirements for Epinephrine hydrogen tartrate for parenteral use

Complies with the monograph for "[Parenteral preparations](#)".