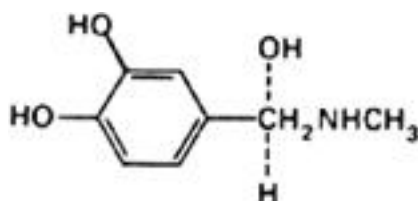


Epinephrine (Epinephrinum)**Molecular formula.** $C_9H_{13}NO_3$ **Relative molecular mass.** 183.2**Graphic formula.**

Chemical name. (-)-(R)-3,4-Dihydroxy- α -[(methylamino)methyl]benzyl alcohol; (-)-(R)-4-[1-hydroxy-2-(methylamino)ethyl]-1,2-benzenediol; (-)- α -3,4-dihydroxyphenyl- β -methylaminoethanol; CAS Reg. No. 51-43-4.

Other name. Adrenaline. (In certain countries the name Adrenaline 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 or almost white, microcrystalline powder; odourless.

Solubility. Very slightly soluble in water; practically insoluble in ethanol (~750 g/l) TS, ether R and acetone R.

Category. Sympathomimetic.

Storage. Epinephrine should be kept in a hermetically closed container, protected from light.

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

Requirements

Definition. Epinephrine contains not less than 98.5% and not more than 101.0% of $C_9H_{13}NO_3$, calculated with reference to the dried substance.

Identity tests

A. The absorption spectrum of a 0.030 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 0.45 (preferably use 2-cm cells for the measurement and calculate the absorbance of a 1-cm layer).

B. Dissolve 10 mg in 10 mL of hydrochloric acid (0.01 mol/l) VS 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).

Specific optical rotation. Use a 40 mg/mL solution in hydrochloric acid (1 mol/l) VS; $[\alpha]_D^{20} = -50^\circ$ to -53° .

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 18 hours; it loses not more than 10 mg/g.

pH value. pH of a 5.0 mg/mL solution in carbon-dioxide-free water R, above 7.5.

Adrenalone. The absorbance of a 1-cm layer of a 2.0 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 5.0 mg in 1 mL of tartaric acid (5 g/L) TS, 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. Treat 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. Any red or purple colour in the toluene layer is not more intense than that of the reference solution when compared as described under [1.11.1 Colour of liquids](#).

Assay. Dissolve about 0.35 g, accurately weighed, in 30 mL of glacial acetic acid R1, 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 18.32 mg of $C_9H_{13}NO_3$.

Additional requirements for Epinephrine for parenteral use

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

Bacterial endotoxins. Carry out the test as described under [3.4 Test for bacterial endotoxins](#); contains not more than 357.0 IU of endotoxin RS per mg.