

Amount (mg) of ephedrine hydrochloride ($C_{10}H_{15}NO \cdot HCl$)
= amount (mg) of ephedrine hydrochloride for assay

$$\times \frac{Q_T}{Q_S}$$

Internal standard solution—A solution of etilefrine hydrochloride (1 in 500).

Operating conditions—

Detector, column, column temperature, mobile phase, and flow rate: Proceed as directed in the operating conditions in the Purity (4) under Ephedrine Hydrochloride.

System suitability—

System performance: When the procedure is run with 10 μ L of the standard solution under the above operating conditions, the internal standard and ephedrine are eluted in this order with the resolution between these peaks being not less than 15.

System repeatability: When the test is repeated 6 times with 10 μ L of the standard solution under the above operating conditions, the relative standard deviation of the ratios of the peak area of ephedrine to that of the internal standard is not more than 1.0%.

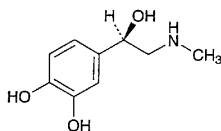
Containers and storage Containers—Well-closed containers.

Epinephrine

Adrenaline

Epirenamine

エピネフリン



$C_9H_{13}NO_3$: 183.20
(1*R*)-1-(3,4-Dihydroxyphenyl)-2-(methylamino)ethanol
[51-43-4]

Epinephrine, when dried, contains not less than 98.0% of $C_9H_{13}NO_3$.

Description Epinephrine occurs as a white to grayish white, crystalline powder. It has no odor.

It is freely soluble in acetic acid (100), very slightly soluble in water, and practically insoluble in methanol, in ethanol (95) and in diethyl ether.

It dissolves in dilute hydrochloric acid.

It gradually changes to brown in color by air and by light.

Identification (1) Dissolve 0.01 g of Epinephrine in 10 mL of diluted acetic acid (31) (1 in 500), and use this solution as the sample solution. To 1 mL of the sample solution add 4 mL of water and 1 drop of iron (III) chloride TS: a deep green color is produced, and it gradually changes to red.

(2) Place 1 mL each of the sample solution obtained in (1) in test tubes A and B. Add 10 mL of potassium hydrogen phthalate buffer solution, pH 3.5, to A, and add 10 mL of

phosphate buffer solution, pH 6.5, to B. To each of the test tubes add 1 mL of iodine TS, allow to stand for 5 minutes, and add 2 mL each of sodium thiosulfate TS: a red color develops in test tube A, and a deep red color develops in test tube B.

Optical rotation $[\alpha]_D^{20}$: $-50.0 - -53.5^\circ$ (after drying, 1 g, 1 mol/L hydrochloric acid TS, 25 mL, 100 mm).

Purity (1) Clarity and color of solution—Dissolve 0.10 g of Epinephrine in 10 mL of dilute hydrochloric acid: the solution is clear, and has no more color than Matching Fluid A.

(2) Adrenalone—Dissolve 0.050 g of Epinephrine in 0.05 mol/L hydrochloric acid TS to make exactly 25 mL, and determine the absorbance of this solution at 310 nm as directed under the Ultraviolet-visible Spectrophotometry: it is not more than 0.40.

(3) Norepinephrine—Dissolve 10.0 mg of Epinephrine in 2.0 mL of a L-tartaric acid solution (1 in 200). Pipet 1 mL of the solution, add 3.0 mL of pyridine, then add 1.0 mL of freshly prepared sodium naphthoquinone sulfonate TS, and allow to stand in a dark place for 30 minutes. To this solution add 5.0 mL of pyridine containing 0.05 g of L-ascorbic acid: the solution has no more color than the following control solution.

Control solution: Dissolve 2.0 mg of Norepinephrine Bitartrate Reference Standard and 90 mg of Epinephrine Bitartrate Reference Standard in methanol to make exactly 10 mL. Pipet 1 mL of this solution, and proceed in the same manner.

Loss on drying Not more than 1.0% (2 g, in vacuum, silica gel, 18 hours).

Residue on ignition Not more than 0.10% (1 g).

Assay Weigh accurately about 0.3 g of Epinephrine, previously dried, dissolve in 50 mL of acetic acid (100), and titrate with 0.1 mol/L perchloric acid VS (indicator: 2 drops of crystal violet TS). Perform a blank determination, and make any necessary correction.

Each mL of 0.1 mol/L perchloric acid VS
= 18.321 mg of $C_9H_{13}NO_3$

Containers and storage Containers—Tight containers.

Storage—Light-resistant, under nitrogen atmosphere, and in a cold place.

Epinephrine Injection

Adrenaline Hydrochloride Injection

Epinephrine Hydrochloride Injection

Epirenamine Hydrochloride Injection

エピネフリン注射液

Epinephrine Injection is aqueous solution for injection. It contains not less than 0.085 w/v% and not more than 0.115 w/v% of epinephrine ($C_9H_{13}NO_3$: 183.20).

Method of preparation Dissolve Epinephrine in diluted