Amount (mg) of ephedrine hydrochloride ($C_{10}H_{15}NO.HCl$) = 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 μL 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.

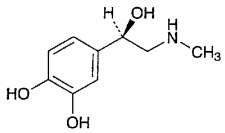
System repeatability: When the test is repeated 6 times with 10 μL of the standard solution under the above operating conditions, the relative standard deviation of the ratios of the peak area of ephedrine to that of the internal standard is not more than 1.0%.

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° (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

Hydrochloric Acid (9 in 10,000), and prepare as directed under Injections.

Description Epinephrine Injection is a colorless, clear liquid.

It changes gradually to pale red and then to brown on exposure to air and light.

pH: 2.3 - 5.0

Identification (1) To 1 mL of Epinephrine Injection 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 Epinephrine Injection in test tubes A and B, and proceed as directed in the Identification (2) under Epinephrine.

Assay Pipet 30 mL of Epinephrine Injection into a separator, add 25 mL of carbon tetrachloride, shake vigorously for 1 minute, allow the liquids to separate, and discard the carbon tetrachloride. Repeat this procedure three times. Rinse the stopper and mouth of the separator with a small amount of water. Add 0.2 mL of starch TS, then while swirling the separator add iodine TS dropwise until a persistent blue color develops, and immediately add sodium thiosulfate TS to discharge the blue color. Add 2.1 g of sodium hydrogen carbonate to the liquid in the separator, preventing it from coming in contact with the mouth of the separator, and shake until most of the sodium hydrogen carbonate dissolves. Rapidly inject 1.0 mL of acetic anhydride into the contents of the separator. Immediately stopper the separator loosely, and allow to stand until the evolution of gas ceases. Shake vigorously, allow to stand for 5 minutes, extract with six 25-mL portions of chloroform, and filter each chloroform extract through a pledget of absorbent cotton. Evaporate the combined chloroform extracts on a water bath in a current of air to 3 mL, completely transfer this residue by means of small portions of chloroform to a tared beaker, and heat again to evaporate to dryness. Dry the residue at 105°C for 30 minutes, cool in a desiccator (silica gel), and accurately measure the mass W (mg) of the dried residue. Dissolve in chloroform to make exactly 5 mL, and determine the optical rotation $[\alpha]_D^{20}$ using a 100-mm cell.

$$\text{Amount (mg) of epinephrine } (C_9H_{13}NO_3) = 0.5923 \times W \times \left(0.5 + \frac{0.5 \times |[\alpha]_D^{20}|}{93}\right)$$

Containers and storage Containers—Hermetic containers, and colored containers may be used.

Storage—Light-resistant.

Epinephrine Solution

Adrenaline Hydrochloride Solution
Epinephrine Hydrochloride Solution
Epirenamine Hydrochloride Solution

エピネフリン液

Epinephrine Solution 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

Epinephrine	1 g
Sodium Chloride	8.5 g
Diluted Hydrochloric Acid (9 in 100)	10 mL
Stabilizer	a suitable quantity
Preservative	a suitable quantity
Purified Water	a sufficient quantity
To make	1000 mL

Prepare by mixing the above ingredients.

Description Epinephrine Solution is clear, colorless or slightly reddish liquid.

It changes gradually to pale red and then to brown on exposure to air and light.

pH: 2.3 - 5.0

Identification Proceed as directed in the Identification under Epinephrine Injection.

Assay Proceed as directed in the Assay under Epinephrine Injection.

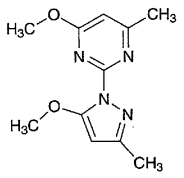
Containers and storage Containers—Tight containers.

Storage—Light-resistant.

Epirizole

Mepirizole

エピリゾール



$C_{11}H_{14}N_4O_2$: 234.25

4-Methoxy-2-(5-methoxy-3-methyl-1*H*-pyrazol-1-yl)-6-methylpyrimidine [*18694-40-1*]

Epirizole, when dried, contains not less than 99.0% of $C_{11}H_{14}N_4O_2$.

Description Epirizole occurs as white crystals or crystalline powder. It is odorless, and has a bitter taste.

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

It dissolves in dilute hydrochloric acid and in sulfuric acid.

The pH of a solution of Epirizole (1 in 100) is between 6.0 and 7.0.

Identification (1) To 0.1 g of Epirizole add 0.1 g of vanillin, 5 mL of water and 2 mL of sulfuric acid, and mix with shaking for a while: a yellow precipitate is formed.

(2) Dissolve 0.1 g of Epirizole in 10 mL of water, and add 10 mL of 2,4,6-trinitrophenol TS: a yellow precipitate is produced. Collect the precipitate by filtration, wash with 50 mL of water, and dry at 105°C for 1 hour: it melts between 163°C and 169°C.