

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—Hermetic containers.
Storage—Light-resistant.

10% Ephedrine Hydrochloride Powder

Ephedrine Hydrochloride Powder

塩酸エフェドリン散 10%

10% Ephedrine Hydrochloride Powder contains not less than 9.3% and not more than 10.7% of ephedrine hydrochloride ($C_{10}H_{15}NO.HCl$: 201.69).

Method of preparation

Ephedrine Hydrochloride	100 g
Starch, Lactose or their mixture	a sufficient quantity
To make 1000 g	

Prepare as directed under Powders, with the above ingredients.

Identification To 0.5 g of 10% Ephedrine Hydrochloride Powder add 100 mL of water, shake for 20 minutes, and filter. Determine the absorption spectrum of the filtrate as directed under the Ultraviolet-visible Spectrophotometry: it exhibits maxima between 249 nm and 253 nm, between 255 nm and 259 nm, and between 261 nm and 265 nm.

Assay Weigh accurately about 0.4 g of 10% Ephedrine Hydrochloride Powder, add 150 mL of water, and extract with the aid of ultrasonicator for 10 minutes with occasional shaking. Shake more for 10 minutes, then add exactly 10 mL of the internal standard solution and water to make 200 mL, centrifuge, and use the supernatant liquid as the sample solution. Separately, weigh accurately about 0.04 g of ephedrine hydrochloride for assay, previously dried at 105°C for 3 hours, add exactly 10 mL of the internal standard solution to dissolve, add water to make 200 mL, and use this solution as the standard solution. Perform the test with 10 μ L each of the sample solution and the standard solution as directed under the Liquid Chromatography according to the following conditions, and calculate the ratios, Q_T and Q_S , of the peak area of ephedrine to that of the internal standard of each solution.

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: Perform 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.

Ephedrine Hydrochloride Tablets

塩酸エフェドリン錠

Ephedrine Hydrochloride Tablets contain not less than 93% and not more than 107% of the labeled amount of ephedrine hydrochloride ($C_{10}H_{15}NO.HCl$: 201.69).

Method of preparation Prepare as directed under Tablets, with Ephedrine Hydrochloride.

Identification To an amount of powdered Ephedrine Hydrochloride Tablets, equivalent to 0.05 g of Ephedrine Hydrochloride, add 100 mL of water, shake for 20 minutes, and filter. Determine the absorption spectrum of the filtrate as directed under the Ultraviolet-visible Spectrophotometry: it exhibits maxima between 249 nm and 253 nm, between 255 nm and 259 nm, and between 261 nm and 265 nm.

Assay Weigh accurately not less than 20 tablets of Ephedrine Hydrochloride Tablets, and powder. Weigh accurately an amount of the powder, equivalent to about 0.04 g of ephedrine hydrochloride ($C_{10}H_{15}NO.HCl$), add 150 mL of water, and extract with the aid of ultrasonicator for 10 minutes with occasional shaking. Shake more for 10 minutes, then add exactly 10 mL of the internal standard solution and water to make 200 mL, centrifuge, and use the supernatant liquid as the sample solution. Separately, weigh accurately about 0.04 g of ephedrine hydrochloride for assay, previously dried at 105°C for 3 hours, add exactly 10 mL of the internal standard solution to dissolve, add water to make 200 mL, and use this solution as the standard solution. Perform the test with 10 μ L each of the sample solution and the standard solution as directed under the Liquid Chromatography according to the following conditions, and calculate the ratios, Q_T and Q_S , of the peak area of ephedrine to that of the internal standard of each solution.

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%.

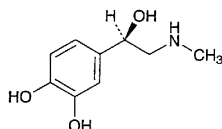
Containers and storage Containers—Well-closed containers.

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