Dopamine Hydrochloride Injection

Dopamine Hydrochloride Injection is an aqueous solution for injection. It contains not less than 97% and not more than 103% of the labeled amount of dopamine hydrochloride (C₈H₁₁NO₂.HCl: 189.64).

Method of preparation Prepare as directed under Injections, with Dopamine Hydrochloride.

Description Dopamine Hydrochloride Injection occurs as a clear, colorless liquid.

Identification To a volume of Dopamine Hydrochloride Injection, equivalent to 0.04 g of Dopamine Hydrochloride according to the labeled amount, add 0.1 mol/L hydrochloric acid TS to make 100 mL. To 5 mL of this solution add 0.1 mol/L hydrochloric acid TS to make 50 mL. Determine the absorption spectrum of this solution as directed under the Ultraviolet-visible Spectrophotometry: it exhibits a maximum between 278 nm and 282 nm.

pH 3.0 – 5.0

Bacterial endotoxins Less than 4.2 EU/mg.

Assay To an exact volume of Dopamine Hydrochloride Injection, equivalent to about 0.04 g of dopamine hydrochloride (C₈H₁₁NO₂.HCl), add the mobile phase to make exactly 20 mL. Pipet 2.5 mL of this solution, add exactly 2.5 mL of the internal standard solution and the mobile phase to make 50 mL, and use this solution as the sample solution. Separately, weigh accurately about 0.04 g of dopamine hydrochloride for assay, previously dried at 105°C for 3 hours, dissolve in the mobile phase to make exactly 20 mL. Pipet 2.5 mL of this solution, add exactly 2.5 mL of the internal standard solution and the mobile phase to make 50 mL, and use this solution as the standard solution. Perform the test with 10 µL each of the sample solution and the standard solution as directed under the Liquid Chromatography according to the following conditions, and calculate the ratios, Q₁ and Q₂, of the peak area of dopamine to that of the internal standard.

Amount (mg) of dopamine hydrochloride (C₈H₁₁NO₂.HCl) = amount (mg) of dopamine hydrochloride for assay × Q₁/Q₂

Internal standard solution—A solution of uracil in the mobile phase (1 in 1000).

Operating conditions—

Detector: An ultraviolet absorption photometer (wavelength: 280 nm).

Column: A stainless steel column 4.6 mm in inside diameter and 25 cm in length, packed with octadecysilanized silica gel for liquid chromatography (5 µm in particle diameter).

Column temperature: A constant temperature of about 25°C.

Mobile phase: Disodium hydrogenphosphate-citric acid buffer solution, pH 3.0

Flow rate: Adjust the flow rate so that the retention time of dopamine is about 10 minutes.

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 dopamine are eluted in this order with the resolution between these peaks being not less than 10.

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 peak area of dopamine to that of the internal standard is not more than 1.0%.

Containers and storage Containers—Hermetic containers.

Doxapram Hydrochloride

Doxapram Hydrochloride contains not less than 98.0% of C₂₄H₂₈N₂O₂.HCl (mol. wt.: 414.97), calculated on the anhydrous basis.

Description Doxapram Hydrochloride occurs as white crystals or crystalline powder.

It is freely soluble in methanol and in acetic acid (100), sparingly soluble in water, in ethanol (95) and in acetic anhydride, and practically insoluble in diethyl ether.
Doxorubicin Hydrochloride

Identification (1) Determine the absorption spectrum of a solution of Doxapram Hydrochloride (1 in 2500) as directed under the Ultraviolet-visible Spectrophotometry, and compare the spectrum with the Reference Spectrum: both spectra exhibit similar intensities of absorption at the same wavelengths.

(2) Determine the infrared absorption spectrum of Doxapram Hydrochloride as directed in the potassium bromide disk method under the Infrared Spectrophotometry, and compare the spectrum with the Reference Spectrum: both spectra exhibit similar intensities of absorption at the same wave numbers.

(3) A solution of Doxapram Hydrochloride (1 in 50) responds to the Qualitative Tests for chloride.

pH Dissolve 1.0 g of Doxapram Hydrochloride in 50 mL of water: the pH of this solution is between 3.5 and 5.0.

Melting point 218 – 222°C

Purity (1) Clarity and color of solution—Dissolve 1.0 g of Doxapram Hydrochloride in 50 mL of water: the solution is clear and colorless.

(2) Sulfate—Perform the control solution with 0.50 mL of 0.005 mol/L sulfuric acid VS (not more than 0.024%).

(3) Heavy metals—Proceed with 2.0 g of Doxapram Hydrochloride according to Method 2, and perform the test.

Prepare the control solution with 2.0 mL of Standard Lead Solution (not more than 10 ppm).

(4) Arsenic—Prepare the test solution with 1.0 g of Doxapram Hydrochloride according to Method 3, and perform the test using Apparatus B (not more than 2 ppm).

(5) Related substances—Dissolve 0.5 g of Doxapram Hydrochloride in 10 mL of methanol, and use this solution as the sample solution. Pipet 3 mL of the sample solution, and add methanol to make exactly 100 mL. Pipet 5 mL of this solution, add methanol to make exactly 50 mL, and use this solution as the standard solution. Perform the test with these solutions as directed under the Thin-layer Chromatography. Spot 6 μL each of the sample solution and the standard solution on a plate of silica gel for thin-layer chromatography. Develop the plate with a mixture of chloroform, formic acid, ethyl formate and methanol (8:3:3:2) to a distance of about 10 cm, and air-dry the plate. Allow the plate to stand in iodine vapor: the spots other than the principal spot from the sample solution are not more intense than the spot from the standard solution.

Water 3.5 – 4.5% (0.5 g, direct titration).

Residue on ignition Not more than 0.30% (1 g).

Assay Weigh accurately about 0.8 g of Doxapram Hydrochloride, dissolve in 50 mL of a mixture of acetic anhydride and acetic acid (100:7:3), and titrate with 0.1 mol/L perchloric acid VS (potentiometric titration). Perform a blank determination, and make any necessary correction.

Each mL of 0.1 mol/L perchloric acid VS = 41.50 mg of C_{27}H_{38}NO_{11}.HCl

Containers and storage Containers—Tight containers.