

of about 10 cm, and air-dry the plate. Spray evenly a solution of ninhydrin in acetone (1 in 50) on the plate, and heat at 90°C for 10 minutes: the spots other than the principal spot from the sample solution are not more intense than the spot from the standard solution.

Loss on drying Not more than 0.5% (1 g, 105°C, 3 hours).

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

Assay Weigh accurately about 0.2 g of Dopamine Hydrochloride, previously dried, dissolve in 5 mL of formic acid, add exactly 15 mL of 0.1 mol/L perchloric acid VS, and heat on a water bath for 15 minutes. After cooling, add 50 mL of acetic acid (100), and titrate the excess perchloric acid with 0.1 mol/L sodium acetate VS (potentiometric titration). Perform a blank determination.

Each mL of 0.1 mol/L perchloric acid VS
= 18.964 mg of C₈H₁₁NO₂.HCl

Containers and storage Containers—Tight containers.

Dopamine Hydrochloride Injection

塩酸ドパミン注射液

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 ra-

tios, Q_T and Q_S, 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
× $\frac{Q_T}{Q_S}$

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 octadecylsilanized 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—

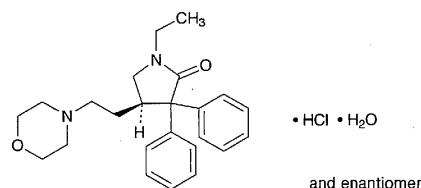
System performance: When the procedure is run with 10 μL of the standard solution under the above operating conditions, the internal standard and dopamine are eluted in this order with the resolution between these peaks being not less than 10.

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

塩酸ドキサプラム



C₂₄H₃₀N₂O₂.HCl.H₂O: 432.98
(*RS*)-1-Ethyl-4-[2-(morpholin-4-yl)ethyl]-3,3-diphenylpyrrolidin-2-one monohydrochloride monohydrate [7081-53-0]

Doxapram Hydrochloride contains not less than 98.0% of C₂₄H₃₀N₂O₂.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.