Procainamide Hydrochloride Injection

塩酸プロカインアミド注射液

Procainamide Hydrochloride Injection is an aqueous solution for injection.

It contains not less than 95% and not more than 105% of the labeled amount of procainamide hydrochloride ($C_{13}H_{21}N_3O$.HCl: 271.79).

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

Description Procainamide Hydrochloride Injection is a clear, colorless or light yellow liquid.

pH: 4.0 - 6.0

Identification **(1)** Proceed with a volume of Procainamide Hydrochloride Injection, equivalent to 1 g of Procainamide Hydrochloride according to the labeled amount, as directed in the Identification (1) under Procainamide Hydrochloride.

(2) Dilute a volume of Procainamide Hydrochloride Injection, equivalent to 0.01 g of Procainamide Hydrochloride according to the labeled amount, with 1 mL of dilute hydrochloric acid and water to 5 mL: the solution responds to the Qualitative Tests for primary aromatic amines.

(3) Procainamide Hydrochloride Injection responds to the Qualitative Tests (2) for chloride.

Assay Dilute an accurately measured volume of Procainamide Hydrochloride Injection, equivalent to about 0.5 g of procainamide hydrochloride ($C_{13}H_{21}N_3O$.HCl), with 5 mL of hydrochloric acid and water to 50 mL, cool to 15°C, and titrate with 0.1 mol/L sodium nitrite VS according to the Potentiometric titration method or the Amperometric titration method under the Electrometric Titration.

Each mL of 0.1 mol/L sodium nitrite VS
= 27.179 mg of $C_{13}H_{21}N_3O$.HCl

Containers and storage Containers—Hermetic containers.

Procainamide Hydrochloride Tablets

塩酸プロカインアミド錠

Procainamide Hydrochloride Tablets contain not less than 95% and not more than 105% of the labeled amount of procainamide hydrochloride ($C_{13}H_{21}N_3O$.HCl: 271.79).

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

Identification **(1)** Shake a quantity of powdered Procainamide Hydrochloride Tablets, equivalent to 1.5 g of Procainamide Hydrochloride according to the labeled amount, with 30 mL of water, filter, and use the filtrate as the sample solution. To 20 mL of the sample solution add 10 mL of sodium hydroxide TS, and proceed as directed in the Identification (1) under Procainamide Hydrochloride.

(2) To 0.2 mL of the sample solution obtained in (1) add 1 mL of dilute hydrochloric acid and 4 mL of water: the solution responds to the Qualitative Tests for primary aromatic amines.

Dissolution test Perform the test with 1 tablet of Procainamide Hydrochloride Tablets at 50 revolutions per minute according to Method 2 under the Dissolution Test, using 900 mL of water as the test solution. Take 30 mL or more of the dissolved solution 30 minutes after start of the test, and filter through a membrane filter with pore size of not more than 0.8 μm. Discard the first 10 mL of the filtrate, pipet the subsequent V mL, add diluted phosphate buffer solution, pH 6.8, (1 in 2) to make exactly V' mL so that each mL contains about 7 μg of procainamide hydrochloride ($C_{13}H_{21}N_3O$.HCl) according to the labeled amount, and use this solution as the sample solution. Separately, weigh accurately about 0.125 g of procainamide hydrochloride for assay, previously dried at 105°C for 4 hours, and dissolve in water to make exactly 1000 mL. Pipet 5 mL of this solution, add diluted phosphate buffer solution, pH 6.8, (1 in 2) to make exactly 100 mL, and use this solution as the standard solution. Determine the absorbances, A_T and A_S, of the sample solution and the standard solution at 278 nm as directed under the Ultraviolet-visible Spectrophotometry. The dissolution rate of Procainamide Hydrochloride Tablets in 30 minutes is not less than 80%.

Dissolution rate (%) with respect to the labeled amount of procainamide hydrochloride ($C_{13}H_{21}N_3O$.HCl)

$$= W_S \times \frac{A_T}{A_S} \times \frac{V'}{V} \times \frac{1}{C} \times 4.5$$

W_S: Amount (mg) of procainamide hydrochloride for assay.

C: Labeled amount (mg) of procainamide hydrochloride ($C_{13}H_{21}N_3O$.HCl) in 1 tablet.

Assay Weigh accurately and powder not less than 20 Procainamide Hydrochloride Tablets. Weigh accurately a portion of the powder, equivalent to about 0.5 g of procainamide hydrochloride ($C_{13}H_{21}N_3O$.HCl), stir well with 25 mL of 1 mol/L hydrochloric acid TS, centrifuge, and separate the supernatant liquid. Wash the residue with four 10-mL portions of 1 mol/L hydrochloric acid VS in the same manner. Add 10 mL of a solution of potassium bromide (3 in 10) to the combined supernatant liquid, cool to below 15°C, and titrate with 0.1 mol/L sodium nitrite VS according to the Potentiometric titration method or the Amperometric titration method under the Electrometric Titration.

Each mL of 0.1 mol/L sodium nitrite VS
= 27.179 mg of $C_{13}H_{21}N_3O$.HCl

Containers and storage Containers—Tight containers.