

tion, add water to make exactly 25 mL, and use this solution as the standard solution. Perform the test with these solutions as directed under the Thin-layer Chromatography. Spot 5 μ L 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 ethanol (99.5), water, 1-butanol and ammonia water (28) (2:1:1:1) to a distance of about 10 cm, and dry the plate at 100°C for 30 minutes. Spray evenly a solution of ninhydrin in acetone (1 in 50) on the plate, and heat at 80°C for 5 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 0.20% (1 g, 105°C, 3 hours).

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

Assay Weigh accurately about 0.1 g of L-Arginine Hydrochloride, previously dried, dissolve in 2 mL of formic acid, add exactly 15 mL of 0.1 mol/L perchloric acid VS, and heat on a water bath for 30 minutes. After cooling, add 45 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
= 10.533 mg of $C_6H_{14}N_4O_2 \cdot HCl$

Containers and storage Containers—Tight containers.

L-Arginine Hydrochloride Injection

Arginine Hydrochloride Injection

塩酸 L-アルギニン注射液

L-Arginine Hydrochloride Injection is an aqueous solution for injection. It contains not less than 9.5 w/v% and not more than 10.5 w/v% of L-arginine hydrochloride ($C_6H_{14}N_4O_2 \cdot HCl$: 210.66).

Method of preparation

L-Arginine Hydrochloride	100 g
Water for Injection	a sufficient quantity
To make 1000 mL	

Prepare as directed under Injections, with the above ingredients. No preservative is added.

Description L-Arginine Hydrochloride Injection is a clear, colorless liquid.

Identification (1) To 5 mL of a solution of L-Arginine Hydrochloride Injection (1 in 100) add 1 mL of ninhydrin TS, and heat for 3 minutes: a blue-purple color develops.

(2) To 5 mL of a solution of L-Arginine Hydrochloride Injection (1 in 10) add 2 mL of sodium hydroxide TS and 1 to 2 drops of a solution of 1-naphthol in ethanol (95) (1 in 1000), allow to stand for 5 minutes, and add 1 to 2 drops of sodium hypochlorite TS: a red-orange color develops.

pH 5.0 – 6.0

Pyrogen Perform the test with L-Arginine Hydrochloride Injection stored in a container in a volume exceeding 10 mL: it meets the requirements of the Pyrogen Test.

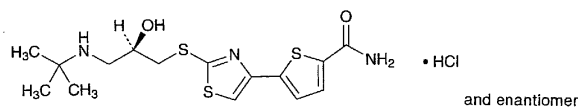
Assay Pipet 20 mL of L-Arginine Hydrochloride Injection, add 7.5 mol/L hydrochloric acid TS to make exactly 100 mL, and determine the optical rotation α_D as directed under the Optical Rotation Determination at $20 \pm 1^\circ C$ in a 100-mm cell.

Amount (mg) of L-arginine hydrochloride ($C_6H_{14}N_4O_2 \cdot HCl$)
= $\alpha_D \times 4444$

Containers and storage Containers—Hermetic containers.

Arotinolol Hydrochloride

塩酸アロチノロール



$C_{15}H_{21}N_3O_2S_3 \cdot HCl$: 408.00

5-{2-[(*RS*)-3-*tert*-Butylamino-2-hydroxypropylsulfanyl]-thiazol-4-yl}thiophene-2-carboxamide monohydrochloride [68377-91-3]

Arotinolol Hydrochloride, when dried, contains not less than 99.0% of $C_{15}H_{21}N_3O_2S_3 \cdot HCl$.

Description Arotinolol Hydrochloride occurs as a white to light yellow crystalline powder.

It is freely soluble in dimethylsulfoxide, slightly soluble in methanol and in water, very slightly soluble in ethanol (99.5), and practically insoluble in diethyl ether.

A solution of Arotinolol Hydrochloride in methanol (1 in 125) does not show optical rotation.

Identification (1) Determine the absorption spectrum of a solution of Arotinolol Hydrochloride in methanol (1 in 75,000) 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 Arotinolol Hydrochloride, previously dried, 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 Arotinolol Hydrochloride (1 in 200) responds to the Qualitative Tests (2) for chloride.

Purity (1) Heavy metals—Proceed with 1.0 g of Arotinolol Hydrochloride according to Method 2, and perform the test. Prepare the control solution with 1.0 mL of Standard Lead Solution (not more than 10 ppm).

(2) Related substances—Dissolve 0.05 g of Arotinolol Hydrochloride in 10 mL of methanol, and use this solution as the sample solution. Pipet 1 mL of the sample solution, add methanol to make exactly 100 mL. Pipet 1 mL of this solution, add methanol to make exactly 10 mL, and use this so-