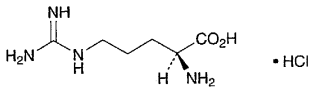
Description Arbekacin Sulfate occurs as a white powder.

It is very soluble in water, and practically insoluble in ethanol (95) and in diethyl ether.

L-Arginine Hydrochloride

Arginine Hydrochloride

塩酸 L-アルギニン



$C_6H_{14}N_4O_2.HCl$: 210.66

(2*S*)-2-Amino-5-guanidinopentanoic acid monohydrochloride [*1119-34-2*]

L-Arginine Hydrochloride, when dried, contains not less than 98.5% of $C_6H_{14}N_4O_2.HCl$.

Description L-Arginine Hydrochloride occurs as white crystals or crystalline powder. It is odorless, and has a slight, characteristic taste.

It is freely soluble in water and in formic acid, and very slightly soluble in ethanol (95).

Identification **(1)** Determine the infrared absorption spectrum of L-Arginine 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.

(2) A solution of L-Arginine Hydrochloride (1 in 50) responds to the Qualitative Tests for chloride.

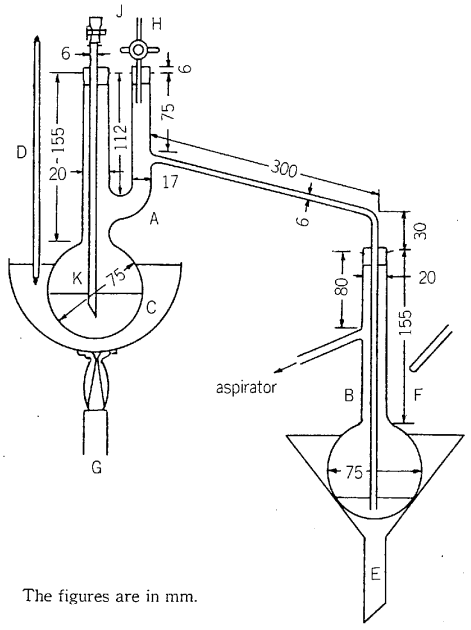
Optical rotation $[\alpha]_D^{20}$: +21.5 – +23.5° (after drying, 2 g, 6 mol/L hydrochloric acid TS, 25 mL, 100 mm).

pH Dissolve 1.0 g of L-Arginine Hydrochloride in 10 mL of water: the pH of this solution is between 4.7 and 6.2.

Purity **(1)** Clarity and color of solution—Dissolve 1.0 g of L-Arginine Hydrochloride in 10 mL of water: the solution is clear and colorless.

(2) Sulfate—Perform the test with 0.6 g of L-Arginine Hydrochloride. Prepare the control solution with 0.35 mL of 0.005 mol/L sulfuric acid VS (not more than 0.028%).

(3) Ammonium—(i) Apparatus: Use the apparatus illustrated in the figure. It is thoroughly constructed of hard glass, and ground glass surfaces may be used for joints. All rubber parts used in the apparatus should be boiled for 10 to 30 minutes in sodium hydroxide TS and for 30 to 60 minutes in water, and finally washed thoroughly with water before use.



The figures are in mm.

A: Vacuum distilling flask (200 mL)
B: Receiver (200-mL flask)
C: Water bath
D: Thermometer
E: Funnel
F: Cooling water
G: Gas burner
H: Glass cock
J: Rubber tube with screw cock
K: Glass tube for bumping prevention

(ii) Procedure: Take 0.25 g of L-Arginine Hydrochloride in a vacuum distilling flask A, add 70 mL of water and 1 g of magnesium oxide, and connect the flask with a vacuum distilling apparatus. Place 20 mL of a solution of boric acid (1 in 200) as an absorbing liquid in receiver B, immerse the end of the branch of the vacuum distilling flask in the absorbing liquid, and distil in a water bath of 60°C, adjusting the degree of vacuum so that the distillatory rate is between 1 mL and 2 mL per minute, until 30 mL of distillate is obtained. During distillation, cool the bulb of receiver B with water. Lift the end of the branch from the absorbing liquid, rinsing the end with a small quantity of water, and add water to make exactly 100 mL. Perform the test using this solution as the test solution. Prepare the control solution as follows: take 5.0 mL of Standard Ammonium Solution in vacuum distilling flask A, and proceed in the same manner as the preparation of the test solution (not more than 0.02%).

(4) Heavy metals—Proceed with 1.0 g of L-Arginine Hydrochloride according to Method 1, and perform the test. Prepare the control solution with 2.0 mL of Standard Lead Solution (not more than 20 ppm).

(5) Arsenic—Prepare the test solution with 1.0 g of L-Arginine Hydrochloride according to Method 1, and perform the test using Apparatus B (not more than 2 ppm).

(6) Other amino acids—Dissolve 0.20 g of L-Arginine Hydrochloride in 10 mL of water, and use this solution as the sample solution. Pipet 1 mL of the sample solution, and add water to make exactly 10 mL. Pipet 1 mL of this solu-

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 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 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 $C_6H_{14}N_4O_2.HCl$

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 ($C_6H_{14}N_4O_2.HCl$: 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.

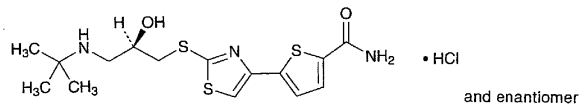
Assay Pipet 20 mL of L-Arginine Hydrochloride Injection, add 7.5 mol/L hydrochloric acid TS to make exactly 100 mL, and determine the optical rotation α_D as directed under the Optical Rotation Determination at 20 ± 1°C in a 100-mm cell.

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

Containers and storage Containers—Hermetic containers.

Arotinolol Hydrochloride

塩酸アロチノロール



$C_{15}H_{21}N_3O_2S_3.HCl$: 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 $C_{15}H_{21}N_3O_2S_3.HCl$.

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-