L-Lysine Monohydrochloride [1]

$C_6H_{14}N_2O_2 \cdot HCl$: 182.65

L-Lysine Monohydrochloride, when dried, contains not less than 98.5 percent and not more than 101.0 percent of L-Lysine Monohydrochloride ($C_6H_{14}N_2O_2 \cdot HCl$).

Description

White powder; slightly characteristic taste.
Freely soluble in water and in formic acid, practically insoluble in ethanol (95).

Identification

Compare the infrared absorption spectrum of the sample with that of the standard by potassium bromide disc method.[2]

Specifications

Item	Limit	Test
Specific rotation $[\alpha]_D^{20}$	+20.8 to +21.5°	AJI TEST 1 [Dried sample, C=8, 6mol/L HCl][3]
State of solution (Transmittance)	Clear and colorless Not less than 98.0%	AJI TEST 2 [1.0g in 10mL of H_2O, spectrophotometer, 430nm, 10mm cell thickness]
Chloride (Cl)	19.12 to 19.51%	AJI TEST 3 [Dried sample, 1.0g[4], B]
Ammonium (NH_4)	Not more than 0.02%	AJI TEST 4 [D-1]
Sulfate (SO_4)	Not more than 0.020%	AJI TEST 5 [0.85g, (1), ref: 0.35mL of 0.005mol/L H_2SO_4]
Iron (Fe)	Not more than 10ppm	AJI TEST 6 [0.75g, B-1, ref: 0.75mL of Iron Std. (0.01mg/mL)]
Heavy metals (Pb)	Not more than 10ppm	AJI TEST 7 [1.0g, (1), ref: 1.0mL of Pb Std. (0.01mg/mL)]
Arsenic (As_2O_3)	Not more than 1ppm	AJI TEST 8 [2.0g, (1), ref: 2.0mL of As_2O_3 Std.]
Related substances	1) Conforms[5] 2) Any unspecified impurity Not more than 0.20% Total impurities Not more than 1.00%	AJI TEST 9 [Test sample: 50μg, S-6-a, control; L-Lys· HCl 0.25 μg] AJI TEST 26[6]
Loss on drying	Not more than 0.40%	AJI TEST 11 [1g, at 105°C for 3 hours]
Residue on ignition (Sulfated)	Not more than 0.10%	AJI TEST 13 [1g, at 550°C to 650°C for 3 hours]

L-Lysine Monohydrochloride

Specifications (cont'd)

Item	Limit	Test
Assay	98.5 to 101.0%	AJI TEST 14 [Dried sample, 100mg, (3), 2mL of formic acid, 0.1mol/L $HClO_4$ 1mL=9.132mg $C_6H_{14}N_2O_2 \cdot HCl$]
pH	5.0 to 6.0	AJI TEST 33 [1.0g in 10mL of H_2O]

The test for endotoxin when the material will be used for manufacturing parenteral products is as follows:

Item	Limit	Test
Endotoxin	Less than 6.0EU/g	AJI TEST 34 [C=1, kinetic-turbidimetric technique]

[1] This product, in terms of actual quality, conforms to USP, EP, and JP.

[2] If the spectrum obtained shows differences from the reference spectrum, dissolve the sample in the minimum volume of water, evaporate to dryness at 60°C, and measure spectrum of the residue.

[3] Temperature coefficient of $[\alpha]_D^t$: -0.02°

[4] Weigh accurately 1.0g of the sample and add water to make exactly 100mL.

[5] Any secondary spot in the chromatogram obtained from the Test Solution is less intense than the principal spot in the chromatogram obtained from the Standard Solution: the number of those spots is not more than four and not more than 2.0% of the total impurities found.

[6] Disregard limit: 0.05%

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