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L-Lysine Monohydrochloride		
Issued Date: Mar. 25, 2026		

L-Lysine Monohydrochloride¹

$C_6H_{14}N_2O_2 \cdot HCl$: 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 crystals or crystalline powder; slightly characteristic taste.

Freely soluble in water and in formic acid, practically insoluble in ethanol (95).

Identification

- 1) Compare the infrared absorption spectrum of the sample with that of the standard by potassium bromide disc method.²
- 2) Compare the position and ninhydrin reaction of the test solution with that of the reference solution by chromatographic separation technique.
- 3) The aqueous solution yields the reactions characteristic of chlorides [ChP].

Specifications

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

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Specifications (cont'd)

Item	Limit	Test
Assay	98.5 to 101.0%	AJI TEST 14 [Dried sample, 100 mg, (3), 2 mL of formic acid, 0.1 mol/L HClO ₄ 1 mL = 9.132 mg C ₆ H ₁₄ N ₂ O ₂ ·HCl]
pH	5.0 to 6.0	AJI TEST 33 [1.0 g in 10 mL of H ₂ O]

The following test item is added for parenteral products:

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

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

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 $[\alpha]_D^{25}$: -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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