L-Lysine Acetate[1]

$C_6H_{14}N_2O_2 \cdot C_2H_4O_2$: 206.24

L-Lysine Acetate, when dried, contains not less than 98.5 percent and not more than 101.0 percent of L-Lysine Acetate ($C_6H_{14}N_2O_2 \cdot C_2H_4O_2$).

Description

White crystals or crystalline powder; slightly acid taste.
Very soluble in water, soluble in formic acid, practically insoluble in ethanol (99.5).

Identification

(1)Compare the infrared absorption spectrum of the sample with that of the standard by potassium bromide disc method.
(2)When an acetate is warmed with sulfuric acid and a small quantity of ethanol (95), the odor of ethyl acetate is evolved.

Specifications

Item	Limit	Test
Specific rotation $[\alpha]_D^{20}$	+8.5 to +10.0°	AJI TEST 1 [Dried sample, C=10, H_2O][2]
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)	Not more than 0.020%	AJI TEST 3 [0.5g, A-1, ref: 0.28mL of 0.01mol/L HCl]
Ammonium (NH_4)	Not more than 0.02%	AJI TEST 4 [B-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 [1.0g, A-1, ref: 1.0mL of Iron Std. (0.01mg/mL)]
Heavy metals (Pb)	Not more than 10ppm	AJI TEST 7 [1.0g, (4), 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[3] 2)Not more than 0.20% of Any unspecified impurity Not more than 1.0% of Total impurities	AJI TEST 9 [Test sample: 50μg, S-6-a, control: L-Lys·AcOH 0.25μg] AJI TEST 26[4]
Loss on drying	Not more than 0.20%	AJI TEST 11 [1g, at 80°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]

Specifications(cont'd)

Item	Limit	Test
Assay	98.5 to 101.0%	AJI TEST 14 [Dried sample, 110mg, (1), 3mL of formic acid, 50mL of acetic acid (100), 0.1mol/L $HClO_4$ 1mL=10.31mg $C_6H_{14}N_2O_2 \cdot C_2H_4O_2$]
pH	6.5 to 7.5	AJI TEST 33 [1.0g in 10mL of H_2O]
Residual solvents Methanol	Not more than 500ppm	AJI TEST 27 [1] [5]

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

[3] 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.

[4] Disregard limit: 0.03%

[5] Weigh exactly 1.0g of the sample and dissolve with sodium hydroxide TS to make 50mL, and use this solution as the sample solution.

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