L-Histidine[1]

$C_6H_9N_3O_2$: 155.15

L-Histidine contains not less than 99.0 percent and not more than 101.0 percent of L-Histidine ($C_6H_9N_3O_2$), calculated on the dried basis.

Description

White crystals or white crystalline powder; slightly bitter taste.
Freely soluble in formic acid, and soluble in water, and practically insoluble in ethanol (99.5).
Dissolves in 6mol/L hydrochloric acid.

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 $[\alpha]_D^{20}$	+12.0 to +12.8°	AJI TEST 1 [Calculated on the dried basis, C=11, 6mol/L HCl][3]
State of solution (Transmittance)	Clear and colorless Not less than 98.0%	AJI TEST 2 [0.5g in 10mL of H_2O, dissolve by heating, 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 [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 [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, dissolve by warming, weakly acidic, (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[4] 2)Any unspecified impurity Not more than 0.20% Total impurities Not more than 0.50%	AJI TEST 9 [Test sample: 50μg, B-6-a, control; L-His 0.25μg] AJI TEST 26[5]
Loss on drying	Not more than 0.20%	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-Histidine[1]

Specifications (cont'd)

Item	Limit	Test
Assay	99.0 to 101.0%	AJI TEST 14 [Calculated on the dried basis, 150mg, (1), 2mL of formic acid, 50mL of acetic acid (100), 0.1mol/L $HClO_4$ 1mL=15.52 mg $C_6H_9N_3O_2$][6]
pH	7.0 to 8.5	AJI TEST 33 [1.0g in 50mL 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 any difference appears between the spectra, dissolve the sample with a little amount of water, evaporate the water at 60°C under reduced pressure, dry the residue, and perform the test.

[3] Temperature coefficient of $[\alpha]_D^t$: +0.19°

[4] 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.

[5] Disregard limit: 0.05%

[6] Titration curve of L-Histidine shows two inflection points. Determine the end-point from the first inflection point which is sharper than the second one (Titration speed: about 1.5mL/min).

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