L-Leucine[1]

$C_6H_{13}NO_2$: 131.17

L-Leucine, when dried, contains not less than 98.5 percent and not more than 101.0 percent of L-Leucine ($C_6H_{13}NO_2$).

Description

White crystals or crystalline powder; slightly bitter taste.
Freely soluble in formic acid, sparingly soluble in water, practically insoluble in ethanol (95).
Dissolves in dilute hydrochloric acid.

Identification

1) Compare the infrared absorption spectrum of the sample with that of the standard by potassium bromide disc method.
2) Compare the position and ninhydrin reaction of the test solution with that of the reference solution by chromatographic separation technique.

Specifications

Item	Limit	Test
Specific rotation $[\alpha]_D^{20}$	+14.9 to +16.0°	AJI TEST 1 [Dried sample, C = 4, 6 mol/L HCl][2]
State of solution (Transmittance)	1) Clear and colorless Not less than 98.0%	AJI TEST 2 [0.5 g in 10 mL of 1 mol/L HCl, spectrophotometer, 430 nm, 10 mm cell thickness]
	2) Clear and colorless Not less than 98.0%	AJI TEST 2 [0.50 g in 50 mL of H_2O, dissolve by heating, spectrophotometer, 430 nm, 10 mm cell thickness]
Chloride (Cl)	Not more than 0.020%	AJI TEST 3 [0.5 g, A-1, ref: 0.28 mL of 0.01 mol/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 [0.85 g, (1), ref: 0.35 mL of 0.005 mol/L H_2SO_4]
Iron (Fe)	Not more than 10 ppm	AJI TEST 6 [0.75 g, B-1, ref: 0.75 mL of Iron Std. (0.01 mg/mL)]
Heavy metals (Pb)	Not more than 10 ppm	AJI TEST 7 [1.0 g, (4), ref: 1.0 mL of Pb Std. (0.01 mg/mL)]
Arsenic (As_2O_3)	Not more than 1 ppm	AJI TEST 8 [2.0 g, (1), ref: 2.0 mL of As_2O_3 Std.]
Related substances	1) Conforms[3]	AJI TEST 9 [Test sample: 50 μg, B-6-a, control; L-Leu 0.25 μg]
	2) Isoleucine Not more than 0.80% Any unspecified impurity Not more than 0.20% Total impurities Not more than 1.00%	AJI TEST 26[4]

Specifications (cont'd)

Item	Limit	Test
Loss on drying	Not more than 0.20%	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]
Assay	98.5 to 101.0%	AJI TEST 14 [Dried sample, 130 mg, (1), 3 mL of formic acid, 50 mL of acetic acid (100), 0.1 mol/L $HClO_4$ 1 mL = 13.12 mg $C_6H_{13}NO_2$]
pH	5.5 to 6.5	AJI TEST 33 [1.0 g in 100 mL of H_2O]

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] Temperature coefficient of $[\alpha]_D^t$: +0.06°

[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: 0.05%

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