L-Isoleucine[1]

$C_6H_{13}NO_2$: 131.17

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

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

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

Specifications

Item	Limit	Test
Specific rotation $[\alpha]_D^{20}$	+40.0 to +41.5°	AJI TEST 1 [Dried sample, C=4, 6mol/L HCl][2]
State of solution (Transmittance)	Clear and colorless Not less than 98.0%	AJI TEST 2 [0.5g in 10mL of 1mol/L HCl, 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 [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), dissolve by warming, 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) Leucine Not more than 0.30% Valine Not more than 0.30% Any unspecified impurity Not more than 0.20% Total impurities Not more than 1.00%	AJI TEST 9 [Test sample: 50μg, B-6-a, control; L-Ile 0.25μg] AJI TEST 26[4]
Loss on drying	Not more than 0.20%	AJI TEST 11 [1g, at 105℃ for 3 hours]

L-Isoleucine

Specifications (cont'd)

Item	Limit	Test
Residue on ignition (Sulfated)	Not more than 0.10%	AJI TEST 13 [1g, at 550℃ to 650℃ for 3 hours]
Assay	98.5 to 101.0%	AJI TEST 14 [Dried sample, 130mg, (1), 3mL of formic acid, 50mL of acetic acid (100), 0.1mol/L $HClO_4$ 1mL=13.12mg $C_6H_{13}NO_2$]
pH	5.5 to 6.5	AJI TEST 33 [1.0g in 100mL 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] Temperature coefficient of $[\alpha]_D^t$: -0.09°

[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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