

Amino Acids Specifications / Monographs	page	1/2
L-Isoleucine		
Issued Date: Mar. 31, 2026		

L-Isoleucine¹

C₆H₁₃NO₂: 131.17

L-Isoleucine, when dried, contains not less than 98.5 percent and not more than 101.0 percent of L-Isoleucine (C₆H₁₃NO₂).

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 $[\alpha]_D^{20}$	+40.0 to +41.5°	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% 2) 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] AJI TEST 2 [0.50 g in 20 mL of H ₂ O, 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 ₂ SO 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, (1), dissolve by warming, 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.]

Amino Acids Specifications / Monographs	page	2/2
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Specifications (cont'd)

Item	Limit	Test
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: 50 µg, B-6-a, control; L-Ile 0.25 µg] AJI TEST 26 ⁴
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 ₆ H ₁₃ NO ₂]
pH	5.5 to 6.5	AJI TEST 33 [1.0 g in 100 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 Temperature coefficient of $[\alpha]_D^{25}$: -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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