

Amino Acids Specifications / Monographs		Page	1/2
L-Isoleucine food grade	AOC product code <b>B35066-21</b>		
Mnftg site: Ajinomoto do Brazil Ind. E Com. De Alimentos Ltda.	Issued date: 8 May 2015		

## L-Isoleucine – Food Grade – EP conformity

C<sub>6</sub>H<sub>13</sub>NO<sub>2</sub>: 131.17

This product is obtained by fermentation.

L-Isoleucine, when dried, contains, not less than 98.5 percent and not more than 101.0 percent of L-Isoleucine (C<sub>6</sub>H<sub>13</sub>NO<sub>2</sub>).

### Description

White crystals or crystalline powder

No odor or slightly characteristic odor, bitter taste.

### Identification

Compare the infrared absorption spectrum of the sample with that of the reference standard using FTIR methodologies.

### Specifications

Item	Limit	Test
Specific rotation [ $\alpha$ ] <sup>20</sup> <sub>D</sub>	+40.0 to +41.5	AJI Test 1 [Dried sample, C=4, 6mol/L HCl]
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, 10 mm cell thickness]
Chloride (Cl)	Not more than 0.020%	AJI Test 3 [0.5g, A-1, ref: 0.28mL of 0.01 mol/L HCl]
Ammonium (NH <sub>4</sub> )	Not more than 0.02%	AJI Test 4 [D-1]
Sulfate (SO <sub>4</sub> )	Not more than 300 ppm	AJI Test 5 [0.57g, (1), ref: 0.35mL of 0.005 mol/L H <sub>2</sub> SO <sub>4</sub> ]
Iron (Fe)	Not more than 10 ppm	AJI Test 6 [0.75g, B-1, ref: 0.75mL of Iron Std. (0.01 mg/mL)]
Heavy metals	Not more than 10 ppm	AJI Test 7 [1.0g, (1), ref: 1.0mL of Pb Std. (0.01 mg/mL)]
Related substances (HPLC)	Leucine <sup>2</sup> Not more than 0.30%  Valine <sup>2</sup> Not more than 0.30%  Any unspecified impurity Not more than 0.20%  Total impurities Not more than 1.00%	Method PR-0904 (LA Test) <sup>3</sup>
Loss on drying	Not more than 0.3%	AJI Test 11 [1g, at 105°C for 3 hours]
Residue on ignition (Sulfated)	Not more than 0.1%	AJI Test 13 [1g, at 550°C to 650°C for 3 hours]

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Item	Limit	Test
Assay	98.5 to 101.0%	AJI test 14 [Dried sample, 130mg, (1), 3mL of formic acid, 50 mL of acetic acid (100), 0.1mol/L HClO <sub>4</sub> 1mL=13.12mg C <sub>6</sub> H <sub>13</sub> NO <sub>2</sub> ]
pH	5.5 to 7.0	AJI Test 33 [1g in 100mL of H <sub>2</sub> O]
Total viable aerobic count	NMT 500cfu/g	AJI Test 28
Total Yeast and Mould count	NMT 100 cfu/g	AJI Test 28
E. Coli	Absent / g	AJI Test 28
Salmonella	Absent / 30 g	AJI Test 28
E. sakazakii	0 cfu / 30 g	AJI Test 28
Enterobactereaceae	0 cfu / g	AJI Test 28

<sup>1</sup> Temperature coefficient of  $[\alpha]_D^{20}$  : -0.09°

2 Calculation method in conformity to EP

- For specific impurity, calculated using appropriate reference standard

- For any unspecified impurity, calculated using sample itself as the standard

<sup>3</sup> Disregard limit 0.05%

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