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L-Leucine food grade	AOC product code B35063-21		
Mnftg site: Ajinomoto do Brazil Ind. E Com. De Alimentos Ltda.	Issued date: 8 May 2015		

L-Leucine – Food Grade – EP conformity

C₆H₁₃NO₂: 131.17

This product is obtained by fermentation.

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

Description

White crystals or crystalline powder

No odor or slightly 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 [α] ²⁰ _D	+14.6 to +16.5	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 [1.0g in 50mL of H ₂ O with heating, spectrophotometer, 430nm, 10 mm cell thickness]
Chloride (Cl)	Not more than 200 ppm	AJI Test 3 [0.5g, A-1, ref: 0.28mL 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 300 ppm	AJI Test 5 [0.61g, (1), ref: 0.35mL of 0.005 mol/L H ₂ SO ₄]
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)	Isoleucine ² Not more than 0.50% Any unspecified impurity Not more than 0.20% Total impurities Not more than 1.00%	Method PR-0904 (LA Test) ³
Loss on drying	Not more than 0.2%	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 ₄ 1mL=13.12mg C ₆ H ₁₃ NO ₂]
pH	5.5 to 7.0	AJI Test 33 [1g in 100mL of H ₂ 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

¹ Temperature coefficient of $[\alpha]_D^{25}$: +0.06°

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

³ Disregard limit 0.05%

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