

Amino Acids Specifications / Monographs	page	1 / 2
L- Glutamine		
Issued Date: Sep. 5, 2014		

L-Glutamine¹

C₅H₁₀N₂O₃: 146.14

L-Glutamine, when dried, contains not less than 99.0 percent and not more than 101.0 percent of L-Glutamine (C₅H₁₀N₂O₃).

Description

White crystals or crystalline powder; slightly characteristic taste.

Freely soluble in formic acid, soluble in water, practically insoluble in ethanol (99.5) .

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 [α] _D ²⁰	+31.5 to +33.0°	AJI TEST 1 [Dried sample, C=10, 2mol/L HCl] ²
	+6.3 to +7.3°	AJI TEST 1 [Dried sample, C=4, H ₂ O, Warming at 40°C] ³
State of solution (Transmittance)	Clear and colorless Not less than 98.0%	AJI TEST 2 [0.5g in 20mL of H ₂ O, 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 0.10%	AJI TEST 4 [45°C, A-Titrimetry]
Sulfate (SO ₄)	Not more than 0.020%	AJI TEST 5 [0.85g, (1), ref: 0.35mL of 0.005mol/L H ₂ SO ₄]
Iron (Fe)	Not more than 10ppm	AJI TEST 6 [1.0g, A-1, ref: 1.0mL of Iron Std. (0.01mg/mL)]
Heavy metals (Pb)	Not more than 10ppm	AJI TEST 7 [1.0g, (1), ref: 1.0mL of Pb Std. (0.01mg/mL)]
Arsenic (As ₂ O ₃)	Not more than 1ppm	AJI TEST 8 [2.0g, (1), ref: 2.0mL of As ₂ O ₃ Std.]
Related substances ⁴	Conforms	AJI TEST 9 [Test sample: 50μg, B-6-a, control; L-Glu (NH ₂) 0.25μg]
Loss on drying	Not more than 0.30%	AJI TEST 11 [1g, at 105°C for 3 hours]
Residue on ignition (Sulfated)	Not more than 0.10%	AJI TEST 13 [1g, at 550°C to 650°C for 3 hours]
Assay	99.0 to 101.0%	AJI TEST 14 [Dried sample, 150mg, (1), 3mL of formic acid, 50mL of acetic acid (100), 0.1mol/L HClO ₄ 1mL=14.61mg C ₅ H ₁₀ N ₂ O ₃]
pH	4.5 to 6.0	AJI TEST 33 [1.0g in 50mL of H ₂ O]

Amino Acids Specifications / Monographs		page	2 / 2
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The test for Endotoxin when the material will be used for manufacturing parenteral products is as follows:

Item	Limit	Test
Endotoxin	Less than 50.0EU/g	AJI TEST 34 [C=0.12, kinetic-turbidimetric technique]

¹ This product, in terms of actual quality, conforms to USP, DAB, and JP.

² To prevent the decomposition of L-Glutamine by hydrochloric acid, measure within 30 minutes after preparation of sample solution.

³ To prevent the decomposition of L-Glutamine by hydrochloric acid, measure within 60 minutes after preparation of sample solution.

⁴ Likely impurity: L-Glutamic acid.

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