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L-Arginine		
Issued Date: Mar. 25, 2026		

L-Arginine¹

C₆H₁₄N₄O₂: 174.20

L-Arginine, when dried, contains not less than 99.0 percent and not more than 101.0 percent of L-Arginine (C₆H₁₄N₄O₂).

Description

White crystals or crystalline powder.

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

Dissolves in dilute hydrochloric acid and it shows hygroscopic.

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 [α] _D ²⁰	+26.9 to +27.9°	AJI TEST 1 [Dried sample, C = 8, 6 mol/L HCl] ²
State of solution (Transmittance)	Clear and colorless Not less than 98.0%	AJI TEST 2 [1.0 g in 10 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 [1.0g, A-1, ref: 1.0 mL of Iron Std. (0.01 mg/mL)]
Heavy metals (Pb)	Not more than 10 ppm	AJI TEST 7 [1.0 g, weakly acidic, (1), 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.]
Related substances	1)Conforms ³	AJI TEST 9 [Test sample: 50 µg, S-6-a, control; L-Arg 0.1 µg]
	2)Any unspecified impurity Not more than 0.20% Total impurities Not more than 0.50%	AJI TEST 26 ⁴
Loss on drying	Not more than 0.30%	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]

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Specifications (cont'd)

Item	Limit	Test
Assay	99.0 to 101.0%	AJI TEST 14 [Dried sample, 80 mg, (1), 3 mL of formic acid, 50 mL of acetic acid (100), 0.1 mol/L HClO ₄ 1 mL = 8.710 mg C ₆ H ₁₄ N ₄ O ₂]
pH	10.5 to 12.0	AJI TEST 33 [1.0 g in 10 mL of H ₂ O] ⁵
Protein	Conforms	[ChP]

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 $[\alpha]_D^{25}$: -0.04°

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 one.

⁴ Disregard limit: 0.05%

⁵ Care should be taken during measurement against atmospheric carbon dioxide.

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