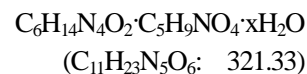


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L-Arginine L-Glutamate		
Issued Date: Feb. 15, 2016		

## L-Arginine L-Glutamate



L-Arginine L-Glutamate, when calculated on the anhydrous basis, contains not less than 98.5 percent and not more than 101.0 percent of L-Arginine L-Glutamate ( $\text{C}_{11}\text{H}_{23}\text{N}_5\text{O}_6$ ).

### Description

White crystals or crystalline powder; characteristic taste.

Freely soluble in water and in formic acid, very slightly soluble in acetic acid (100), practically insoluble in methanol and in ethanol (95) and in diethyl ether.

Dissolves in dilute hydrochloric acid.

### 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 $[\alpha]_D^{20}$	+28.0 to +30.0°	AJI TEST 1 [Sample calculated on the anhydrous basis, C=8, 6mol/L HCl]
State of solution (Transmittance)	Clear and colorless Not less than 98.0%	AJI TEST 2 [0.5g in 10mL of H <sub>2</sub> 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 <sub>4</sub> )	Not more than 0.02%	AJI TEST 4 [B-1]
Sulfate (SO <sub>4</sub> )	Not more than 0.030%	AJI TEST 5 [0.56g, (1), ref: 0.35mL of 0.005mol/L H <sub>2</sub> SO <sub>4</sub> ]
Iron (Fe)	Not more than 10ppm	AJI TEST 6 [0.75g, B-1, ref: 0.75mL of Iron Std. (0.01mg/mL)]
Heavy metals (Pb)	Not more than 10ppm	AJI TEST 7 [2.0g, (1), ref: 2.0mL of Pb Std. (0.01mg/mL)]
Arsenic (As <sub>2</sub> O <sub>3</sub> )	Not more than 1ppm	AJI TEST 8 [2.0g, (1), ref: 2.0mL of As <sub>2</sub> O <sub>3</sub> Std. ]
Related substances	Conforms	AJI TEST 9 [Test sample: 50μg, B-1-a, control; L-Glu 0.25μg]
Water	Not more than 5.00%	AJI TEST 12 [300mg, methanol for Karl Fischer Method, A, for 30 minutes]
Residue on ignition (Sulfated)	Not more than 0.20%	AJI TEST 13 [1g, at 550°C to 650°C for 3 hours]

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Specifications (cont'd)

Item	Limit	Test
Assay	98.5 to 101.0%	AJI TEST 14 [Sample calculated on the anhydrous basis, 110mg, (1), 3mL of formic acid, 50mL of acetic acid (100), 0.1mol/L HClO <sub>4</sub> 1mL=10.711mg C <sub>11</sub> H <sub>23</sub> N <sub>5</sub> O <sub>6</sub> ]
pH	6.0 to 7.0	AJI TEST 33 [1.0g in 10mL of H <sub>2</sub> O]

The test for Endotoxin when the material will be used for manufacturing parenteral products is as follows:

Item	Limit	Test
Endotoxin	Less than 25.0EU/g	AJI TEST 34 [C=0.24, kinetic-turbidimetric technique]

**End of document**