L-Aspartic Acid[1]

$C_4H_7NO_4$: 133.10

L-Aspartic Acid, when dried, contains not less than 98.5 percent and not more than 101.0 percent of L-Aspartic Acid ($C_4H_7NO_4$).

Description

White crystals or crystalline powder.
Slightly soluble in water, practically insoluble in ethanol (99.5).
Dissolves in dilute hydrochloric acid and in 0.2mol/L sodium hydroxide.

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 $[\alpha]_D^{20}$	+24.8 to +25.8°	AJI TEST 1 [Dried sample, C=8, 6mol/L HCl]
State of solution (Transmittance)	Clear and colorless Not less than 98.0%	AJI TEST 2 [1.0g in 10mL of 1mol/L HCl, 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 0.02%	AJI TEST 4 [D-1]
Sulfate (SO_4)	Not more than 0.020%	AJI TEST 5 [0.85g, (1), ref: 0.35mL of 0.005mol/L H_2SO_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, (4), ref: 1.0mL of Pb Std. (0.01mg/mL)]
Arsenic (As_2O_3)	Not more than 1ppm	AJI TEST 8 [2.0g, (2), ref: 2.0mL of As_2O_3 Std.]
Related substances	1) Glutamic acid Not more than 0.20% Asparagine Not more than 0.20% Alanine Not more than 0.20% Any unspecified impurity Not more than 0.10% Total impurities Not more than 1.00%	[Amino acid analyzer method][2]

L-Aspartic Acid

Specifications (cont'd)

Item	Limit	Test
Related substances (cont'd)	2) ①[3]Maleic acid Not more than 0.05% Malic acid Not more than 0.20% Fumaric acid Not more than 0.10% Any unspecified impurity Not more than 0.05% Total unspecified impurities Not more than 0.10% ②[4]Maleic acid Not more than 0.10% Malic acid Not more than 0.20% Fumaric acid Not more than 0.10% Any unspecified impurity Not more than 0.10% Total impurities Not more than 0.30%	[Liquid Chromatography] [5]
Enantiomeric purity	Not more than 0.3% of D-Asp	[Liquid Chromatography] [6]
Loss on drying	Not more than 0.20%	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	98.5 to 101.0%	AJI TEST 17 [Dried sample, 150mg, dissolve by warming, (2), 50mL of H_2O, 0.1mol/L NaOH 1mL=13.31mg $C_4H_7NO_4$]
pH	2.5 to 3.5	AJI TEST 33 [0.4g in 100mL of H_2O, dissolve by warming]

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

Item	Limit	Test
Endotoxin	Less than 6.0EU/g	AJI TEST 34 [C=1, kinetic-turbidimetric technique]

L-Aspartic Acid

1 This product, in terms of actual quality, conforms to USP, EP, and JP.
2 Disregard limit:0.05%
3 USP
4 EP
5 Disregard limit:0.03%
6 The test conditions are as EP except the detection wavelength.
The detection : UV254nm