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 0.2 mol/L sodium hydroxide.

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 $[\alpha]_D^{20}$	+24.8 to +25.8°	AJI TEST 1 [Dried sample, C = 8, 6 mol/L HCl]
State of solution (Transmittance)	Clear and colorless Not less than 98.0%	AJI TEST 2 [1.0 g in 10 mL of 1 mol/L HCl, 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_2SO_4]
Iron (Fe)	Not more than 10 ppm	AJI TEST 6 [1.0 g, 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, (4), ref: 1.0 mL of Pb Std. (0.01 mg/mL)]
Arsenic (As_2O_3)	Not more than 1 ppm	AJI TEST 8 [2.0 g, (2), ref: 2.0 mL of As_2O_3 Std.]
Related substances	1) Conforms 2) 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%	[ChP] [Amino acid analyzer method][2]

Specifications (cont'd)

Item	Limit	Test
Related substances (cont'd)	3) 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 [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]
Assay	98.5 to 101.0%	AJI TEST 17 [Dried sample, 150 mg, dissolve by warming, (2), 50 mL of H_2O, 0.1 mol/L NaOH 1mL = 13.31 mg $C_4H_7NO_4$]
pH	2.5 to 3.5	AJI TEST 33 [0.4 g in 100 mL of H_2O, dissolve by warming]

The following test items are added for parenteral products:

Item	Limit	Test
Endotoxin	Less than 6.0 EU/g	AJI TEST 34 [C = 1, kinetic-turbidimetric technique]
Pyrogen	Conforms[7]	[ChP]

[1] This product, in terms of actual quality, conforms to USP, EP, JP and ChP.
[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
[7] This result is based on the result of Endotoxin.

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