L-Glutamic Acid[1]

$C_5H_9NO_4$: 147.13

L-Glutamic Acid contains not less than 99.0 percent and not more than 100.5 percent of L-Glutamic Acid ($C_5H_9NO_4$) calculated on the dried basis.

Description

White crystals or white crystalline powder; slightly characteristic taste and acid taste.
Slightly soluble in water, and practically insoluble in ethanol (99.5).
Dissolves in 2mol/L hydrochloric acid

Identification

Compare the infrared absorption spectrum of the sample with that of the standard by potassium bromide disc method.[2]

Specifications

Item	Limit	Test
Specific rotation $[\alpha]_D^{20}$	+31.5 to +32.4°	AJI TEST 1 [Calculated on the dried basis, C=10, 2mol/L HCl]
State of solution (Transmittance)	Clear and colorless Not less than 98.0%	AJI TEST 2 [1.0g in 10mL of 2mol/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 [B-1]
Sulfate (SO_4)	Not more than 0.020%	AJI TEST 5 [0.85g, (2), 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, (1)[3], 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)Conforms 2)Not more than 0.20% of Any unspecified impurity Not more than 1.0% of Total impurities	AJI TEST 9 [Dilute ammonia R2[4], test sample[5]: 50μg, B-6-a, control; L-Glu 0.25μg] AJI TEST 26[6]
Loss on drying	Not more than 0.1%	AJI TEST 11 [1g, at 105°C for 3 hours]
Residue on ignition (Sulfated)	Not more than 0.1%	AJI TEST 13 [1g at 550°C to 650°C for 3 hours]
Assay	99.0 to 100.5%	AJI TEST 17 [Calculated on the dried basis, 300mg, dissolve by warming, (2), 0.1mol/L NaOH 1mL=14.71mg $C_5H_9NO_4$]

Specifications(cont'd)

Item	Limit	Test
pH	3.0 to 3.5	AJI TEST 33 [0.7g 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]

[1] This product, in terms of actual quality, conforms to EP and JP.

[2] If any difference appears between the spectra, dissolve L-Glutamic Acid in a small amount of water, evaporate water at 60℃ under reduced pressure, and perform the test in the same manner with the dried residue.

[3] Add 7mL of a solution of sodium hydroxide (1 in 25) and warm to dissolve.

[4] dilute ammonia R2: 33g/L~35g/L(Dilute 41g of concentrated ammonia R to 100 mL with water)

[5] Test solution : Dissolve 0.10 g of the substance to be examined in 5 mL of dilute ammonia R2 and dilute to 10 mL with water

[6] Disregard limit: 0.05%

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