L-Serine[1]

$C_3H_7NO_3$: 105.09

L-Serine, when dried, contains not less than 98.5 percent and not more than 101.0 percent of L-Serine ($C_3H_7NO_3$).

Description

White crystals or crystalline powder; slightly sweet taste.
Freely soluble in water and in formic acid, 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.

Specifications

Item	Limit	Test
Specific rotation $[\alpha]_D^{20}$	+14.4 to +15.5°	AJI TEST 1 [Dried sample, C=10, 2mol/L HCl][2]
State of solution (Transmittance)	Clear and colorless Not less than 98.0%	AJI TEST 2 [0.5g in 10mL of H_2O, 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 [2.0g, (1), ref: 2.0mL of Pb Std. (0.01mg/mL)]
Arsenic (As_2O_3)	Not more than 1ppm	AJI TEST 8 [2.0g, (1), ref: 2.0mL of As_2O_3 Std.]
Related substances	1)Conforms[3] 2)Any unspecified impurity Not more than 0.20% Total impurities Not more than 0.50%	AJI TEST 9 [Test sample: 50μg, B-6-a, control; L-Ser 0.25μg] AJI TEST 26[4]
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 14 [Dried sample, 110mg, (1), 3mL of formic acid, 50mL of acetic acid (100), 0.1mol/L $HClO_4$ 1mL=10.51mg $C_3H_7NO_3$]

L-Serine[1]

Specifications(cont'd)

Item	Limit	Test
pH	5.2 to 6.2	AJI TEST 33 [1.0g in 10mL of H_2O]
Residual solvents Methanol	Not more than 500ppm	AJI TEST 27 [1] [5]

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 USP, EP, and JP.

[2] Temperature coefficient of $[\alpha]_D^t$: -0.08°

[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 four and not more than 2.0% of the total impurities found.

[4] Disregard limit: 0.05%

[5] Weigh exactly 1.0g of the sample and dissolve with sodium hydroxide TS to make 50mL, and use this solution as the sample solution.

End of document