L–Cysteine*1

L–Cys

: For Manufacturing, Processing or Repacking

$C_3H_7NO_2S$: 121.16

L-Cysteine, when calculated on the dried basis, contains not less than 98.0 percent and not more than 101.0 percent of L-Cysteine ($C_3H_7NO_2S$).

Description: L-Cysteine occurs as white crystals or a white crystalline powder. It has a characteristic odor and a pungent taste. It is freely soluble in water, and practically insoluble in ethanol(99.5). It dissolves in 1mol/L hydrochloric acid TS.

Identification: Compare the infrared absorption spectrum <NP TEST 35> of the sample with that of the standard by potassium bromide disc method.

Specifications:

Item	Limit	Test Method
Specific rotation $[\alpha]^{20}_D$	+8.3 to +9.5°	NP TEST 1 [sample calculated on the dried basis, C=8, 1mol/L HCl]
State of solution (Transmittance)	clear and colorless not less than 95.0%	NP TEST 2 [1.0g in 10mL of 2mol/L HCl, spectrophotometer, 430nm, 10mm cell thickness]
	clear and colorless not less than 98.0%	NP TEST 2 [1.0g in 20mL of H_2O, spectrophotometer, 430nm, 10mm cell thickness]
Chloride (Cl)	not more than 0.040%	NP TEST 3 [0.25g, A-3, ref: 0.28mL of 0.01mol/L HCl]
Ammonium (NH_4)	not more than 0.02%	NP TEST 4 [(1)]
Sulfate (SO_4)	not more than 0.028%	NP TEST 5 [0.60g, (1), ref: 0.35mL of 0.005mol/L H_2SO_4]
Iron (Fe)	not more than 10ppm	NP TEST 6 [0.75g, B-1, ref: 0.75mL of Iron Std. (0.01mg/mL)]
Heavy metals (Pb)	not more than 10ppm	NP TEST 7 [1.0g, (3), ref: 1.0mL of Pb Std. (0.01mg/mL)]
Arsenic (As_2O_3)	not more than 1ppm	NP TEST 8 [2.0g, (1), ref: 2.0mL of As_2O_3 Std.]
Related substances	conforms	NP TEST 9 [test sample: 100μg, B-1-a, Control; L-Cys 1.0μg]*2
	not more than 0.5% of L-Cystine not more than 0.2% of each impurity not more than 1.0% of total impurities	NP TEST 26 [Amino acid analysis]

Item	Limit	Test Method
Loss on drying	not more than 0.50%	NP TEST 11 [1g, in vacuum, molecular sieve, at room temperature for 3 hours]
Residue on ignition (sulfated)	not more than 0.05%	NP TEST 13 [1g, at 550℃ to 650℃ for 3 hours]
Assay	98.0 to 101.0%	NP TEST 16 [sample calculated on the dried basis, 200mg, 0.05mol/L I_2 1mL = 12.12mg $C_3H_7NO_2S$]
pH	4.5 to 5.5	NP TEST 33 [1.25g in 50mL of H_2O]
Residual solvent (Methanol)	not more than 100ppm	NP TEST 27 [Method B]

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

Item	Limit	Test Method
Endotoxin	less than 24.0EU/g	NP TEST 34 [C = 0.25, kinetic-turbidimetric technique]

＊1 : DAB

＊2 : Test Solution: Dissolve 100mg of the sample in N-ethylmaleimide solution (1→50) to make 10mL and stand for 30 minutes. Test Solution (50μg/5μL) should be spotted twice (100μg/10μL).
Standard Solution: Dilute 2mL of Test Solution with water to 100mL.
Proceed as directed for procedure under NP TEST 9 (Thin-layer chromatography).

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