L–Cysteine Hydrochloride Monohydrate*1

L–Cys·HCl·H_2O

: For Manufacturing, Processing or Repacking

$C_3H_7NO_2S$·HCl·H_2O : 175.63

L-Cysteine Hydrochloride Monohydrate, when calculated on the dried basis, contains not less than 98.5 percent and not more than 101.0 per cent of L-Cysteine Hydrochloride ($C_3H_7NO_2S$·HCl).

Description: L-Cysteine Hydrochloride Monohydrate occurs as white crystals or crystalline powder. It has a characteristic odor and a strong acid taste. It is very soluble in water, and soluble in ethanol (99.5). It dissolves in 6 mol/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 $[\alpha]^{20}_D$	+6.1 to +7.8°	NP TEST 1 [sample calculated on the dried basis, C=8, 1mol/L HCl]*2
	+6.0 to +7.1°	[sample calculated on the dried basis, C=8, 6mol/L HCl]*3
State of solution (Transmittance)	clear and colorless not less than 98.0%	NP TEST 2 [1.0g in 10mL of H_2O, spectrophotometer, 430nm, 10mm cell thickness]
Chloride (Cl)	19.89 to 20.29%	NP TEST 3 [350mg, B-2]
Ammonium (NH_4)	not more than 0.02%	NP TEST 4 [(1)]
Sulfate (SO_4)	not more than 0.020%	NP TEST 5 [0.85g, (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 TEST8 [2.0g, (1), ref: 2.0mL of As_2O_3 Std.]
Related substances	conforms*4	NP TEST 9 [test sample: 50μg, B-1-a, Control; L-Cys·HCl·H_2O 0.25μg]*5
	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	8.50 to 12.00%	NP TEST 11 [1g, in vacuum, molecular sieve, at room temperature for 20 hours]
Residue on ignition (sulfated)	not more than 0.10%	NP TEST 13 [1g, at 550℃ to 650℃ for 3 hours]
Assay	98.5 to 101.0%	NP TEST 16 [sample calculated on the dried basis, 250mg, 0.05mol/L I_2 1mL = 15.762mg $C_3H_7NO_2S \cdot HCl$]
pH	1.5 to 2.0	NP TEST 33 [1.0g in 100mL of H_2O]

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

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

＊1 : USP, EP
＊2 : Temperature coefficient of $[\alpha]_D^t$: -0.03°
＊3 : Temperature coefficient of $[\alpha]_D^t$: -0.06°
＊4 : 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 total impurities is found.
＊5 : Test Solution: Dissolve 100mg of the sample in N-ethylmaleimide solution (1→50) to make 10mL and stand for 30 minutes.
Standard Solution: Dilute 2mL of Test Solution with water to 100mL. Dilute 5mL of this solution with water to 20mL.
Proceed as directed for procedure under NP TEST9 (Thin-layer chromatography).

End of document