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L-Cysteine Hydrochloride Monohydrate		
Issued Date: Feb. 5, 2018		

L-Cysteine Hydrochloride Monohydrate

$C_3H_7NO_2S \cdot HCl \cdot H_2O$: 175.63

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

Description

White crystals or crystalline powder; characteristic odor and strong acid taste.

Very soluble in water, soluble in ethanol (99.5).

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 $[\alpha]_D^{20}$	+6.0 to +7.1°	AJI TEST 1 [Calculated on the dried basis, C=8, 6mol/L HCl] ¹
State of solution (Transmittance)	Clear and colorless Not less than 98.0%	AJI TEST 2 [1.0g in 10mL of H ₂ O, spectrophotometer, 430nm, 10mm cell thickness]
Chloride (Cl)	19.89 to 20.29%	AJI TEST 3 [350mg, C-2]
Ammonium (NH ₄)	Not more than 0.02%	AJI TEST 4 [A-1]
Sulfate (SO ₄)	Not more than 0.020%	AJI TEST 5 [0.85g, (1), ref: 0.35mL of 0.005mol/L H ₂ SO ₄]
Iron (Fe)	Not more than 10ppm	AJI TEST 6 [0.75g, B-1, ref: 0.75mL of Iron Std. (0.01mg/mL)]
Heavy metals (Pb)	Not more than 10ppm	AJI TEST 7 [1.0g, (4), ref: 1.0mL of Pb Std. (0.01mg/mL)]
Arsenic (As ₂ O ₃)	Not more than 1ppm	AJI TEST 8 [2.0g, (1), ref: 2.0mL of As ₂ O ₃ Std.]
Related substances	Conforms ²	AJI TEST 9 [Test sample: 50μg, B-6-a, control; L-Cys·HCl·H ₂ O 0.25μg] ³
Loss on drying	8.50 to 12.00%	AJI TEST 11 [1g, in vacuum, P ₂ O ₅ , at room temperature for 20 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 16 [Calculated on the dried basis, 250mg, 0.05mol/L I ₂ 1mL=15.76mg C ₃ H ₇ NO ₂ S·HCl]
pH	1.5 to 2.0	AJI TEST 33 [1.0g in 100mL of H ₂ O]

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¹ Temperature coefficient of $[\alpha]_D^{25}$: -0.06°

² 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.

³ 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 AJI TEST9 (Thin-layer chromatography).

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