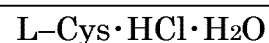


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## L-Cysteine Hydrochloride Monohydrate (M) \*1



L-Cysteine Hydrochloride Monohydrate, when calculated on the dried basis, contains not less than 98.5 percent and not more than 101.0 percent of L-Cysteine Hydrochloride (C<sub>3</sub>H<sub>7</sub>NO<sub>2</sub>S·HCl).

**Description:** White crystals or crystalline powder; Characteristic odor and strong acid taste. Very soluble in water, and soluble in ethanol (99.5). Dissolves in 6mol/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 [ $\alpha$ ] <sup>20D</sup>	+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 <sub>2</sub> O, spectrophotometer, 430nm, 10mm cell thickness]
Chloride (Cl)	19.89 to 20.29%	NP TEST 3 [350mg, B-2]
Ammonium (NH <sub>4</sub> )	not more than 0.02%	NP TEST 4 [(1)]
Sulfate (SO <sub>4</sub> )	not more than 0.020%	NP TEST 5 [0.85g, (1), ref: 0.35mL of 0.005mol/L H <sub>2</sub> SO <sub>4</sub> ]
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 <sub>2</sub> O <sub>3</sub> )	not more than 1ppm	NP TEST 8 [2.0g, (1), ref: 2.0mL of As <sub>2</sub> O <sub>3</sub> Std.]
Related substances	conforms*4	NP TEST 9 [test sample: 50μg, B-1-a, Control; L-Cys·HCl·H <sub>2</sub> O 0.25μg]*5
Loss on drying	8.50 to 12.00%	NP TEST 11 [1g, in vacuum, P <sub>2</sub> O <sub>5</sub> , at room temperature for 20 hours]

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Item	Limit	Test Method
<b>Residue on ignition (sulfated)</b>	not more than 0.10%	NP TEST 13 [1g, at 550°C to 650°C for 3 hours]
<b>Assay</b>	98.5 to 101.0%	NP TEST 16 [sample calculated on the dried basis, 250mg, 0.05mol/L I <sub>2</sub> 1mL = 15.76mg C <sub>3</sub> H <sub>7</sub> NO <sub>2</sub> S·HCl]
<b>pH</b>	1.5 to 2.0	NP TEST 33 [1.0g in 100mL of H <sub>2</sub> O]
<b>Total aerobic microbial count</b>	not more than 500 CFU/g	NP TEST 28 [1g/100mL MF Method]
<b>Total combined yeasts / molds count</b>	not more than 100 CFU/g	NP TEST 28 [1g/100mL MF Method]
<b>Coliform bacteria</b>	negative	NP TEST 28 [1g/100mL]
<b>Enterobacteriaceae</b>	0 CFU/g	NP TEST 28 [1g/100mL MF Method]
<b>Enterobacter Sakazakii</b>	0 CFU/25g	NP TEST 28 [5g/500mL × 6 MF Method]
<b>Salmonella</b>	0 CFU/25g	NP TEST 28 [30g/500mL phosphate buffer solution pH7.2 MF Process*6] *7

\* 1 : USP

\* 2 : Temperature coefficient of  $[\alpha]_{\text{D}}$ :  $-0.03^{\circ}$

\* 3 : Temperature coefficient of  $[\alpha]_{\text{D}}$ :  $-0.06^{\circ}$

\* 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).

\* 6 : Dissolve 30g of the product in 500mL of phosphate buffer solution(pH7.2), and filter. Inoculate membrane filter processed with Total Aerobic Microbial Count Test(MF method) in 100mL of soybean casein dygest medium.

The rest of procedure, perform the test in the same manner as the test method of Salmonella.

\* 7 : Test method is qualitative evaluation. However, the limit is described as 0cfu/25g in CoA if the test result is negative.

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