

L-Cysteine hydrochloride monohydrate

Meets USP, EP, BP and JP testing specifications

Product Code: TC058M

Product Description :

Molecular weight: 175.63

Molecular formula: $C_3H_7NO_2S.HCl.H_2O$

CASNo.: 7048-04-6

Quality Control:

Appearance (USP, JP)

White crystals or crystalline powder

Appearance (EP, BP)

A white or almost white, crystalline powder or colourless crystals

Solubility (USP)

Soluble in water, in alcohol, and in acetone

Solubility (JP)

Very soluble in water, and soluble in ethanol (99.5%). It dissolves in 6 mol/L hydrochloric acid TS

Solubility (EP, BP)

Freely soluble in water, slightly soluble in ethanol (96%)

Identification A : FTIR (USP)

Matches with the standard pattern

Identification A : Specific optical rotation (EP, BP)

+5.50° to +7.00° (c= 8% in hydrochloric acid R1 at 25°C, dried substance)

Identification 1 : FTIR (JP)

Both spectra exhibit similar intensities of absorption at the same wave numbers

Identification 2 : Chloride (JP)

10 mL of 2% solution and 1 mL of hydrogen peroxide responds to the qualitative test for chloride

Identification B : FTIR (EP, BP)

Matches with the standard pattern

Clarity and color of solution : (JP)

10% solution in water is clear and colorless 10% solution in water is clear and colorless

Identification C : TLC (EP, BP)

The principal spot in the chromatogram obtained with the test solution is similar in position, colour and size to the principal spot in the chromatogram obtained with the reference solution

Identification D : (EP, BP)

The solution becomes green

Identification E : (EP, BP)

The solution gives reaction (a) of chlorides

pH (1% in water at 25°C) : (JP)

1.30 - 2.30

Appearance of solution (EP, BP)

2.5% solution in water is not more intensely coloured than reference solution BY6

Clarity and color of solution : (JP)

10% solution in water is clear and colorless 10% solution in water is clear and colorless

Optical rotation : (JP)

+6.00° to +7.50° (c= 8% in 6M hydrochloric acid at 20°C, dried basis)

Optical rotation : (USP)

+5.70° to +6.80° (c = 8% in 6N hydrochloric acid, 25°C)

Specific optical rotation : (EP, BP)

+5.50° to +7.00° (c = 8% in hydrochloric acid R1, 20 ± 0.5°C)

Sulfate : (JP)

≤ 0.021%

Sulfate : (USP, EP, BP)

≤ 0.03%

Heavy metals : (JP)

≤ 0.0010%

Iron (JP)

≤ 0.0010%

Iron (USP)

≤ 0.0030%

Iron (EP, BP)

≤ 0.0020%

Loss on drying (JP)

8.50 - 12.00% (in vacuum on phosphorus (V) oxide, 20 hours)

Loss on drying (USP)

8.00 - 12.00% (dry at room temperature in vacuum at pressure NMT 5 mm of mercury, 24 hr)

Loss on drying (EP, BP)

8.00 - 12.00% (at a pressure NMT 0.7kPa for 24 hr)

Residue on ignition : (JP)

<= 0.10%

Residue on ignition : (USP)

<= 0.40%

Sulfated ash (EP, BP)

<= 0.10%

Ammonium (Amino acid analysis) : (EP, BP)

<= 0.02%

Ammonium (JP)

<= 0.02%

Related compounds, System suitability : TLC (USP)

The chromatogram of the system suitability solution exhibits two clearly separated spots

Related compounds, TLC : (USP)

Any secondary spot of the sample solution is not larger or more intense than the principal spot of the standard solution

Related substances, TLC : (JP)

The spot other than the principal spot obtained with the sample solution is not more intense than the spot obtained with the standard solution.

Related compounds, Individual impurities, TLC : (USP)

<= 0.5%

Related compounds, Total impurities, TLC : (USP)

<= 2.0%

Ninhydrin-positive substances, system suitability (Amino acid analysis) : Resolution (EP, BP)

>=1.50 between the peaks due to isoleucine and leucine

Ninhydrin-positive substances 1 (Amino acid analysis) : Impurity A (EP, BP)

<= 0.50%

Ninhydrin-positive substances 2 (Amino acid analysis) : Any ninhydrin-positive substance for each impurity (EP, BP)

<= 0.20%

Ninhydrin-positive substances 3 (Amino acid analysis) : Total impurity (EP, BP)

<= 1.00%

Assay (Iodometry, dried substance) : (EP, BP, JP)

98.50 - 101.00%

Assay (Iodometry, dried basis) : (USP)

98.50 - 101.50%

Storage and Shelf Life:

Store below 30°C away from bright light.

Shelf life is 48 months.

Use before expiry date given on the product label.

Revision : 02/2022

Disclaimer :

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