

L-Cystine (From non-animal source)

Meets USP 41-NF 36, EP 9.0, JP 17, BP 2016 and IP 2018 testing specification

Product Code: TC070M

Product Description :

Molecular weight : 240.30

Molecular formula : $C_6H_{12}N_2O_4S_2$

CAS No.: 56-89-3

Quality Control:

Appearance (EP, BP)

White or almost white, crystalline powder

Appearance (JP)

White crystals or crystalline powder

Solubility (BP, EP)

Practically insoluble in water and in alcohol (96%). It dissolves in dilute solutions of alkali hydroxides

Solubility (JP)

Practically insoluble in water and in ethanol (99.5%). It dissolves in 1 mol/L hydrochloric acid TS.

Identification 1 : FTIR (JP)

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

Identification A : FTIR (USP)

Matches with the standard pattern

Identification A : Specific rotation (EP, BP)

-224.00 to -218.00° (c = 2% in 1M HCl acid at 20 ± 0.5°C, dried substance)

Identification B : Specific rotation (USP)

-225.00° to -215.00° (c = 2% in 1N hydrochloric acid at 20°C, perform the measurements immediately after preparation)

Identification B : FTIR (EP, BP)

Matches with the standard pattern

Identification C : TLC (USP)

The R_f value of the principal spot of the sample solution in the test for organic impurities corresponds to that of the standard solution

Identification C : TLC (BP, EP)

The principal spot in the chromatogram obtained with test solution (b) is similar in position, colour and size to the principal spot in the chromatogram obtained with reference solution (a).

Identification D : (EP, BP)

Turbidity or a white precipitate develops within 3 min

Appearance of solution (EP, BP)

10% solution in dilute hydrochloric acid R is clear and not more intensely coloured than reference solution Y7

Clarity and color of solution : (JP)

10% solution in 2M hydrochloric acid TS is clear and colorless

Specific rotation (EP, BP)

-224.00 to -218.00° (c = 2% in 1M HCl acid at 20 ± 0.5°C, dried substances)

Specific rotation (USP)

-225.00° to -215.00° (c = 2% in 1N hydrochloric acid at 20°C)

Specific rotation (JP)

-225.00° to -215.00° (c = 2% in 1M hydrochloric acid at 20°C, after drying)

Ammonium : Amino acid analysis (EP)

≤ 0.02%

Ammonium : (JP, BP)

≤ 0.02%

Iron (USP, EP, BP, JP)

≤ 0.0010%

Sulfate (USP)

≤ 0.02%

Sulfate (JP)

≤ 0.028%

Sulfate (EP, BP)

≤ 0.03%

Chloride (USP, EP, BP)

≤ 0.02%

Chloride (JP)

≤ 0.021%

Heavy metals (USP, JP, BP)

≤ 0.0010%

Loss on drying (at 105°C, 2h) : (EP, BP)

<= 0.50%

Loss on drying (at 105°C, 3h) : (USP)

<= 0.20%

Loss on drying (at 105°C, 3h) : (JP)

<= 0.30%

Residue on ignition (USP, JP)

<= 0.10%

Sulfated ash (EP, BP)

<= 0.10%

Organic impurities 1 : Individual impurities, TLC (USP)

<= 0.20%

Organic impurities 2 : Total impurities, TLC (USP)

<= 2.00%

Ninhydrin-positive substances, system suitability : Resolution,

Amino acid analysis (EP)

>= 1.50 between the peaks due to isoleucine and leucine

Ninhydrin-positive substances 1 : for each impurity, Amino acid analysis (EP)

<= 0.20%

Ninhydrin-positive substances 2 : total impurities, Amino acid analysis (EP)

<= 0.50%

Ninhydrin-positive substances, TLC : (BP)

Complies

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

98.50 - 101.00%

Assay (Iodometry, dried basis): (USP)

98.50 - 101.50%

Assay (Nitrogen, dried basis): (JP)

99.00 - 101.00%

Storage and Shelf Life:

Store below 30°C.

Shelf life is 48 months.

Use before expiry date given on the product label.

Revision: 04/2022

Disclaimer :

User must ensure suitability of the product(s) in their application prior to use. Products conform solely to the information contained in this and other related HiMedia™ Publications. The information contained in this publication is based on our research and development work and is to the best of our knowledge true and accurate. HiMedia™ Laboratories Pvt Ltd reserves the right to make changes to specifications and information related to the products at any time. Products are not intended for human or animal diagnostic or therapeutic use but for laboratory, research or further manufacturing use only, unless otherwise specified. Statements contained herein should not be considered as a warranty of any kind, expressed or implied, and no liability is accepted for infringement of any patents.