

L-Histidine monohydrochloride monohydrate

Meets EP, BP and JP testing specifications

Product Code: TC077M

Product Description :

Molecular weight : 209.63

Molecular formula : $C_6H_9N_3O_2 \cdot HCl \cdot H_2O$

CAS No.: 5934-29-2

Quality Control:

Appearance (EP, BP)

White or almost white, crystalline powder or colourless crystals

Appearance (JP)

White crystals or a white crystalline powder

Solubility (EP, BP)

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

Solubility (JP)

It is freely soluble in water and practically insoluble in ethanol (99.5%). It dissolves in 6 mol/L hydrochloric acid.

Identification 1, FTIR (JP)

Matches with the standard pattern

Identification A, Specific rotation (EP, BP)

+9.20 to +10.60° (c = 2.75g in 12 mL of 6M HCl and dilute to 25.0 mL with water, at 20 ± 0.5°C, dried substance)

Identification 2 (JP)

Reactions for chlorides

Identification B, pH (EP, BP)

3.00 - 5.00 (c = 5% in water at 25°C)

Identification C, FTIR (EP, BP)

Matches with the standard pattern

Identification D, TLC (EP, BP)

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

Identification E (EP, BP)

An orange colour develops

Identification F (EP, BP)

Reactions for chlorides

Appearance of solution (EP, BP)

Solution is clear and not more intensely coloured than reference solution BY6

Clarity and colour of solution (JP)

10% solution in water is clear and colourless

pH (5% in water at 25°C) (EP, BP)

3.00 - 5.00

pH (10% in water at 25°C) (JP)

3.50 - 4.50

Ammonium (Amino acid analysis) (EP, BP)

Complies

Ammonium (JP)

≤ 0.02%

Sulfates (EP, BP)

≤ 0.03%

Sulfates (JP)

≤ 0.028%

Iron (EP, BP, JP)

≤ 0.001%

Heavy metals (JP)

≤ 0.001%

Specific rotation (EP, BP)

+9.20 to +10.60° (c = 2.75g in 12 mL of 6M HCl and dilute to 25.0 mL with water, at 20 ± 0.5°C, dried substance)

Specific rotation (JP)

+9.20 to +10.60° (c = 11.0% in 6M HCl, on anhydrous basis, at 25°C)

Related substances : TLC (JP)

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

Ninhydrin-positive substances : System suitability :

Resolution : Amino acid analysis (EP, BP)

min. 1.5 between the peaks due to isoleucine and leucine

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

<= 0.20%

Ninhydrin-positive substances (Amino acid analysis - total impurity) (EP, BP)

<= 0.5%

Sulfated ash (EP, BP)

<= 0.10%

Residue on ignition (JP)

<= 0.10%

Loss on drying (EP, BP)

7.00 - 10.00% (at 145 - 150°C, 2hr)

Water (JP)

7.20 - 10.00%

Assay (NaOH Titration, on dry basis) (EP, BP)

98.50 - 101.00%

Assay (NT, anhydrous basis) (JP)

99.00 - 101.00%

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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