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Technical Datasheet

L-Histidine

(From non-animal source)

Meets USP-NF, EP, BP and JP testing specifications

Product Code: TC076M

Product Description :

Molecular weight: 155.15
Molecular formula: $C_6H_9N_3O_2$
CAS No.: 71-00-1

Quality Control:

Appearance (USP)
White, odourless crystals

Appearance (EP, BP)
White or almost white, crystalline powder or colourless crystals

Appearance (JP)
White, crystals or crystalline powder

Solubility (USP)
Soluble in water; very slightly soluble in alcohol; insoluble in ether

Solubility (EP, BP)
Soluble in water, very slightly soluble in ethanol (96%)

Solubility (JP)
Freely soluble in formic acid, and soluble in water and practically insoluble in ethanol (99.5%), It dissolves in 6 mol/L HCl TS

pH (2% in water) : (JP, USP)
7.00 -8.50

Identification : FTIR (JP)
Matches with the standard pattern

Identification A : FTIR (USP)
Matches with the standard pattern

Identification A : Specific rotation (dried substance) (EP, BP)
+11.40° to +12.40° (dissolve 2.75 gm in 12 mL of hydrochloric acid R1and dilute to 25 mL with water at 20 ± 0.5°C, dried basis)

Identification B : FTIR (EP, BP)
Matches with the standard pattern

Identification C : TLC (EP, BP)
The principal spot in the chromatogram obtained with test solution is similar in position, colour and size to the principal spot in the chromatogram obtained with reference solution

Identification D (EP, BP)
An orange-red colour develops

Appearance of the solution (EP, BP)
5% solution in water is clear and not more intensely coloured than reference solution BY7

Clarity and color of solution (JP)
2% solution in water is clear and colourless

Chloride (USP)
<= 0.05%

Chloride (EP, BP)
<= 0.02%

Chloride (JP)
<= 0.021%

Ammonium (JP)
<= 0.02%

Ammonium : Amino acid analysis (EP, BP)
<= 0.02%

Heavy metals (JP)
<= 0.001%

Iron (USP)
<= 0.003%

Iron (JP, EP, BP)
<= 0.001%

Sulphate (JP)
<= 0.028%
Sulphate (USP, EP, BP)
<= 0.03%
Optical rotation (JP)
+11.80° to +12.80° (c=11% in 6 mol/L hydrochloric acid TS at 20°C , dried basis)
Specific rotation (EP, BP)
+11.40° to +12.40° (dissolve 2.75 gm in 12 mL of hydrochloric acid R1 and dilute to 25 mL with water at 20 ±0.5°, dried basis)
Specific rotation (USP)
+12.60° to +14.00° (c=11% in 6N hydrochloric acid at 25°C)
Loss on drying (JP)
<= 0.30% (at 105°C, 3 hr)
Loss on drying (USP)
<= 0.20% (at 105°C , 3 hr)
Loss on drying (BP, EP)
<= 0.50% (at 105°C, till constant weight)
Residue on ignition (JP)
<= 0.10%
Residue on ignition (USP)
<= 0.40%
Sulfated ash (EP, BP)
<= 0.10%
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:Amino acid analysis: resolution (EP, BP)
min.1.5 between the peaks due to isoleucine and leucine
Ninhydrin-positive substances : any ninhydrin-positive substance, for each impurity : Amino acid analysis (EP,BP)
<= 0.20 %
Ninhydrin-positive substances : Total impurity : Amino acid analysis (EP, BP)
<= 0.50%
Related componds, TLC : (USP)
Any secondary spot of the sample solution is not larger or more intense than the principal spot of the standard solution
Related compounds, individual impurities : TLC (USP)
<= 0.50%
Related compounds, total impurities : TLC (USP)
<= 2.0%

Assay (NT, dried basis) : (USP)
98.50 -101.50%
Assay (HCl Titration, dried substance) : (EP, BP)
98.50 -101.00%
Assay (NT, dried basis) : (JP)
99.00 -101.00%
Bacterial endotoxin
<= 6 EU/g

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.