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Technical Datasheet

L-Isoleucine

(From non-animal source)
Meets USP-NF, EP, BP and JP testing specifications
Product Code: TC049M

Molecular weight: 131.17
Molecular formula: $C_6H_{13}NO_2$
CAS No.: 73-32-5

Quality Control

Appearance (USP)
White crystals
Appearance (JP)
White crystals or a crystalline powder
Appearance (EP, BP)
White or almost white, crystalline powder or flakes
Solubility (USP)
Soluble in water; slightly soluble in hot alcohol, insoluble in ether
Solubility (EP, BP)
Sparingly soluble in water, slightly soluble in ethanol (96%). It dissolves in dilute mineral acids and in dilute solutions of alkali hydroxides.
Solubility (JP)
Freely soluble in formic acid, sparingly soluble in water, and practically insoluble in ethanol (95). It dissolves in dilute hydrochloric acid
Identification A : FTIR (USP)
Matches with the standard pattern
Identification A : Specific optical rotation (EP, BP)
+40.00° to +43.00° (c = 4% in hydrochloric acid R1 at 20 ± 0.5°C, dried substance)
Identification : FTIR (JP)
Matches with the standard pattern
Identification B : FTIR (EP, BP)
Matches with the standard pattern
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
Appearance of solution (EP, BP)
The solution of 0.5 g in 10 mL of 103 g/L solution of HCl is clear and not more intensely coloured than reference solution BY6
Clarity and color of solution (JP)
5% solution in 1M HCl is clear and colourless
pH (1% in water) : (USP)
5.50 - 7.00
pH (1% in water) : (JP)
5.50 - 6.50
Specific rotation (USP)
+38.90° to +41.80° (c = 4% in 6N HCl at 25°C) **Specific rotation (EP, BP)**
+40.00° to +43.00° (c = 4% in hydrochloric acid R1 at 20 ± 0.5°C, dried substance)
Specific rotation (JP)
+39.50° to +41.50° (c = 4% in 6M HCl at 20°C, after drying)
Chloride (USP)
<= 0.05%
Chloride (JP)
<= 0.021%
Chloride (EP, BP)
<= 0.02%
Sulfate (USP)
<= 0.03%
Sulfate (EP, BP)
<= 0.03%
Sulfate (JP)
<= 0.028%
Iron (USP)
<= 0.0030%
Iron (EP, BP)
<= 0.0010%
Heavy metals (USP)
<= 0.0015%
Heavy metals (JP)
<= 0.0020%
Ammonium (JP)
<= 0.020%
Arsenic (JP)
<= 0.00020%
Loss on drying (USP, JP)
<= 0.30% (at 105°C, 3 hr)
Loss on drying (EP, BP)
<= 0.50% (at 105°C, till constant weight)

Sulfated ash (EP, BP)
<= 0.10%
Residue on ignition (USP)
<= 0.30%
Residue on ignition (JP)
<= 0.10%
Related compounds, System suitability requirements : TLC (USP)
The chromatogram of the system suitability solution exhibits two clearly separated spots
Related compounds, acceptance criteria: 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 impurity : TLC (USP)
<= 0.50%
Related compounds, Total impurities : TLC (USP)
<= 2.00%
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 1: System suitability: Resolution, Amino acid analysis : (EP, BP)
min. 1.5 between the peaks due to and isoleucine and impurity C
Ninhydrin-positive substances 2: Impurities A and C at 570 nm, for each impurity, Amino acid analysis : (EP, BP)
<= 0.30%
Ninhydrin-positive substances 3: Each impurity, Amino acid analysis : (EP, BP)
<= 0.20%
Ninhydrin-positive substances 4: Total impurities, Amino acid analysis : (EP, BP)
<= 1.00%
Ammonium, Amino acid analysis : (EP, BP)
<= 0.020% (at 570 nm)
Assay (NT, dried basis) : (USP)
98.50 - 101.50%
Assay (NT, dried substance) : (EP, BP)
98.50 - 101.00%
Assay (NT, dried substance) : (JP)
min. 98.50%

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.

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