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Technical Datasheet

L-Valine (From non-animal source)

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

Product Code: TC132M

Product description :

Molecular weight: 117.15
Molecular formula: $C_5H_{11}NO_2$
CAS No.: 72-18-4

Quality Control

Appearance (USP)
White crystals.

Appearance (JP)
White crystals or crystalline powder.

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

Solubility (USP)
Soluble in water, practically insoluble in ether, in alcohol, and in acetone

Solubility (JP)
It is freely soluble in formic acid, soluble in water and practically insoluble in ethanol (95%). It dissolves in dilute hydrochloric acid

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

Identification : FTIR (USP)
Matches with the standard pattern

Identification, FTIR, dried substance (JP)
Matches with the standard pattern

Identification A, specific rotation (EP, BP)
+26.5 to +29.0 (c = 8% in HCl R1, at 20 ± 0.5°C, dried substance)

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

Identification C, TLC (EP, BP)
The principle 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)
Solution of 2.5g in 100 mL of water is clear and not more intensely coloured than reference solution BY6

Colour and clarity of solution (JP)
Solution of 0.5g in 20 mL of water is clear and colourless

pH (5% in water at 25°C) (USP)
5.50 - 7.00

pH (2.5% in water at 25°C) (JP)
5.50 - 6.50

Chloride (USP)
<= 0.05%

Chlorides (EP, BP)
<= 0.02%

Chlorides (JP)
<= 0.021%

Sulfates (USP)
<= 0.03%

Sulfates (EP, BP)
<= 0.03%

Sulfates (JP)
<= 0.028%

Iron (USP)
<= 0.003%

Iron (EP, BP)
<= 0.001%

Ammonium (JP)
<= 0.02%

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

Arsenic (JP)
<= 0.0002%

Heavy metals (JP)
<= 0.0020%

Sulfated ash (EP, BP)
<= 0.10%

Specific rotation (EP, BP)
+26.5 to +29.0° (c = 8% in HCl R1, at 20 ± 0.5°C, dried substance)
Specific rotation (JP)
+26.5 to +29.0° (c = 8% in 6M HCl at 20°C, dried substance)
Specific rotation (USP)
+26.6 to +28.8° (c = 8% in 6N HCl at 25°C)
Residue on ignition (JP, USP)
<= 0.10%
Loss on drying (at 105°C, 2 hr) (EP, BP)
<= 0.5%
Loss on drying (at 105°C, 3 hr) (USP, JP)
<= 0.3%
Related substances : TLC (JP)
The spot other than the principal spot from the sample solution are not more intense than the spot from the standard solution
Ninhydrin-positive substances, System suitability: Resolution, Amino acid analysis (EP, BP)
>= 1.5 between the peaks due to impurities B and C
Ninhydrin-positive substances: Impurity B at 570nm, Amino acid analysis (EP, BP)
<= 0.40%
Ninhydrin-positive substances: Each impurity, Amino acid analysis (EP, BP)
<= 0.20%
Ninhydrin-positive substances: Total impurities, Amino acid analysis (EP, BP)
<= 1.0%
Related compounds : System suitability : TLC (USP)
The chromatogram of the system suitability solution exibits two clearly separated spot
Related compounds : Individual impurity : TLC (USP)
<= 0.5%
Related compounds : Total impurity : TLC (USP)
<= 2.0%
Assay (NT, dried substance) (EP, BP)
98.50 - 101.00%
Assay (NT, on dry basis) (USP)
98.50 - 101.50%
Assay (NT, dried substance) (JP)
min. 98.50%

Storage and Shelf Life:

Store below 30°C.
Shelf life is 48 months.
Use before expiry date given on the product label.

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