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Technical Datasheet

L-Proline

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

Product Code: TC109M

Product Description:

Molecular weight: 115.13
Molecular formula: $C_5H_9NO_2$
CAS No.: 147-85-3

Quality Control:

Appearance (USP)
White or almost white, crystalline powder or colourless crystals
Appearance (JP)
White deliquescent crystals or crystalline powder.
Appearance (USP)
White crystals
Solubility (EP, BP)
Very soluble in water, freely soluble in ethanol (96%)
Solubility (JP)
Very soluble in water and in formic acid, and slightly soluble in ethanol (99.5%).
Solubility (USP)
Freely soluble in water and in absolute alcohol; insoluble in ether, in butanol, and in isopropanol **Clarity and color of solution (JP)**
The solution 1.0 gm dissolved in 10 mL of water is clear and colourless
Identification : FTIR (JP)
Matches with the standard pattern
Identification A : FTIR (USP)
Matches with the standard pattern
Identification A : Specific optical rotation (EP, BP)
-86.0° to -84.0° (c = 4% in water at 20 ± 0.5°C, dried substance)
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
Appearance of solution (EP, BP)
Solution of 2.5 gm in 50 mL of water is clear and colourless
pH (10% in water at 25°C) : (JP)
5.9 - 6.9
Specific optical rotation : (EP, BP, JP)
-86.0° to -84.0° (c = 4% in water at 20 ± 0.5°C, dried substance)
Specific optical rotation : (USP)
-86.3° to -84.3° (c = 4% in water at 25°C)
Chloride (JP)
<= 0.021%
Chloride (USP)
<= 0.05%
Chloride (EP, BP)
<= 0.02%
Sulphate (JP)
<= 0.028%
Sulphate (USP)
<= 0.03%
Sulphate (EP, BP)
<= 0.03%
Iron (EP, BP, JP)
<= 0.001%
Iron (USP)
<= 0.003%
Ammonium (JP)
<= 0.02%
Heavy metals (JP)
<= 0.001%
Loss on drying (at 105°C, till constant weight) : (EP, BP)
<= 0.5%
Loss on drying (at 105°C, 3hr) : (USP
<= 0.4%
Loss on drying (at 105°C, 3hr) : (JP)
<= 0.3%

Sulfated ash (EP, BP)
<= 0.1%
Residue on ignition (JP)
<= 0.1%
Residue on ignition (USP)
<= 0.4%
Related substances, system suitability 1, HPLC : resolution (JP)
>= 1.2 between the peaks of glycine and alanine
Related substances, system suitability 2, HPLC : RSD of peak height of each amino acid other than proline in standard solution (JP)
<= 5.0%
Related substances, system suitability 3, HPLC : RSD of the retention time (JP)
<= 1.0%
Related substances, Amount of each amino acid other than proline : (JP)
<= 0.1%
Related compounds (TLC): Acceptance criteria (USP)
Any secondary spot of the sample solution is not larger or more intense than the principal spot of the standard solution
Related substances (TLC) : individual impurities (USP)
<= 0.5%
Related compounds (TLC) : total impurities (USP)
<= 2.0%
Ninhydrin-positive substance 1 (Amino acid analysis) : system suitability, resolution (EP, BP)
>= 1.5 between the peaks isoleucine and leucine
Ninhydrin-positive substance 2 (Amino acid analysis) : for each impurity, (EP, BP)
<= 0.2%
Ninhydrin-positive substance 3 (Amino acid analysis) : total impurity, (EP, BP)
<= 0.5%
Ammonium (Amino acid analysis) : (EP, BP)
<= 0.02% (at 570nm)
Assay (NT, dried substance) : (EP, BP)
98.5 - 101.0%
Assay (NT, dried basis) : (USP)
98.5 - 101.5%
Assay (NT, dried basis) : (JP)
99.0 - 101.0%
Endotoxin content
<= 25 IU/g
Total aerobic microbial count (TAMC)
<= 100 CFU/g
Total yeasts and molds count (TYMC)
<= 100 CFU/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.

Revision: 05/2025