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Technical Datasheet

L-Arginine

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

Product Code: TC052M

Molecular weight: 174.20
Molecular formula: $C_6H_{14}N_4O_2$
CAS No.: 74-79-3

Quality Control

Appearance (USP)
White crystals
Appearance (EP, BP, IP)
White or almost white, crystalline powder or colourless crystals, hygroscopic
Appearance (JP)
White, hygroscopic crystals or crystalline powder.
Solubility (USP)
Freely soluble in water; sparingly soluble in alcohol; insoluble in ether
Solubility (EP, BP)
Freely soluble in water, very slightly soluble in ethanol (96%)
Solubility (JP)
It is freely soluble in water and in formic acid, and practically insoluble in ethanol (99.5%) It dissolves in dilute hydrochloric acid
Solubility (IP)
Freely soluble in water, sparingly soluble in ethanol (95%); insoluble in ether
Identification : FTIR (USP, IP, JP)
Matches with the standard pattern
Identification A : Specific optical rotation (EP, BP)
+25.50° to +28.50° (c = 8% in HCl R1 at 20 ± 0.5°C, dried substance)
Identification B : (EP, BP)
5% solution in water is strongly alkaline
Identification C : FTIR (EP, BP)
Matches with the standard pattern
Identification D : 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 the reference solution
Identification E : (EP, BP)
A red colour develops
Appearance of solution : (EP, BP)
5% solution in water is clear and not more intensely coloured than reference solution BY6
Clarity and color of solution : (JP)
1% solution in water is clear and colourless
pH : (JP)
10.50 – 12.00 (10% in water at 25°C)
Specific rotation : (USP, IP)
+26.30° to +27.70° (c = 8% in 6N HCl at 25°)
Specific rotation : (EP, BP)
25.50° to +28.50° (c = 8% in HCl R1 at 20 ± 0.5°C, dried substance)
Specific rotation : (JP)
+26.90° to +27.90° (c = 8% in 6M HCl at 20°C, after drying)
Chloride : (USP, IP)
<= 0.05%
Chloride : (EP, BP)
≤ 0.02%
Chloride : (JP)
<= 0.021%
Sulfate : (USP, EP, BP, IP)
<= 0.03%
Sulfate : (JP)
<= 0.028%
Iron: (USP, IP)
<= 0.0030%
Iron : (EP, BP, JP)
<= 0.0010%
Heavy metals : (IP)
<= 0.0015%
Heavy metals : (JP)
<= 0.0010%
Ammonium : (JP)
<= 0.020%
Loss on drying : (USP, IP)
<= 0.50% (at 105°C, 3 hr)
Loss on drying : (EP, BP)
<= 0.50% (at 105°C, 2 hr)
Loss on drying : (JP)
<= 0.30% (at 105°C, 3 hr)
Sulfated ash : (EP, BP)
<= 0.10%
Residue on ignition : (USP)
<= 0.30%
Residue on ignition : (JP)
<= 0.10%

Organic impurities, individual impurities : TLC (USP)
<= 0.50%
Organic impurities, total impurities : TLC (USP)
<= 2.00%
Ninhydrin-positive substances, system suitability : Resolution, Amino acid analysis (EP, BP)
min. 1.5 between the peaks due to isoleucine and leucine
Any ninhydrin-positive substances : for each impurity, Amino acid analysis (EP, BP)
<= 0.20%
Any ninhydrin-positive substances : total impurity, Amino acid analysis (EP, BP)
<= 0.50%
Ammonium: Amino acid analysis (EP, BP)
<= 0.020% (at 570 nm)
Related substances : TLC (JP)
The spot other than the principal spot with the sample solution is not more intense than the spot with the standard solution.
Related substances : TLC (IP)
Any secondary spot in the chromatogram obtained with the test solution is not larger or more intense than the principal spot in the chromatogram obtained with reference solution (a)
Assay (NT, dried basis) : (USP, IP)
98.50 - 101.50%
Assay (HCl Titration, dried substance) : (EP, BP)
98.50 – 101.00%
Assay (NT, dried substance) : (JP)
98.50 - 101.00%.
Microbial contamination (TAMC)
<= 100 CFU/g
Microbial contamination (TYMC)
<= 100 CFU/g
Endotoxin content
<= 6 EU/gm
Pathogens
Absent

Storage and Shelf Life:

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

Revision : 06/2023