

L-Arginine monohydrochloride

(From non-animal source)

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

Product Code: TC053M

Product Description :

Molecular weight : 210.66

Molecular formula: $C_6H_{14}N_4O_2.HCl$

CAS No.: 1119-34-2

Quality Control:

Appearance (EP, BP)

White or almost white, crystalline powder or colorless crystals

Appearance (JP, USP)

White crystals or crystalline powder.

Solubility (EP, BP)

Freely soluble in water, very slightly soluble in ethanol (96%)

Solubility (USP)

Freely soluble in water

Solubility (JP)

Freely soluble in water and in formic acid and very slightly soluble in ethanol (95%)

Appearance of solution (EP, BP)

5% solution in water is clear and not more intensely colored than reference solution BY₆

Clarity and colour of solution (JP)

The solution is clear and colorless

pH (10% in water at 25°C) : (JP)

4.70 -6.20

Identification 1 : FTIR (JP)

Matches with the standard pattern

Identification A : Specific rotation (EP, BP)

+21.00° to +23.50° (c = 8% in HCl R1 at 20 ± 0.5°C, dried substances)

Identification A : FTIR (USP)

Matches with the standard pattern

Identification 2 : Chloride (JP)

Complies

Identification B : FTIR (EP, BP)

Matches with the standard pattern

Identification C : TLC (EP, EP)

The principal spot in the chromatogram obtained with test solution is similar in position, colour and size to the principal spots in the chromatogram obtained with the reference solution

Identification D : (EP, BP)

A red colour develops

Identification E : Chloride (EP, BP)

It gives reaction (a) of chloride

Specific rotation (EP, BP)

+21.00° to +23.50° (c = 8% in HCl R1 at 20 ± 0.5°C, dried substances)

Specific rotation (USP)

+21.40° to +23.60° (c = 8% in 6N HCl at 20°C)

Specific rotation (JP)

+21.50° to +23.50° (c = 8% in 6M HCl at 20°C)

Ninhydrin-positive substances (Amino acid analysis) :

System suitability : Resolution (EP, BP)

≥ 1.5 between the peaks due to isoleucine and leucine

Ninhydrin-positive substances 1 (Amino acid analysis) : For each impurity (EP, BP)

≤ 0.20%

Ninhydrin-positive substances 2 (Amino acid analysis) : Total impurity (EP, BP)

≤ 0.50%

Chromatographic purity, TLC : System suitability (USP)

Any secondary spot from the sample solution is not larger or more intense than the principal spot from the standard solution

Chromatographic purity 1 (TLC) : Individual impurities (USP)

≤ 0.50%

Chromatographic purity 2 (TLC) : Total impurities (USP)

≤ 2.00%

Related substances, TLC : (JP)

The spots other than the principal spot from the sample solution are not more intense than the spot from the standard solution.

Sulfate (EP, BP)

<= 0.03%

Heavy metals : (JP)

<= 0.0020%

Sulfate (USP)

<= 0.03%

Sulfate (JP)

<= 0.028%

Ammonium (Amino acid analysis) : (BP, EP)

Complies

Ammonium (JP)

<= 0.02%

Arsenic (JP)

<= 0.0002%

Iron (EP, BP)

<= 0.0010%

Loss on drying (at 105°C, 2 hr) (EP, BP)

<= 0.50%

Loss on drying (at 105°C, 3 hr) : (JP)

<= 0.20%

Loss on drying (at 105°C, 2 hr) : (USP)

<= 0.20%

Residue on ignition (USP, JP)

<= 0.10%

Sulfated ash (EP, BP)

<= 0.10%

Chloride content : AT (USP)

16.50 - 17.10%

Assay (NT, dried substance) (EP, BP)

98.50 - 101.00%

Assay (NT, on dried basis) : (USP)

98.50 - 101.50%

Assay (NT, on dried basis) : (JP)

>= 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.

Revision : 04/2023

Disclaimer :

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