

L-Serine

(From non-animal source)

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

Product Code: TC113M

Product Description :

Molecular weight : 105.09

Molecular formula : $C_3H_7NO_3$

CAS No.: 56-45-1

Quality Control

Appearance (USP)

White crystals

Appearance (EP, BP)

White or almost white, crystalline powder or colourless crystals

Appearance (JP)

White, crystals or a crystalline powder

Solubility (USP)

Soluble in water; practically insoluble in absolute alcohol and in ether

Solubility (EP, BP)

Freely soluble in water, practically insoluble in ethanol (96%)

Solubility (JP)

Freely soluble in water and in formic acid, and practically insoluble in ethanol (99.5). It dissolves in 2 mol/L hydrochloric acid TS

pH (10% in water at 25°C) : (JP)

5.20 - 6.20

Identification : FTIR (JP)

Matches with the standard pattern

Identification A : FTIR (USP)

Matches with the standard pattern

Identification A : Specific rotation (EP, BP)

+14.00° to +16.00° (10% in dilute hydrochloric acid R 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

Identification D (EP, BP)

A violet-red colour is produced

Appearance of the solution (EP, BP)

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

Clarity and color of solution (JP)

10% solution in water is clear and colourless

Chloride (USP)

≤ 0.05%

Chloride (EP, BP)

≤ 0.02%

Chloride (JP)

≤ 0.021%

Ammonium (JP)

≤ 0.02%

Ammonium : Amino acid analysis (EP,BP)

≤ 0.02%

Heavy metals (JP)

≤ 0.001%

Iron (USP)

≤ 0.003%

Iron (JP, EP, BP)

≤ 0.0010%

Sulphate (JP)

<= 0.028%

Sulphate (USP, EP, BP)

<= 0.03%

Optical rotation (JP)

+14.00° to +16.00° (10% in 2 mol/L hydrochloric acid TS at 20°C)

Specific rotation : (EP, BP)

+14.00° to +16.00° (10% in dilute hydrochloric acid R 20 ± 0.5°C, dried substance)

Specific rotation (USP)

+14.00° to +15.60° (c= 10% in 2N hydrochloric acid at 25°C)

Loss on drying (JP)

<= 0.30% (at 105°C, 3 hr)

Loss on drying (USP)

<= 0.20% (at 105°C, 3 hr)

Loss on drying (BP, EP)

<= 0.50% (at 105°C, 2 hr)

Residue on ignition (JP, USP)

<= 0.10%

Sulfated ash (EP, BP)

<= 0.10%

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 : system suitability :**Amino acid analysis : resolution (EP, BP)**

min. 1.5 between the peaks due to isoleucine and leucine

Ninhydrin-positive substances : any ninhydrin-positive substance, for each impurity : Amino acid analysis (EP, BP)

<= 0.20%

Ninhydrin-positive substances : total impurity :**Amino acid analysis (EP, BP)**

<= 0.50%

Related compounds : 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 impurities : TLC (USP)

<= 0.50%

Related compounds : Total impurities: TLC (USP)

<= 2.00%

Assay (NT, dried basis) : (USP)

98.50 - 101.50%

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

98.50 - 101.00%

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 : 03/2024

Disclaimer :

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