

L-Tyrosine

(From non-animal source)

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

Product Code: TC122M

Product Description :

Molecular weight : 181.19

Molecular formula: $C_9H_9NO_3$

CAS No.: 60-18-4

Quality Control

Appearance (USP)

White, crystals or crystalline powder

Appearance (JP)

White crystals or a crystalline powder

Appearance (EP, BP)

White or almost white, crystalline powder or colourless crystals

Solubility (USP)

Very slightly soluble in water, insoluble in alcohol and in ether

Solubility (EP, BP)

Very slightly soluble in water, practically insoluble in ethanol (96%). It dissolves in dilute mineral acids and in dilute solutions of alkali hydroxides

Solubility (JP)

Freely soluble in formic acid, and practically insoluble in water and in ethanol (99.5%). It dissolves in dilute hydrochloric acid and in ammonia TS

Identification A : FTIR (USP)

Matches with the standard pattern

Identification 1 : UV (JP)

Both spectra exhibit similar intensities of absorption at the same wavelengths

Identification A : Specific rotation (EP, BP)

-12.30 to -11.00° (c = 5% in 1:1 mixture of dilute hydrochloric acid R and water at $20 \pm 0.5^\circ\text{C}$, dried substance)

Identification B : FTIR (EP, BP)

Matches with the standard pattern

Identification 2 : FTIR (JP)

Both spectra exhibit similar intensities of absorption at the same wave numbers

Identification C : TLC (EP, BP)

The principal 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

Identification D (EP, BP)

A dark red colour is produced within 15 min.

Identification E (EP, BP)

An orange-red colour is produced

Appearance of solution (EP, BP)

2.5% solution in dilute hydrochloric acid R is clear and not more intensely coloured than reference solution Y7

Clarity and color of solution (JP)

5% warm solution in 1M hydrochloric acid is clear and colorless

Optical rotation (JP)

-12.50° to -10.50° (c = 5% in 1M hydrochloric acid at 20°C , after drying)

Specific rotation (EP, BP)

-12.30 to -11.00° (c = 5% in 1:1 mixture of dilute hydrochloric acid R and water at $20 \pm 0.5^\circ\text{C}$, dried substance)

Optical rotation (USP)

-11.20 to -9.80° (c = 5% in 1N hydrochloric acid at 25°C)

Residue on ignition (USP)

$\leq 0.40\%$

Residue on ignition (JP)

$\leq 0.10\%$

Sulfated ash (EP, BP)

$\leq 0.10\%$

Chloride (USP)

$\leq 0.04\%$

Chloride (JP)

$\leq 0.021\%$

Chloride (EP, BP)

$\leq 0.02\%$

Sulfate (USP)

$\leq 0.04\%$

Sulfate (JP)

$\leq 0.028\%$

Sulfate (EP, BP)

$\leq 0.03\%$

Ammonium (JP)

<= 0.02%

Iron (USP)

<= 0.0030%

Iron (JP, EP, BP)

<= 0.0010%

Heavy metals (JP)

<= 0.0010%

Loss on drying (USP, JP)

<= 0.30% (at 105°C, 3 hr)

Loss on drying (EP, BP)

<= 0.50% (at 105°C till constant weight)

Related compounds, system suitability : TLC (USP)

The chromatogram of the system suitability solution exhibits two clearly separated spots

Related compounds, any individual impurity : TLC (USP)

<= 0.50%

Related compounds, total impurities : TLC (USP)

<= 2.00%

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

min. 1.5 between the peaks due to isoleucine and leucine

Ninhydrin-positive substances 2, impurity A at 570 nm**(Amino acid analysis) : (EP, BP)**

<= 0.50%

Ninhydrin-positive substances 3, any ninhydrin-positive substance, for each impurity (Amino acid analysis) : (EP, BP)

<= 0.20%

Ninhydrin-positive substances 4, total impurity (Amino acid analysis) : (EP, BP)

<= 0.60%

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

<= 0.02

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

98.50 - 101.50%

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

99.00 - 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.

Disclaimer :

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