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Technical Datasheet

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: $C_9H_{11}NO_3$
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 ± 0.5°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 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 ± 0.5°C, dried substance)
Optical rotation (USP)
-11.20 to -9.80° (c = 5% in 1N hydrochloric acid at 25°C)
Residue on ignition (USP)
<= 0.40%
Residue on ignition (JP)
<= 0.10%
Sulfated ash (EP, BP)
<= 0.10%
Chloride (USP)
<= 0.04%
Chloride (JP)
<= 0.021%
Chloride (EP, BP)
<= 0.02%
Sulfate (USP)
<= 0.04%
Sulfate (JP)
<= 0.028%
Sulfate (EP, BP)
<= 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 solutiois 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.