

# L-Phenylalanine (From non-animal source)

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

**Product Code: TC098M**

Molecular weight: 165.19

Molecular formula:  $C_9H_{11}NO_2$

CAS No.: 63-91-2

## Quality Control

### Appearance (USP)

White crystals

### Appearance (EP, BP)

White or almost white, crystalline powder or shiny, white flakes

### Appearance (JP)

White crystals or crystalline powder

### Solubility (USP)

Sparingly soluble in water; very slightly soluble in methanol, in alcohol and in dilute mineral acids

### Solubility (EP, BP)

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

### Solubility (JP)

It is freely soluble in formic acid, sparingly soluble in water and practically insoluble in ethanol (95%). It dissolves in dilute hydrochloric acid.

### Identification : FTIR (JP)

Matches with the standard pattern

### Identification A : FTIR (USP)

Matches with the standard pattern

### Identification A : Specific rotation (EP, BP)

$-35.50^\circ$  to  $-33.00^\circ$  ( $c = 2\%$  in water at  $20 \pm 0.5^\circ\text{C}$ , 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 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 violet-red to violet-brown colour develops.

### Appearance of solution (EP, BP)

5% solution in 103 g/L solution of HCl is clear and not more intensely coloured than reference solution BY6

### Clarity & colour of solution (JP)

5% solution in 1 mol/L HCl is clear and colourless

### pH (1% in water at $25^\circ\text{C}$ ) (JP)

5.30 - 6.30

### pH (1% in water at $25^\circ\text{C}$ ) (USP)

5.40 - 6.00

### Specific rotation (USP)

$-34.70^\circ$  to  $-32.70^\circ$  ( $c = 2\%$  in water at  $25^\circ\text{C}$ )

### Specific rotation (EP, BP)

$-35.50^\circ$  to  $-33.00^\circ$  ( $c = 2\%$  in water at  $20 \pm 0.5^\circ\text{C}$ , dried substance)

### Specific rotation (JP)

$-35.50^\circ$  to  $-33.00^\circ$  ( $c = 2\%$  in water at  $20^\circ\text{C}$ , dried substance)

### Chloride (USP)

$\leq 0.05\%$

### Chloride (EP, BP)

$\leq 0.02\%$

### Chloride (JP)

$\leq 0.021\%$

### Sulfates (USP)

$\leq 0.03\%$

### Sulfates (EP, BP)

$\leq 0.03\%$

### Sulfates (JP)

$\leq 0.028\%$

### Ammonium (JP)

$\leq 0.02\%$

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

Ammonium at 570 nm : not more than the area of the corresponding peak in the chromatogram obtained with reference solution C (0.02%) taking into account the peak due to ammonium in the chromatogram obtained with the blank solution

### Iron (USP)

$\leq 0.003\%$

### Iron (EP, BP)

$\leq 0.0010\%$

### Heavy metals (JP)

$\leq 0.002\%$

### Arsenic (JP)

$\leq 0.0002\%$

**Loss on drying (EP, BP)**

≤ 0.50% (at 105°C, 2hr)

**Loss on drying (USP, JP)**

≤ 0.30% (at 105°C, 3hr)

**Sulfated ash (EP, BP)**

≤ 0.10%

**Residue on ignition (USP)**

≤ 0.4%

**Residue on ignition (JP)**

≤ 0.1%

**Ninhydrin-positive substances : system suitability :****Resolution : Amino acid analysis (EP, BP)**

min. 1.5 between the peaks due to isoleucine and leucine

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

≤ 0.20%

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

≤ 0.50%

**Related compound : system suitability : TLC (USP)**

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

**Related compound : 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 impurity : TLC (USP)**

≤ 2.0%

**Related substances : TLC (JP)**

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

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

98.50 - 101.50%

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

98.50 - 101.00%

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

min. 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.

**Disclaimer :**

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