

## L-Threonine (From non-animal source)

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

**Product Code: TC120M**

### Product description :

Molecular weight: 119.12

Molecular formula:  $C_4H_9NO_3$

CAS No.: 72-19-5

### Quality Control

#### Appearance (USP)

White crystals

#### Appearance (JP)

White crystals or a crystalline powder

#### Appearance (EP, BP)

White or almost white, crystalline powder or colourless crystals

#### Solubility (USP)

Freely soluble in water; insoluble in absolute alcohol, in ether, and in chloroform

#### Solubility (EP, BP)

Soluble in water, practically insoluble in ethanol (96%)

#### Solubility (JP)

Freely soluble in formic acid, soluble in water, and practically insoluble in ethanol (95%)

#### Identification A : FTIR (USP)

Matches with the standard pattern

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

$-29.00^\circ$  to  $-27.60^\circ$  ( $c = 6\%$  in water at  $20 \pm 0.5^\circ\text{C}$ , dried substance)

#### Identification : FTIR (JP)

Matches with the standard pattern

#### 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 blue colour develops that changes to yellow after a few minutes

#### Appearance of solution (EP, BP)

2.5% in water is clear and colourless

#### Clarity and color of solution (JP)

5% solution in water is clear and colourless

#### pH (5% in water at $25^\circ\text{C}$ ) : (USP)

5.00 - 6.50

#### pH (2.5% in water at $25^\circ\text{C}$ ) : (EP, BP)

5.00 - 6.50

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

5.20 - 6.20

#### Specific rotation (USP)

$-29.10^\circ$  to  $-26.70^\circ$  ( $c = 6\%$  in water at  $25^\circ\text{C}$ )

#### Specific rotation (EP, BP)

$-29.00^\circ$  to  $-27.60^\circ$  ( $c = 6\%$  in water at  $20 \pm 0.5^\circ\text{C}$ , dried substance)

#### Specific rotation (JP)

$-29.00^\circ$  to  $-26.00^\circ$  ( $c = 6\%$  in water at  $20^\circ\text{C}$ , after drying)

#### Chloride (USP)

$\leq 0.05\%$

#### Chloride (JP)

$\leq 0.021\%$

#### Chloride (EP, BP)

$\leq 0.02\%$

#### Sulfate (USP)

$\leq 0.03\%$

#### Sulfate (EP, BP)

$\leq 0.03\%$

#### Sulfate (JP)

$\leq 0.028\%$

#### Iron (USP)

$\leq 0.003\%$

#### Iron (EP, BP)

$\leq 0.0010\%$

#### Heavy metals (JP)

$\leq 0.0020\%$

**Ammonium (JP)**

<= 0.020%

**Arsenic (JP)**

<= 0.00020%

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

<= 0.20% (at 105°C, 3 hr)

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

<= 0.50% (at 105°C, 2 hr)

**Sulfated ash (EP, BP)**

<= 0.10%

**Residue on ignition (USP)**

<= 0.40%

**Residue on ignition (JP)**

<= 0.10%

**Related compounds, System suitability requirements : TLC (USP)**

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

**Related compounds, acceptance criteria: 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 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, system suitability : Resolution, Amino acid analysis (EP, BP)**

min. 1.5 between the peaks due to impurity D and leucine

**Any ninhydrin-positive substances, for each impurity, Amino acid analysis (EP, BP)**

<= 0.20%

**Any ninhydrin-positive substances, total impurity, Amino acid analysis (EP, BP)**

<= 0.50%

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

<= 0.020% (at 570 nm)

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

98.50 - 101.50%

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

99.00 - 101.00%

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

min. 98.50%

**Storage and Shelf Life:**

Store below 30°C.

Shelf life is 48 months.

Use before expiry date given on the product label.

**Disclaimer :**

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