

# L-Asparagine monohydrate (From non-animal source)

Meets USP-NF, EP and BP testing specifications

**Product Code: TC057M**

## Product Description :

Molecular weight: 150.13

Molecular formula:  $C_4H_8N_2O_3 \cdot H_2O$

CAS No.: 5794-13-8

## Quality Control:

### Appearance (USP)

White crystals or a crystalline powder

### Appearance (EP, BP)

White or almost white crystalline powder or colourless crystals

### Solubility (USP)

Soluble in water, practically insoluble in alcohol and in ether

### Solubility (EP, BP)

Slightly soluble in water, practically insoluble in ethanol (96%) and in methylene chloride

### pH (c = 2% in water at 25°C) (EP, BP)

4.00 - 6.00

### Identification A, FTIR (USP)

Matches with the standard pattern

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

+33.7° to +36.0° (c = 10% in 3N HCl, dried substance)

### Identification B, FTIR (EP, BP)

Matches with the standard pattern

### Identification C, TLC (EP, BP)

The principle spot in the chromatogram obtained with test solution (b) is similar in position, colour and size to the principle spot in the chromatogram obtained with reference solution

### Identification D, Loss on drying (at 130°C, 3hr) (EP, BP)

10.50 - 12.50%

### Appearance of solution (EP, BP)

2% solution is clear and colourless.

### Lead (USP)

≤ 0.0005%

### Chloride (EP, BP)

≤ 0.02%

### Sulphate (EP, BP)

≤ 0.02%

### Iron (EP, BP)

≤ 0.001%

### Ammonium (EP, BP)

≤ 0.1%

### Chromatographic purity, TLC (USP)

No secondary spot from the sample solution is larger or more intense than the principal spot from the standard solution (0.5%), and ≤ 1.0% of total impurities is found

### Microbial enumeration test, TAMC (USP)

≤ 1000 cfu/g

### Microbial enumeration test, TYMC (USP)

≤ 100 cfu/g

### Related substances, system suitability, Resolution, HPLC: (EP, BP)

≥ 5.0, between the peaks due to asparagine and impurity A

### Related substances 1 (HPLC): Impurities A (EP, BP)

≤ 0.50%

### Related substances 2 (HPLC): Impurity C (EP, BP)

≤ 0.1%

### Related substances 3 (HPLC): Unspecified impurities for each impurity (EP, BP)

≤ 0.05%

### Related substances : Total impurities, HPLC (EP, BP):

≤ 0.8%

### Sulphated ash (EP, BP)

≤ 0.1%

### Residue on ignition (USP)

≤ 0.1%

### Specific rotation (EP, BP)

+33.7° to +36.0° (c = 10% in 3N HCl, dried substance)

### Specific rotation (USP)

+33.0° to +36.5° (c = 1% in 6N HCl, at 20°C)

### Loss on drying (at 130°C, 3hr) (EP, BP)

10.50 - 12.50%

### Loss on drying (at 130°C, 3hr) (USP)

11.50 - 12.50%

**Assay (NT, on dry basis) (USP)**

98.00 - 101.50%

**Assay (NT, on dry basis) (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.

Revision : 03/2024

**Disclaimer :**

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