HiMedia CellCulture
Enabling Breakthroughs

Product Information

N-Acetyl- L-Cysteine (From non-animal source)

Meets USP 41-NF 36, EP 9.0, JP 17 and BP 2016 testing specification

Product Code: TC054M

Molecular weight: 163.191
Molecular formula: $C_5H_9NO_3S$
CAS No.: 616-91-1

Quality Control

Appearance (USP) White crystalline powder

Appearance (EP, BP)
White or almost white crystalline powder or colourless crystals

Appearance (JP)
White crystals or crystalline powder

Solubility (USP)

Freely soluble in water and in alcohol; practically insoluble in chloroform and in ether

Solubility (EP, BP)

Freely soluble in water and in ethanol (96%); practically insoluble in methylene chloride

Solubility (JP)

It is freely soluble in water and in ethanol (99.5%). It dissolves in sodium hydroxide solution

Identification : FTIR (JP)
Matches with the standard pattern

Identification A : FTIR (USP)
Matches with the standard pattern

Identification A : Specific rotation (dried substance) (EP, BP)

+21.0° to +27.0° (mix 1.25 gm with 1 mL of 10 g/L sodium edetate R. Add 7.5 mL of a 40 g/L solution of sodium hydroxide R, mix and dissolve. Dilute to 25.0 mL with phosphate buffer solution pH 7.0 R2

Identification B : Melting range (EP, BP)
104 - 110°C

Identification C : FTIR (EP, BP)
Matches with the standard pattern

Identification D : HPLC (EP, BP)

The principal spot in the chromatogram obtained with test solution (b) is similar in retention time and size to the principal peak in the chromatogram obtained with reference solution (b)

Identification E (EP, BP) An dark violet colour develops

pH (1% in water at 25°C) (USP, EP, BP)
2.00 - 2.80

Appearance of the solution (EP, BP)
5% solution in water is clear and colourless

Melting range (EP, BP) 104 - 110°C

Melting range (JP)
107 - 111°C

Heavy metals (USP, EP, JP)
<= 0.001%

Zinc (EP, BP)
<= 0.001%

Ammonium (JP)
<= 0.02%

Chloride (JP)
<= 0.040%

Iron (JP)
<= 0.001%

Sulphate (JP)
<= 0.030%

Specific rotation (USP, EP, BP, JP)

+21.0° to +27.0° (mix 1.25 gm with 1 mL of 10 g/L sodium edetate R. Add 7.5 mL of a 40 g/L solution of sodium hydroxide R, mix and dissolve. Dilute to 25.0 mL with phosphate buffer solution pH 7.0 R2

Loss on drying (JP)
<= 0.50% (at 80°C, 3 hr)

Loss on drying (USP)
<= 1.0% (about 50mm of mercury at 70°C, 4 hr)

Loss on drying (EP, BP)
<= 1.0% (over P_2O_5, 1.5 kPa to 2.5 kPa at 70°C, 3 hr)

Residue on ignition (JP)
<= 0.30%

Residue on ignition (USP)
<= 0.50%

Sulfated ash (EP, BP)
<= 0.20%

Related substances : system suitability : RSD : HPLC (JP)
<= 2.0%

Related substances : any other impurities : HPLC (JP)
<= 0.3%

Related substances : Total impurities : HPLC (JP)
<= 0.6%

Related substance : system suitability : resolution 1 : HPLC (EP, BP)

>= 1.5 between the peaks due to impurities A and B

Related substance : system suitability : resolution 2 : HPLC (EP, BP)

>= 2.0 between the peaks due to impurities C and D

Related substances : impurities A, B, C,D : for each impurity : HPLC (EP, BP)
<= 0.50%

Related substance : any other impurity : for each impurity : HPLC (EP,BP)
<= 0.50%

Related substance : Total impurities: HPLC (EP, BP)

<= 0.50%

System suitability : Resolution : HPLC (USP)

>= 6.0 between acetylcysteine and L-phenylalanine

System suitability : RSD : HPLC (USP)

<= 2.0%

Assay (HPLC, dried basis) : (USP)
98.00 - 102.00%

Assay (Iodimetry, dried substance) : (EP, BP)

98.00 - 101.00%

Assay (Iodometry, dried basis) : (JP)

99.00 - 101.00%

Storage and Shelf Life:

Store at 2 to 8°C
Shelf life is 48 months.
Use before expiry date given on the product label.

Revision: 02/ 2022

Address : C-40, Road No.21/Y, MIDC, Wagle Ind. Area, Thane(W) - 400604, Maharashtra, India. Phone:+91-022-6147 1919, 6903 48 00 Fax: +91-022-6147 1920,6903 48 90
email : info@himedialabs.com. Visit us at our website: www.himedialabs.com