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Technical Datasheet

Glycine

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

Product Code: TC075M

Product Description :

Molecular weight: 75.07
Molecular formula: $C_2H_5NO_2$
CAS No.: 56-40-6
Synonym: Aminoacetic acid

Quality Control:

Appearance (USP, IP)
White, odorless, crystalline powder
Appearance (EP, BP)
White or almost white, crystalline powder
Appearance (JP)
White crystals or crystalline powder
Solubility (USP)
Freely soluble in water, very slightly soluble in alcohol and in ether
Solubility (EP, BP)
Freely soluble in water, very slightly soluble in ethanol (96%)
Solubility (IP)
Freely soluble in water, very slightly soluble in ethanol (95%), Practically insoluble in ether
Solubility (JP)
Freely soluble in water and in formic acid and practically insoluble in ethanol (95%)
pH (5% in water at 25°C) (EP, BP)
5.90 - 6.40
pH (5% in water at 25°C) (JP)
5.60 - 6.60
pH (5% in water at 25°C) (IP)
5.90 - 6.30
Identification : FTIR (JP)
Matches with the standard pattern
Identification A : FTIR (USP, EP, BP, IP)
Matches with the standard pattern
Identification B : TLC (EP, BP)
The principal spot in the chromatogram obtained with test solution is similar in position, colour and size to the principal spot in the chromatogram obtained with reference solution
Identification B (IP)
The resulting solution is violet with greenish-yellow fluorescence. After a few minutes, the colour becomes orange and then yellow and an intense fluorescence remains
Identification C (EP, BP)
The solution is violet with greenish-yellow fluorescence. After a few minutes, the colour becomes orange and then yellow and an intense fluorescence remains.
Appearance of solution (EP, BP)
10% solution in water is clear and not more intensely coloured than reference solution Y7
Appearance of solution (IP)
10% solution in water is clear and not more intensely coloured than reference solution YS7
Clarity and color of solution (JP)
10% solution in water is clear and colorless
Chloride (JP)
<= 0.021%
Chloride (USP)
<= 0.007%
Chloride (EP, BP)
<= 0.0075%
Chloride (IP)
<= 0.01%
Ammonium (Amino acid analysis) : (EP, BP)
Complies
Ammonium (JP)
<= 0.02%
Sulfate (USP)
<= 0.0065%
Sulfate (JP)
<= 0.028%
Heavy metals (JP)
<= 0.0020%
Heavy metals (IP)
<= 0.0010%
Arsenic (JP)
<= 0.0002%
Residue on ignition (USP, JP)
<= 0.10%
Loss on drying (USP)
<= 0.20% (at 105°C, 2 hr)

Loss on drying (EP, BP, IP)
<= 0.50% (at 105°C, 2 hr)
Loss on drying (JP)
<= 0.30% (at 105°C, 3 hr)
Sulfated ash (EP, BP, IP)
<= 0.10%
Hydrolyzable substances (USP)
The solution appears as clear and as mobile as 10 mL of the same solution that has not been boiled
Ninhydrin-positive substances : System suitability : Resolution (Amino acid analysis) (EP, BP)
>= 1.5 between the peaks due to isoleucine and leucine
Ninhydrin-positive substances 1 (Amino acid analysis) : For each impurity (EP, BP)
<= 0.10%
Ninhydrin-positive substances 2 (Amino acid analysis) : Total impurity (EP, BP)
<= 1.00%
Related substances : TLC (JP)
The spots other than the principal spot from the sample solution are not more intense than the spot from the standard solution.
Related substances (system suitability, HPLC) : Resolution (EP, BP)
>= 5.0, between the peaks due to impurity A and glycine
Related substances 1 (HPLC) : Impurities B, H, I for Each impurity (EP, BP)
<= 0.10%
Related substances 2 (HPLC) : Unspecified impurities for each impurity (EP, BP)
<= 0.10%
Related substances 3 (HPLC) : Total impurity (EP, BP)
<= 0.20%
Related compounds, system suitability, HPLC : Resolution (USP)
>= 2.0 between the diglycine and triglycine peaks
Related compounds, system suitability, HPLC : RSD (USP) <= 5.00% each for the specified peaks
Related compounds: Glycine anhydride: HPLC (USP)
<= 0.1%
Related compounds: Iminodiacetic acid: HPLC (USP)
<= 0.1%
Related compounds: Diglycine : HPLC (USP)
<= 0.1%
Related compounds: Triglycine : HPLC (USP)
<= 0.1%
Related compounds: Hexamethylenetetramine: HPLC (USP)
<= 0.1%
Related compounds: Total impurities: HPLC (USP)
<= 1.0%
Assay (NT, on dried basis) : (USP, IP)
98.50 - 101.50%
Assay (NT, on dried substance) : (EP, BP)
98.50 - 101.00%
Assay (NT, on dried basis) : (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.

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