



## **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<sub>2</sub>H<sub>5</sub>NO<sub>2</sub>

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  $25^{\circ}$ 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)

 $\leq 0.20\%$  (at 105°C, 2 hr)



## Loss on drying (EP, BP, IP)

<= 0.50% (at  $105^{\circ}$ C, 2 hr)

#### Loss on drying (JP)

<= 0.30% (at  $105^{\circ}$ 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%

 $\label{lem:Related compounds} \textbf{Related compounds, system suitability, HPLC:}$ 

Resolution (USP)

>= 2.0 between the diglycine and triglycine peaks

Related compounds, system suitability, HPLC: RSD

 $(USP) \le 5.00\%$  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)

(USF) <= 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.

Revision: 04/2023

## Disclaimer:

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