Glycine[1]

$C_2H_5NO_2$: 75.07

Glycine, when dried, contains not less than 98.5 percent and not more than 101.0 percent of Glycine ($C_2H_5NO_2$).

Description

White crystals or crystalline powder; sweet taste.

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

Identification

Compare the infrared absorption spectrum of the sample with that of the standard by potassium bromide disc method.[2]

Specifications

Item	Limit	Test
State of solution (Transmittance)	Clear and colorless Not less than 98.0%	AJI TEST 2 [1.0g in 10mL of H_2O, spectrophotometer, 430nm, 10mm cell thickness]
Chloride (Cl)	Not more than 0.007%	AJI TEST 3 [1.4g, A-1, ref: 0.28mL of 0.01mol/L HCl]
Ammonium (NH_4)	Not more than 0.02%	AJI TEST 4 [D-1]
Sulfate (SO_4)	Not more than 0.006%	AJI TEST 5 [2.8g, (1), ref:0.35mL of 0.005mol/L H_2SO_4]
Iron (Fe)	Not more than 10ppm	AJI TEST 6 [0.75g, B-1, ref:0.75mL of Iron Std. (0.01mg/mL)]
Heavy metals (Pb)	Not more than 10ppm	AJI TEST 7 [2.0g, (1), ref: 2.0mL of Pb Std. (0.01mg/mL)]
Arsenic (As_2O_3)	Not more than 1ppm	AJI TEST 8 [2.0g, (1), ref: 2.0mL of As_2O_3 Std.]

Specifications(cont'd)

Item	Limit	Test
Related substances	1)Any unspecified impurity Not more than 0.10% Total impurities Not more than 1.00% 2)Glycine anhydride Not more than 0.10% Diglycine Not more than 0.10% Triglycine Not more than 0.10% Any unspecified impurity Not more than 0.10% Total impurities Not more than 0.20% 3)[5] Glycine anhydride Not more than 0.10% Iminodiacetic acid Not more than 0.10% Diglycine Not more than 0.10% Triglycine Not more than 0.10% Hexamethylenetetramine Not more than 0.10% Any unspecified impurity ---[6] Total impurities Not more than 1.00%	AJI TEST26 [Amino acid analyzer method][3] [EP][4] [USP][7]
Loss on drying	Not more than 0.20%	AJI TEST 11 [1g, at 105°C for 3 hours]

Specifications (cont'd)

Item	Limit	Test
Residue on ignition (Sulfated)	Not more than 0.10%	AJI TEST 13 [1g at 550°C to 650°C for 3 hours]
Assay	98.5 to 101.0%	AJI TEST 14 [Dried sample, 80mg, (1), 3mL of formic acid, 50mL of acetic acid (100), 0.1mol/L $HClO_4$ 1mL=7.507mg $C_2H_5NO_2$]
pH	5.9 to 6.4	AJI TEST 33 [0.5g in 10mL of H_2O]
Hydrolyzable substances	Passed test	[USP]

The test for Endotoxin when the material will be used for manufacturing parenteral products is as follows:

Item	Limit	Test
Endotoxin	Less than 6.0EU/g	AJI TEST 34 [C=1, kinetic-turbidimetric technique]

[1] This product, in terms of actual quality, conforms to USP, EP, and JP.

[2] If the spectrum obtained shows differences from the reference spectrum, dissolve the sample in the minimum volume of water, evaporate to dryness and measure spectrum of the residue.

[3] Disregard limit: 0.05%

[4] Disregard limit: 0.05%

[5] Since Monochloroacetic acid is neither used for manufacturing process of this product nor produced in the process of this product, it is not contained in this product. Therefore it is not listed according to USP.

[6] The limit isn't set by USP (ref. Compendial Notices "Notice of Intent to Revise" posted 01–Jun–2018).

[7] Disregard limit: 0.03%

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