



# " clyzo " - Monograph Comparison



## AS PER CURRENT USP 2022/EP11/JP18

<b>Product Name</b>	Glycine (USP, BP, Ph. Eur.) pure, pharma grade		<b>Issue Date</b>	March-23
<b>Product Code</b>	141340		<b>Prepared by</b>	Sr. Tech Lead
<b>CAS NO.</b>	56-40-6		<b>Reviewed by</b>	Manager Technical
<b>Manufacturer Name</b>	PanReac AppliChem		<b>Version no.</b>	CLYZO/PAN/141340/01

Sr. No.	Test	Manufacturer COA		Pharmacopeial Specifications	
		Complies USP, BP, Ph. Eur.	USP 2022	EP Version 11.0	JP 18
1	Description	White crystalline powder	White, odorless, crystalline powder, having a sweetish taste. Its solutions are acid to litmus.	White or almost white, crystalline powder. It shows polymorphism	White, crystals or crystalline powder. It has a sweet taste. It shows crystal polymorphism.
2	Solubility	Freely soluble in water	Freely soluble in water; very slightly soluble in alcohol and in ether.	Freely soluble in water, very slightly soluble in ethanol (96 %)	Freely soluble in water and in formic acid, and practically insoluble in ethanol (95).
3	Identification 1	Passes The Test	The infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with glycine reference standard/ working standard.	The infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with glycine reference standard/ working standard.	The infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with glycine reference standard/ working standard.
4	Identification 2	Passes The Test	Not mentioned	By TLC: the principal spot in the chromatogram obtained with the test solution is similar in position, colour and size to the principal spot in the chromatogram obtained with the reference solution.	Not mentioned
5	Identification 3	Passes The Test	Not mentioned	The colour should become orange and then yellow and an intense fluorescence remains.	Not mentioned
6	Appearance of solution	Passes The Test	Not mentioned	Sample solution should be clear and not more intensely coloured than reference solution Y7	Sample solution should be clear and colorless
7	pH	Between 5.9 and 6.4	Not mentioned	Between 5.9 and 6.4	Between 5.6 and 6.6
8	Chloride (Cl)	NMT 0.007 %	NMT 0.007 %	NMT 75 ppm	NMT 0.021 %
9	Ammonium	NMT 0.02%	NA	NMT 0.02%	NMT 0.02 %
10	Sulfates	NMT 0.0065 %	NMT 0.0065 %	NA	NMT 0.028 %
11	Related substances	Glycine anhydride: NMT 0.1% Iminodiacetic acid: NMT 0.1% Diglycine: NMT 0.1% Triglycine: NMT 0.1% Hexamethylenetetramine: NMT 0.1% Monochloroacetic acid: NMT 0.1% Maximum unknown impurity: NMT 0.1% Total impurities: NMT 0.2%	Glycine anhydride: NMT 0.1% Iminodiacetic acid: NMT 0.1% Diglycine: NMT 0.1% Triglycine: NMT 0.1% Hexamethylenetetramine: NMT 0.1% Total impurities: NMT 0.2%	Impurity B: NMT 0.10% Impurity H: NMT 0.10% Impurity I: NMT 0.10% Maximum unknown impurity: NMT 0.10% Total impurities: NMT 0.2%	NMT 0.5%
12	Ninhydrin positive substances	Any ninhydrin positive substance: NMT 0.01% Total ninhydrin positive substances: NMT 1.0%	Not mentioned	Any ninhydrin positive substance: NMT 0.01% Total ninhydrin positive substances: NMT 1.0%	Not mentioned
13	Hydrolyzable substances	Passes The Test	The solution should appear as clear and as mobile as 10 ml of the same solution that has not been boiled.	Not mentioned	Not mentioned

14	Heavy metals	Not mentioned	Not mentioned	Not mentioned	NMT 20 ppm
15	Arsenic	Not mentioned	Not mentioned	Not mentioned	NMT 2 ppm
16	Residue on ignition	Not mentioned	NMT 0.1 %	Not mentioned	NMT 0.1 %
17	Sulfated ash	NMT 0.1 %	Not mentioned	NMT 0.1 %	Not mentioned
18	Loss on drying	NMT 0.2 %	NMT 0.2 %	NMT 0.5 %	NMT 0.30 %
19	Assay (Dried basis)	Between 99.0% and 101.0 %	Between 98.5 % and 101.5 %	Between 98.5 % and 101.0 %	NLT 98.5%
20	Elemental Impurities		Not mentioned	Not mentioned	Not mentioned
	Cd	NMT 0.5 ppm			
	Pb	NMT 0.5 ppm			
	As	NMT 1.5 ppm			
	Hg	NMT 1.5 ppm			
	CO	NMT 5 ppm			
	V	NMT 10 ppm			
	Ni	NMT 20 ppm			
	Tl	NMT 1 ppm			
	Au	NMT 10 ppm			
	Pd	NMT 10 ppm			
	Ir	NMT 10 ppm			
	Os	NMT 10 ppm			
	Rh	NMT 10 ppm			
	Ru	NMT 10 ppm			
	Se	NMT 15 ppm			
	Ag	NMT 15 ppm			
	Pt	NMT 10 ppm			
Li	NMT 55 ppm				
Sb	NMT 120 ppm				
Ba	NMT 140 ppm				
Mo	NMT 25 ppm				
Cu	NMT 250 ppm				
Sn	NMT 600 ppm				
Cr	NMT 25 ppm				
21	Residual solvents	Passes The Test	Not mentioned	Not mentioned	Not mentioned
	Storage	Store at room temperature	Preserve in well-closed containers at room temperature.		Well closed containers

**Note** - If you need any additional testing, you may use our Additional Testing Feature on the product page or contact your Clyzo representative.

**Disclaimer** - The information above is solely for your consideration. We do not recommend or affirm the suitability for any specific end use. We suggest the users should research & verify the specifications in accordance with their intended usage.