



" clyzo " - Monograph Comparison



AS PER CURRENT USP 2022/EP11/JP18

Product Name	L-Serine (Ph. Eur., USP) pure, pharma grade		Issue Date	March-23
Product Code	A1708		Prepared by	Sr. Tech Lead
CAS NO.	56-45-1		Reviewed by	Manager Technical
Manufacturer Name	PanReac AppliChem		Version no.	CLYZO/PAN/A1708/01

Sr. No.	Test	Manufacturer COA		Pharmacopeial Specifications	
		Complies Ph. Eur., USP	USP 2022	EP Version 11.0	JP 18
1	Description	Solid	White, odorless crystals, having a sweet taste	White or almost white, crystalline powder or colourless crystals.	white, crystals or a crystalline powder. It has a slight sweet taste
2	Solubility	Not Mentioned	Soluble in water; practically insoluble in absolute alcohol and in ether.	Freely soluble in water, practically insoluble in ethanol (96 %)	Freely soluble in water and in formic acid, and practically insoluble in ethanol (99.5). It dissolves in 2 M HCl
3	Identification 1	passes test	The Infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with Serine reference standard/working standard	The Infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with Serine reference standard/working standard	The Infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with Serine reference standard/working standard
4	Identification 2	passes test	Not mentioned	Should comply with Specific Optical Rotation Test	Not mentioned
5	Identification 3	passes 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
6	Identification 4	passes test	Not mentioned	A violet-red colour should be produced	Not mentioned
7	Appearance of solution	passes test	Not mentioned	Sample solution should be clear and not more intensely coloured than reference solution BY6	Sample solution should be clear and colorless
8	Specific optical rotation	Between +14.0° - +16.0° (at 20°C) Between +14.0° - +15.6° (at 25°C)	Between +14.0° - +15.6°	Between + 14.0 to + 16.0°	Between + 14.0 – + 16.0°
9	pH	Not Mentioned	Not mentioned	Not mentioned	Between 5.2 and 6.2
10	Heavy metals	max. 0.0015 %	Not mentioned	Not mentioned	NMT 20 ppm
11	Residue on Ignition	Not Mentioned	NMT 0.1%	Not mentioned	NMT 0.1%
12	Sulfated ash	max. 0.1 %	Not mentioned	NMT 0.1%	Not mentioned
13	Loss on drying	max. 0.2 %	NMT 0.2%	NMT 0.5%	NMT 0.3%
14	Chlorides	max. 0.02 %	NMT 0.05%	NMT 200 ppm	NMT 0.021%
15	Ammonium	max. 0.02 %	Not mentioned	NMT 0.02%	NMT 0.02#
16	Sulfate	max. 0.03 %	NMT 0.03%	NMT 300 ppm	NMT 0.028%
17	Iron	max. 0.001 %	NMT 30 ppm	NMT 10 ppm	NMT 10 ppm
18	Ninhydrin positive substances/related substances	By HPLC: Any ninhydrin positive substance: NMT 0.2% Total impurities: NMT 0.5% By TLC: Maximum individual impurity: NMT 0.5% Total impurities: NMT 2.0%	Maximum individual impurity: NMT 0.5% Total impurities: NMT 2.0%	Any ninhydrin positive substance: NMT 0.2% Total impurities: NMT 0.5%	NMT 0.2%
19	Assay (dried basis)	Between 98.5% and 101.0 %	Between 98.5% and 101.5 %	Between 98.5% and 101.0 %	Between 98.5% and 101.0 %
	Storage	Store at room temperature	Preserve in well-closed containers	Protected from light.	Tight 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.