



" clyzo " - Monograph Comparison



AS PER CURRENT USP 2022/EP11/JP18

Product Name	L-Proline (Ph. Eur., USP) pure, pharma grade		Issue Date	March-23
Product Code	A1707		Prepared by	Sr. Tech Lead
CAS NO.	9003-39-8		Reviewed by	Manager Technical
Manufacturer Name	PanReac AppliChem		Version no.	CLYZO/PAN/A1707/01

Sr. No.	Test	Manufacturer COA	Pharmacopeial Specifications		
		Complies USP, Ph. Eur	USP 2022	EP Version 11.0	JP 18
1	Description	Solid	White, odorless crystals, having a slightly sweet taste	White or almost white, crystalline powder or colourless crystals.	L-Proline occurs as white, crystals or crystal line powder. It has a slightly sweet taste. It is deliquescent.
2	Solubility	Freely soluble in water	Freely soluble in water and in absolute alcohol; insoluble in ether, in butanol, and in isopropanol.	Very soluble in water, freely soluble in ethanol (96%)	It is very soluble in water and in formic acid, and slightly soluble in ethanol (99.5%).
3	Identification A	Passes test	The infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with Proline reference standard/working standard	The infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with Proline reference standard/ working standard	The infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with Proline reference standard/working standard
4	Identification B	Passes test	Not mentioned	Should comply with specific optical rotation test	Not mentioned
5	Identification C	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	Appearance of solution	Passes test	Not mentioned	Sample solution should be clear and colorless	Sample solution should be clear and colorless
7	pH	Not mentioned	Not mentioned	Not mentioned	Between 5.9 and 6.9
8	Specific rotation	Between -86.0° and -84.0°	Between -86.3° and -84.3°	Between -86.0° and -84.0°	Between -86.0° and -84.0°
9	Loss on drying	NMT 0.4%	NMT 0.4%	NMT 0.5%	NMT 0.3%
10	Chloride	NMT 0.02%	NMT 0.05%	NMT 200 ppm	NMT 0.021%
11	Sulfate	NMT 0.03%	NMT 0.03%	NMT 300 ppm	NMT 0.028%
12	Iron	NMT 0.001%	NMT 30 ppm	NMT 10 ppm	NMT 10 ppm
13	Heavy metals	NMT 0.0015%	Not mentioned	Not mentioned	NMT 10ppm
14	Ammonium	NMT 0.02%	Not mentioned	NMT 0.02%	NMT 0.02%
15	Ninhydrin-positive substances/ related substances	Maximum individual impurity: NMT 0.5% Total impurities: NMT 2.0% As per EP: Any ninhydrin substance (each impurity):NMT 0.2% Total impurities: NMT 0.5%	Maximum individual impurity: NMT 0.5% Total impurities: NMT 2.0%	Any ninhydrin substance (each impurity):NMT 0.2% Total impurities: NMT 0.5%	Each amino acid except Proline: NMT 0.1%
16	Sulfated ash/ Residue on ignition	NMT 0.1%	NMT 0.4%	NMNT 0.1%	NMT 0.1%
17	Assay (Dried basis)	Between 98.5% and 101.0 %	Between 98.5% and 101.5 %	Between 98.5% and 101.0 %	Between 99.0% and 101.0 %
	Storage	Storage 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.