



" clyzo " - Monograph Comparison



AS PER CURRENT USP 2022/EP11/JP18

Product Name	L-leucine (Ph. Eur., USP) pure, pharma grade		Issue Date	March-23
Product Code	A1426		Prepared by	Sr. Tech Lead
CAS NO.	61-90-5		Reviewed by	Manager Technical
Manufacturer Name	PanReac AppliChem		Version no.	CLYZO/PAN/A1426/01

Sr. No.	Test	Pharmacopeial Specifications			
		Manufacturer COA <i>Complies Ph. Eur., USP</i>	USP 2022	EP Version 11.0	JP 18
1	Description	Solid	White, practically odorless, tasteless crystals	white or almost white, crystalline powder or shiny flakes	White, crystals or crystalline powder. It is odorless or has a faint characteristic odor, and has a slightly bitter taste
2	Solubility	Not mentioned	Sparingly soluble in water; insoluble in ether	Sparingly soluble in water, practically insoluble in ethanol (96 %). It dissolves in dilute mineral acids and in dilute solutions of alkali hydroxides	Freely soluble in formic acid, sparingly soluble in water, and practically insoluble in ethanol (95%).It dissolves in HCl
3	Identification 1	Passes Test	The infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with I-Leucine reference standard/working standard	The infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with I-Leucine reference standard/working standard	The infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with I-Leucine reference standard/working standard
4	Identification 2	Passes Test	Not mentioned	Should comply with 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	Specific optical rotation	Between +14.9° to +17.3° (6N HCl) Between +14.5° to +16.5° (4% HCl)	Between +14.9° to +17.3°	Between + 14.5 ⁰ to + 16.5 ⁰	Between +14.5° to +16.0°
7	pH	Between 5.5 and 7.0	Between 5.5 and 7.0	Not mentioned	Between 5.5 and 6.5
8	Loss on drying	NMT 0.2 %	NMT 0.2%	NMT 0.5%	NMT 0.3%
9	Residue on ignition/Sulfated ash	NMT 0.1%	NMT 0.4%	NMT 0.1%	NMT 0.1%
10	Chloride	NMT 0.02 %	NMT 0.05 %	NMT 200 ppm	NMT 0.021%
11	Iron	NMT 0.001%	NMT 30 ppm	NMT 10 ppm	Not mentioned
12	Sulfate	NMT 0.03 %	NMT 0.03%	NMT 300 ppm	NMT 0.028%
13	Related Compounds/Ninhydrin positive substances	Impurity A: NMT 0.8% Any ninhydrin positive substance: NMT 0.2% Total impurities: NMT 1.0%	Individual impurity: NMT 0.5% Total impurities: NMT 2.0%	Impurity A: NMT 0.8% Any ninhydrin positive substance: NMT 0.2% Total impurities: NMT 1.0%	NMT 0.5%
14	Appearance of solution/clarity and colour of solution	Passes Test	Not mentioned	The solution should be clear and not more intensely coloured than reference solution BY6	Sample solution should be clear and colorless
15	Heavy metals	NMT 0.0015%	Not mentioned	Not mentioned	NMT 20 ppm
16	Ammonium	NMT 0.02%	Not mentioned	NMT 0.02%	NMT 0.02%
17	Arsenic	Not mentioned	Not mentioned	Not mentioned	NMT 2 ppm
18	Assay (Dried basis)	Between 98.5% and 101.0%	Between 98.5% and 101.5%	Between 98.5% and 101.0%	NLT 98.5%
	Storage	Keep container tightly closed in a dry and well-ventilated place	Preserve in well-closed containers	Airtight containers	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.