



" clyzo " - Monograph Comparison



AS PER CURRENT USP 2022/EP11/JP18

Product Name	L-Valine (Ph. Eur., USP) pure, pharma grade		Issue Date	March-23
Product Code	A1637		Prepared by	Sr. Tech Lead
CAS NO.	72-18-4		Reviewed by	Manager Technical
Manufacturer Name	PanReac AppliChem		Version no.	CLYZO/PAN/A1637/01

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, odorless, tasteless crystals.	White or almost white, crystalline powder or colourless crystals	white, crystals or crystalline powder. It is odorless or has a faint characteristic odor, and has a slightly sweet taste, which becomes bitter.
2	Solubility	Soluble in water	Soluble in water; practically insoluble in ether, in alcohol, and in acetone	Soluble in water, very slightly soluble in ethanol (96%)	It is freely soluble in formic acid, soluble in water, and practically insoluble in ethanol (95). It dissolves in dilute hydrochloric acid.
3	Identification 1	Passes the test	The Infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with valine reference standard/working standard	The Infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with valine reference standard/working standard	The Infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with valine reference standard/working standard
4	Identification 2	Passes the test	Not mentioned	Should comply with specific optical rotation test	Not mentioned
5	Identification 3	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
6	Appearance of solution	Passes the test	Not mentioned	Sample solution should be clear and not more intensely coloured than reference solution BY6	Sample solution should be clear and colorless
7	Specific optical rotation	Between +26.5 and +29.0 deg. (8% HCl) Between +26.6 and +28.8 deg. (6M HCl)	Between +26.8 ⁰ and +28.8 ⁰	Between +26.5 ⁰ and +29.0 ⁰	Between +26.5 ⁰ and +29.0 ⁰
8	pH	Between 5.5 and 7.0	Between 5.5 and 7.0	Not mentioned	Between 5.5 and 6.5
9	Heavy metals	NMT 0.0015 %	Not mentioned	Not mentioned	NMT 20 ppm
10	Arsenic	NA	Not mentioned	Not mentioned	NMT 2 ppm
11	Residue on Ignition	NA	NMT 0.1%	Not mentioned	NMT 0.1%
12	Sulfated ash	NMT 0.1 %	Not mentioned	NMT 0.1%	Not mentioned
13	Loss on drying	NMT 0.3 %	NMT 0.3%	NMT 0.5%	NMT 0.3%
14	Chlorides	NMT 0.02 %	NMT 0.05%	NMT 200 ppm	NMT 0.021%
15	Ammonium	NMT 0.02 %	Not mentioned	NMT 0.02%	NMT 0.02%
16	Sulfate	NMT 0.03 %	NMT 0.03%	NMT 300 pppm	NMT 0.028%
17	Iron	NMT 0.001 %	NMT 30 ppm	NMT 10 ppm	Not mentioned
18	Related subsyances/Ninhydrin positive substances	Impurity B: NMT 0.4% Maximum unknlwn impurity: NMT 0.2% Total impurities: NMT 1.0% By TLC Isoleucine: NMT 0.2% Maximum unknown impurity: NMT 0.2% Total impurities: NMT 2.0%	Maximum unknown impurity: NMT 0.5% Total impurities: NMT 2.0%	Impurity B: NMT 0.4% Maximum unknlwn impurity: NMT 0.2% Total impurities: NMT 1.0%	NMT 0.5%
19	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	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.