



# " clyzo " - Monograph Comparison



## AS PER CURRENT USP 2022/EP11/JP18

<b>Product Name</b>	L-Isoleucine (Ph. Eur., USP) pure, pharma grade		<b>Issue Date</b>	March-23
<b>Product Code</b>	A1440		<b>Prepared by</b>	Sr. Tech Lead
<b>CAS NO.</b>	73-32-5		<b>Reviewed by</b>	Manager Technical
<b>Manufacturer Name</b>	PanReac AppliChem		<b>Version no.</b>	CLYZO/PAN/A1440/01

Sr. No.	Test	Manufacturer COA	Pharmacopeial Specifications		
		<i>Complies Ph. Eur., USP</i>	<i>USP 2022</i>	<i>EP Version 11.0</i>	<i>JP 18</i>
1	Description	Solid	White, practically odorless crystals, having a slightly bitter taste	White or almost white, crystalline powder or 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	Soluble in water; slightly soluble in hot alcohol; insoluble in ether	Sparingly soluble in water, slightly soluble 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 dilute HCl
3	Identification 1	Passes Test	The Infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with isoleucine reference standard/ <u>working standard</u>	The Infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with isoleucine reference standard/ <u>working standard</u>	The Infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with isoleucine reference standard/ <u>working standard</u>
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	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
7	Specific optical rotation	Between + 38.9 and +41.8 <sup>o</sup> (at 25 deg) Between +40.0 <sup>o</sup> - +43.0 <sup>o</sup> (bet 20 deg)	Between +38.9 <sup>o</sup> and +41.8 <sup>o</sup>	Between 40.0 <sup>o</sup> and 43.0 <sup>o</sup>	Between + 39.5 <sup>o</sup> and + 41.5 <sup>o</sup> .
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 0.3%	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 ppm	NMT 0.028%
17	Iron	NMT 0.001 %	NMT 30 ppm	NMT 10 ppm	Not mentioned
18	Related substances/ Ninhydrin positive substances	Impurity A: NMT 0.3% Impurity C: NMT 0.3% Maximum unknown impurity: NMT 0.2% Total impurities: NMT 1.0% By TLC: Valine: NMT 0.5% Total Impurities: NMT 2.0%	Maximum unknown impurity: NMT 0.5% Total impurities: NMT 2.0%	Impurity A: NMT 0.3% Impurity C: NMT 0.3% Maximum unknown 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	Airtight containers	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.