



# " clyzo " - Monograph Comparison



## AS PER CURRENT USP 2022/EP11/JP18

<b>Product Name</b>	L-Alanine (Ph. Eur., USP) pure, pharma grade		<b>Issue Date</b>	March-23
<b>Product Code</b>	A1688		<b>Prepared by</b>	Sr. Tech Lead
<b>CAS NO.</b>	56-41-7		<b>Reviewed by</b>	Manager Technical
<b>Manufacturer Name</b>	PanReac AppliChem		<b>Version no.</b>	CLYZO/PAN/A1688/01

Sr. No.	Test	Pharmacopeial Specifications			
		Manufacturer COA <i>Complies Ph. Eur., USP</i>	USP 2022	EP Version 11.0	JP 18
1	Description	Not mentioned	White, odorless crystals or crystalline powder, having a slightly sweet taste	White or almost white, crystalline powder or colourless crystals.	White, crystals or crystalline powder. It has a slightly sweet taste.
2	Solubility	Not mentioned	Freely soluble in water; slightly soluble in 80% alcohol; insoluble in ether	Freely soluble in water, very slightly soluble in ethanol (96 %).	Freely soluble in water and in formic acid, practically insoluble in ethanol (99.5%).It dissolves in 6 M HCl.
3	Identification 1	Passes Test	The Infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with Alanine reference standard/working standard	The Infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with Alanine reference standard/working standard	The Infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with Alanine 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	Should comply by yellow precipitate formation	Not mentioned
7	Clarity and color of solution	Passes Test	Not mentioned	The solution is clear and not more intensely coloured than reference solution BY6	The sample solution should be clear and colorless.
8	Specific Rotation	Between +13.7° and +15.1°	Between +13.7° and +15.1°	Between +13.5° and +15.5°	Between +13.5° and +15.5°
9	pH	Between 5.5 and 7.0	Between 5.5 and 7.0	Not mentioned	Between 5.7 and 6.7.
10	Related Compound (HPLC)	Any ninhydrin -post.Substances: NMT 0.1% Total impurities: NMT 0.5% By TLC: Each individual impurity : NMT 0.5% Total impurities: NMT 2%	Maleic acid: NMT 0.05% Malic acid: NMT 0.05% Fumaric acid: NMT 0.05% Any unspecified impurity: NMT 0.05% Total unspecified impurity: NMT 0.2%	Each individual impurity: NMT 0.1% Total impurities: NMT 0.5%	Each amino acid (other than alanine) : NMT 0.1%
11	Heavy Metals	NMT 0.0015%	Not mentioned	Not mentioned	NMT 10 ppm
12	Chloride	NMT 0.02%	NMT 0.05%	NMT 200 ppm	NMT 0.021%
13	Sulfate	NMT 0.03%	NMT 0.03%	NMT 300 ppm	NMT 0.028%
14	Iron	NMT 0.001%	NMT 30 ppm	NMT 10 ppm	NMT 10 ppm
15	Ammonium	NMT 0.02%	Not mentioned	NMT 0.02%	NMT 0.02%
16	Residue on ignition	Not mentioned	NMT 0.15%	Not mentioned	NMT 0.1%
17	Sulphated Ash	NMT 0.1%	Not mentioned	NMT 0.1%	Not mentioned
18	Loss on Drying	NMT 0.2%	NMT 0.2%	NMT 0.5%	NMT 0.3%
19	Assay (dried basis)	Between 98.5 % and 101.0 %	Between 98.5 % and 101.0 %	Between 98.5 % and 101.0 %	Between 98.5% and 101.%
20	Elemental Impurities	Not Mentioned	Not mentioned	Not mentioned	Not mentioned
21	Residual solvent	Not Mentioned	Not mentioned	Not mentioned	Not mentioned

	Storage	Store at room temperature in tightly closed container	Preserve in tight containers, and store at controlled room temperature.	Protected from light.	Tight containers.
<b>Note</b> - If you need any additional testing, you may use our Additional Testing Feature on the product page or contact your Clyzo representative.					
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