



# " clyzo " - Monograph Comparison



## AS PER CURRENT USP 2022/EP11/JP18

<b>Product Name</b>	L-Phenylalanine (Ph. Eur., USP) pure, pharma grade		<b>Issue Date</b>	March-23
<b>Product Code</b>	A1344		<b>Prepared by</b>	Sr. Tech Lead
<b>CAS NO.</b>	63-91-2		<b>Reviewed by</b>	Manager Technical
<b>Manufacturer Name</b>	PanReac AppliChem		<b>Version no.</b>	CLYZO/PAN/A1344/01

Sr. No.	Test	Pharmacopeial Specifications			
		Manufacturer COA <i>Complies USP, Ph. Eur</i>	USP 2022	EP Version 11.0	JP 18
1	Description	Solid	White, odorless crystals, having a slightly bitter taste	White or almost white, crystalline powder, or shiny, white flakes	White, crystals or crystalline powder. It is odorless or has a faint characteristic odor, and has a slightly bitter taste.
2	Solubility	Sparingly soluble in water	Sparingly soluble in water; very slightly soluble in methanol, in alcohol, and in dilute mineral acids	Sparingly soluble in water, very slightly soluble in ethanol (96%). It dissolves in dilute mineral acids and in dilute solutions of alkali hydroxides	It is freely soluble in formic acid, sparingly soluble in water, and practically insoluble in ethanol (95%). It dissolves in dilute HCl
3	Identification 1	Passes The Test	The Infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with Phenylalanine reference standard/working standard	The Infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with Phenylalanine reference standard/working standard	The Infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with Phenylalanine reference standard/working standard
4	Identification 2	Passes The Test	NA	Should comply with specific optical rotation test	NA
5	Identification 3	Passes The Test	NA	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	NA
6	Identification 4	Passes The Test	NA	A violet-red or violet-brown colour should be formed.	NA
7	Appearance	Passes The Test	NA	Sample solution should be clear and not more intensely coloured than reference solution BY6	Sample solution should be clear and colorless.
8	Optical rotation/Specific rotation	Between -32.7° and -34.7° (at 25°C) 'Between -35.50 and -33.0° (at 20°C)	Between -32.7° and -34.7°	Between -35.50 and -33.0°	'Between -33.00 and 35.5°
9	Loss on drying	NMT 0.3%	NMT 0.3%	NMT 0.5%	NMT 0.3%
10	Residue on ignition/ Sulphated ash	NMT 0.1%	NMT 0.4%	NMT 0.1%	NMT 0.1%
11	pH	Between 5.4 and 6.0	Between 5.4 and 6.0	NA	Between 5.3 and 6.3
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	NA
15	Heavy metals	NMT 0.0015%	NA	NA	NMT 20 ppm
16	Arsenic	Not mentioned	NA	NA	NMT 2ppm
17	Ammonium	NMT 0.02%	NA	NMT 0.02%	NMT 0.02%
18	Related compound/ Ninhydrin positive substances	Any ninhydrin-positive substance: NMT 0.2% for each impurity Total impurities: NMT 0.5% By TLC Maximum individual unknown impurity: NMT 0.5% Total impurities: NMT 2.0%	Maximum individual unknown impurity: NMT 0.5% Total impurities: NMT 2.0%	Any ninhydrin-positive substance: NMT 0.2% for each impurity Total impurities: NMT 0.5%	NMT 0.5%
19	Assay (Dried basis)	Between 98.5% and 101.0%	Between 98.5% and 101.0%	Between 98.5% and 101.0%	NLT 98.5%
	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.