



" clyzo " - Monograph Comparison



AS PER CURRENT USP 2022/EP11/JP18

Product Name	L-Arginine base (Ph. Eur., USP) pure, pharma grade		Issue Date	March-23
Product Code	A1345		Prepared by	Sr. Tech Lead
CAS NO.	74-79-3		Reviewed by	Manager Technical
Manufacturer Name	PanReac AppliChem		Version no.	CLYZO/PAN/A1345/01

Sr. No.	Test	Manufacturer COA	Pharmacopeial Specifications		
		Complies USP, Ph. Eur	USP 2022	EP Version 11.0	JP 18
1	Description	Solid	White, practically odorless crystals.	White or almost white, crystalline powder or colourless crystals, hygroscopic	White, crystals or crystalline powder. It has a characteristic odor. It is hygroscopic.
2	Solubility	Freely soluble in water	Freely soluble in water; sparingly soluble in alcohol; insoluble in ether.	Freely soluble in water, very slightly soluble in ethanol (96 %).	Freely soluble in water and in formic acid, and practically insoluble in ethanol (99.5). 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 Arginine reference standard/working standard	The Infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with Arginine reference standard/working standard	The Infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with Arginine reference standard/working standard
4	Identification 2	Passes The Test	Not mentioned	Should comply by specific optical rotation test	Not mentioned
5	Identification 3	Passes The Test	Not mentioned	Sample solution should be strongly alkaline	Not mentioned
6	Identification 4	Passes The Test	Not mentioned	By TLC test, 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
7	Identification 5	Passes The Test	Not mentioned	Should comply by red colour development	Not mentioned
8	Specific Rotation	Between +26.3° and +27.7° (at 25°C) Between + 25.50 to + 28.50 (at 20°C)	Between +26.3° and +27.7°	Between + 25.50 to + 28.50	Between + 26.90 and + 27.99
9	pH	Not mentioned	Not mentioned	Not mentioned	Between 10.5 and 12.0.
10	Clarity and color of solution	Passes The Test	Not mentioned	Solution solution should be clear and not more intensely coloured than reference solution BY6	Sample solution should be clear and colorless
11	Related substances	Any individual impurity: NMT 0.5% Total impurities: NMT 2.0% Any ninhydrin substance: NMT 0.2% Total ninhydrin substances: NMT 0.5%	Any individual impurity: NMT 0.5% Total impurities: NMT 2.0%	Any ninhydrin substance: NMT 0.2% Total ninhydrin substances: NMT 0.5%	Total impurities: NMT 0.2%
12	Heavy Metals	NMT 0.0015%	Not mentioned	Not mentioned	NMT 10 ppm
13	Chloride	NMT 0.02%	NMT 0.05%	NMT 200 ppm	NMT 0.021%
14	Sulfate	NMT 0.03%	NMT 0.03%	NMT 300 ppm	NMT 0.028%
15	Ammonium	NMT 0.002%	Not mentioned	NMT 0.02%	NMT 0.02%
16	Iron	NMT 0.001%	NMT 30 ppm	NMT 10 ppm	NMT 10 ppm
17	Residue on ignition	Not mentioned	NMT 0.3%	Not mentioned	NMT 0.1%
18	Sulphated Ash	NMT 0.1%	Not mentioned	NMT 0.1%	Not mentioned
19	Loss on Drying	NMT 0.5%	NMT 0.5%	NMT 0.5%	NMT 0.3%
20	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 101.0%
	Storage	Storage at room temperature	Preserve in well-closed containers.	Airtight Container	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.