



" clyzo " - Monograph Comparison



AS PER CURRENT USP 2022/EP11/JP18

Product Name	L-Arginine Hydrochloride (Ph. Eur., USP) pure, pharma grade		Issue Date	March-23
Product Code	A1700		Prepared by	Sr. Tech Lead
CAS NO.	1119-34-2		Reviewed by	Manager Technical
Manufacturer Name	PanReac AppliChem		Version no.	CLYZO/PAN/A1700/01

Sr. No.	Test	Manufacturer COA	Pharmacopeial Specifications		
		Complies USP, Ph. Eur	USP 2022	EP Version 11.0	JP 18
1	Description	Solid	White crystals or crystalline powder, practically odorless.	White or almost white, crystalline powder or colourless crystals.	White, crystals or crystalline powder. It is odorless, and has a slight, characteristic taste
2	Solubility	Freely soluble in water	Freely soluble in water.	Freely soluble in water, very slightly soluble in ethanol (96 %).	Freely soluble in water and in formic acid, and very slightly soluble in ethanol (95).
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 Chloride	Passes The Test	Not mentioned	After addition of AgNO3 TS, should develop a white precipitate which dissolve in Ammonia	1. After mixing & heating with H2SO4 and KMnO4 , odour of chlorine is evolved , the gas turns moistened potassium iodide starch paper blue. (2) After addition of AgNO3 TS, should develop a white precipitate which does not dissolve in dilute HNO3 but dissolve in excess of Ammonia
5	Identification 3	Passes The Test	Not mentioned	Should comply by specific optical rotation test	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 +21.4° and +23.6° (at 25°C) Between + 21.0° to + 23.5° (at 20°C)	Between +21.4° and +23.6°	Between + 21.00 to + 23.50	Between + 21.50 and + 23.59
9	pH	Not mentioned	Not mentioned	Not mentioned	Between 4.7 and 6.2
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 ninhydrin substance: NMT 0.2% Total ninhydrin substances: NMT 0.5% Any individual impurity: NMT 0.5% Total impurities: NMT 2.0%	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 0.4%
12	Heavy Metals	NMT 0.002%	Not mentioned	Not mentioned	NMT 20 ppm
13	Sulfate	NMT 0.03%	NMT 0.03%	NMT 300 ppm	NMT 0.028%
14	Ammonium	NMT 0.02%	Not mentioned	NMT 0.02%	NMT 0.02%
15	Iron	NMT 0.001%	Not mentioned	NMT 10 ppm	NMT 10 ppm

16	Arsenic	Not mentioned	Not mentioned	Not mentioned	NMT 2 ppm
17	Chloride	Between 16.5% and 17.1%	Between 16.5% and 17.1%	Not mentioned	Not mentioned
18	Residue on ignition	Not mentioned	NMT 0.1%	Not mentioned	NMT 0.1%
19	Sulphated Ash	NMT 0.1%	Not mentioned	NMT 0.1%	Not mentioned
20	Loss on Drying	NMT 0.2%	NMT 0.2%	NMT 0.5%	NMT 0.2%
21	Assay (dried basis)	Between 98.5% and 101.0%	Between 98.5% and 101.0%	Between 98.5% and 101.0%	NMT 98.5%
22	Elemental Impurities		Not mentioned	Not mentioned	Not mentioned
	Cd	NMT 0.5 ppm			
	Pb	NMT 0.5 ppm			
	As	NMT 1.5 ppm			
	Hg	NMT 1.5 ppm			
	CO	NMT 5 ppm			
	V	NMT 10 ppm			
	Ni	NMT 20 ppm			
	Tl	NMT 0.8 ppm			
	Au	NMT 10 ppm			
	Pd	NMT 10 ppm			
	Ir	NMT 10 ppm			
	Os	NMT 10 ppm			
	Rh	NMT 10 ppm			
	Ru	NMT 10 ppm			
	Se	NMT 15 ppm			
	Ag	NMT 15 ppm			
	Pt	NMT 10 ppm			
	Li	NMT 55 ppm			
	Sb	NMT 120 ppm			
Ba	NMT 140 ppm				
Mo	NMT 25 ppm				
Cu	NMT 250 ppm				
Sn	NMT 600 ppm				
Cr	NMT 25 ppm				
	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.