



" clyzo " - Monograph Comparison



AS PER CURRENT USP 2022/EP11/JP18

Product Name	L-Lysine Monohydrochloride (Ph. Eur., USP) pure, pharma grade		Issue Date	March-23
Product Code	A1706		Prepared by	Sr. Tech Lead
CAS NO.	657-27-2		Reviewed by	Manager Technical
Manufacturer Name	PanReac AppliChem		Version no.	CLYZO/PAN/A1706/01

Sr. No.	Test	Manufacturer COA	Pharmacopeial Specifications		
		Complies USP, Ph. Eur	USP 2022	EP Version 11.0	JP 18
1	Description	Solid	White, odorless crystals or crystalline powder, having an acid taste	White or almost white, crystalline powder or colourless crystals.	White powder, It has a slight, characteristic taste. It shows polymorphism
2	Solubility	Freely soluble in water	Freely soluble in water	Freely soluble in water, slightly soluble in ethanol (96 %).	It is freely soluble in water and in formic acid, and practically insoluble in ethanol (95).
3	Identification 1	Passes The Test	Not mentioned	Should comply with specific rotation test	1. When mixed with sulfuric acid and potassium permanganate, and heated should evolve odour of chlorine 2. Should comply by formation of a white precipitate with silver nitrate which is not soluble in HNO3 but soluble in excess Ammonia
4	Identification 2	Passes The Test	The Infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with Lysine hydrochloride reference standard/working standard.	The Infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with Lysine hydrochloride reference standard/working standard.	The Infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with Lysine hydrochloride reference standard/working standard.
5	Identification 3	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
6	Identification 4	Passes The Test	Not mentioned	Should comply by a yellowish-white precipitate formation	Not mentioned
7	Identification 5	Passes The Test	Not mentioned	Should comply by formation of a white precipitate with silver nitrate which is soluble in excess Ammonia	Not mentioned
8	Chloride	Between 19.0% and 19.0%	Between 19.0% and 19.0%	Not mentioned	Not mentioned
9	Sulfate	NMT 0.03%	NMT 0.03%	NMT 0.03%	NMT 0.028%
10	Iron	NMT 0.003%	NMT 30 ppm	NMT 30 ppm	NMT 10 ppm
11	Ammonium	NMT 0.02%	Not mentioned	NMT 0.02%	NMT 0.02%
12	Arsenic	Not mentioned	Not mentioned	Not mentioned	NMT 2 ppm
13	Heavy metals	Not mentioned	Not mentioned	Not mentioned	NMT 10 ppm
14	Clarity and color of solution/appearance of solution	Passes The Test	Not mentioned	Sample solution should be clear and not more intensely coloured than B7 or GY7	Sample solution should be colorless and clear.
15	Optical Rotation	Between +20.4° and +21.4° (at 25°C) Between+ 21.00 and + 22.50 (at 20°C)	Between +20.4° and +21.4°	Between+ 21.0° and + 22.5°	Between + 19.5° and + 21.5°
16	pH	Not mentioned	Not mentioned	Not mentioned	Between 5.0 and 6.0
17	Related substances/Ninhydrin positive substances	BY HPLC: Any ninhydrin-positive substance: for each impurity: NMT 0.2% Total ninhydrin-positive substance: total impurities:NMT 1.0% By TLC: Any Individual impurity: NMT 0.5% Total impurities: NMT 2.0%	Any Individual impurity: NMT 0.5% Total impurities: NMT 2.0%	Any ninhydrin-positive substance: for each impurity: NMT 0.2% Total ninhydrin-positive substance: total impurities:NMT 1.0%	NMT 0.5%
18	Sulfated Ash	NMT 0.1%	Not mentioned	NMT 0.1%	Not mentioned
19	Residue on Ignition	Not mentioned	Not mentioned	Not mentioned	NMT 0.1%
20	Loss on drying	NMT 0.4%	NMT 0.4%	NMT 0.5%	NMT 1.0%
21	Assay (dried basis)	Between 98.5% and 101.0%	Between 98.5% and 101.5%	Between 98.5% and 101.0%	NLT 98.5%
22	Elemental Impurities (as per ICH)	Passes The Test			
	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.