



" clyzo " - Monograph Comparison



AS PER CURRENT USP 2022/EP11/JP18

Product Name	L-Histidine base (Ph. Eur., USP) pure, pharma grade		Issue Date	March-23
Product Code	A1341		Prepared by	Sr. Tech Lead
CAS NO.	71-00-1		Reviewed by	Manager Technical
Manufacturer Name	PanReac AppliChem		Version no.	CLYZO/PAN/A1341/01

Sr. No.	Test	Manufacturer COA		Pharmacopeial Specifications	
		Complies USP, Ph. Eur.		USP 2022	EP Version 11.0
1	Description	Solid	White, odorless crystals, having a slightly bitter taste.	white or almost white, crystalline powder or colourless crystals	White, crystals or crystalline powder, having a slight bitter taste. It shows polymerisation
2	Solubility	Soluble in water	Soluble in water, very slightly soluble in alcohol, insoluble in ether.	soluble in water, very slightly soluble in ethanol (96 %).	Freely soluble in formic acid, and soluble in water, and practically insoluble in ethanol (99.5). It dissolves in 6 M HCl.
3	Identification 1 (FTIR)	Passes test	The Infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with L-Histidine reference standard/working standard	The Infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with L-Histidine reference standard/working standard	The Infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with L-Histidine reference standard/working standard
4	Identification 2	Passes test	NA	By TLC, the principal spot in the chromatogram obtained with the test solution is similar in position, colour and size	NA
5	Identification 3	Passes test	NA	Should comply by specific optical rotation test	NA
6	Identification 4	Passes test	NA	Should comply by an orange-red colour development	NA
7	pH	Between 7.0 and 8.5	Between 7.0 and 8.5	NA	Between 7.0 and 8.5
8	Clarity & Colour of Solution	Passes test	NA	Sample solution should be clear and not more intensely coloured than reference solution BY7	Sample solution should be clear and colorless
9	Specific optical rotation	Between + 11.4° and + 12.4° (EP) Between +12.6° and +14.0° (USP)	Between +12.6° and +14.0°	Between + 11.4° and + 12.4° (dried substance).	Between + 11.8° and + 12.8°
10	Residue on Ignition	Not mentioned	NMT 0.4%	NA	NMT 0.1%
11	Sulphated ash	NMT 0.1%	NA	NMT 0.1%	NA
12	Loss on Drying	NMT 0.2%	NMT 0.2%	NMT 0.5%	NMT 0.3%
13	Related Compounds:	Maximum individual impurity: NMT 0.2% Total impurities: NMT 0.5% TLC: Maximum individual impurity: NMT 0.5% Total impurities: NMT 2.0%	By Maximum individual impurity: NMT 0.5% Total impurities: NMT 2.0%	Maximum individual impurity: NMT 0.2% Total impurities: NMT 0.5%	NMT 0.2%
14	Chloride	NMT 0.02%	NMT 0.05%	NMT 0.02%	NMT 0.021%
15	Sulfate	NMT 0.03%	NMT 0.03%	NMT 0.03%	NMT 0.028%
16	Iron	NMT 0.001%	NMT 30 ppm	NMT 10 ppm	NMT 10 ppm
17	Ammonium	NMT 0.002%	NA	NMT 0.02%	NMT 0.02%
18	Heavy Metals	NMT 0.0015%	NA	NA	NMT 10 ppm
19	Assay (Dried Basis)	Between 98.0% and 100.5%	Between 98.5% and 101.0%	Between 98.5% and 101.0%	Between 98.5% and 101.0%
	Storage	Store 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.