



# " clyzo " - Monograph Comparison



## AS PER CURRENT USP 2022/EP11/JP18

<b>Product Name</b>	L-Histidine Hydrochloride 1-hydrate (Ph. Eur.) pure, pharma grade		<b>Issue Date</b>	March-23
<b>Product Code</b>	A1591		<b>Prepared by</b>	Sr. Tech Lead
<b>CAS NO.</b>	5934-29-2		<b>Reviewed by</b>	Manager Technical
<b>Manufacturer Name</b>	PanReac AppliChem		<b>Version no.</b>	CLYZO/PAN/A1591/01

Sr. No.	Test	Pharmacopeial Specifications			
		Manufacturer COA <i>Complies Ph.Eur</i>	USP 2022	EP Version 11.0	JP 18
1	Description	Solid	Product Not Official in European Pharmacopoeia	white or almost white, crystalline powder or colourless crystals	White, crystals or crystalline powder, having a slight bitter taste.
2	Solubility	Soluble in water		Freely 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 Hydrochloride Monohydrate 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		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.	A solution of L-Histidine Hydrochloride Hydrate (1 in 10) responds to Qualitative Tests for chloride.
5	Identification 3	passes test		Should comply by specific optical rotation test	Not mentioned
6	Identification 4	passes test		Should comply by an orange-red colour development	Not mentioned
7	Identification 5	passes test		Should comply by formation of curdled white precipitate	Not mentioned
8	Identification 6	passes test		Should comply by pH test	Not mentioned
9	pH	Between 3.0 and 5.0		Between 3.0 and 5.0	Between 3.5 and 4.5.
10	Appearance of Solution	passes test		Sample solution should be clear and not more intensely coloured than reference solution BY6	Sample solution should be clear and colorless
11	Specific optical rotation	Between +9.2° and +10.6°		Between +9.2° and +10.6° (dried substance).	Between +9.2 and +10.6°
12	Sulfate	NMT 0.03 %		NMT 300 ppm	NMT 0.028%
13	Iron	NMT 0.001%		NMT 10 ppm	NMT 10 ppm
14	Ammonium	NMT 0.02 %		NMT 0.02%	NMT 0.02%
15	Related substances/ Ninhydrin positive substances	Maximum individual impurity: NMT 0.2% Total impurities: NMT 0.5%		Maximum individual impurity: NMT 0.2% Total impurities: NMT 0.5%	NMT 0.2%
16	Heavy Metals	Not mentioned		Not mentioned	NMT 10 ppm
17	Residue on Ignition	NMT 0.4%		Not mentioned	NMT 0.1%

18	Sulfated ash	NMT 0.1 %
19	Water	NA
20	Loss on Drying	Between 7.0% and 10.0 %
21	Assay	Between 98.5% and 101.0%
	Storage	Store at room temperature

NMT 0.1%	NA
Not mentioned	Between 7.2% and 10.0 %
Between 7.0% and 10.0 %	Not mentioned
Between 98.5% and 101.0%	Between 99.0% and 101.0%
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.