



" clyzo " - Monograph Comparison



AS PER CURRENT USP 2022/EP11/JP18

Product Name	L-Cystein Hydrochloride 1-Hydrate (Ph. Eur., USP) pure, pharma grade		Issue Date	March-23
Product Code	A1702		Prepared by	Sr. Tech Lead
CAS NO.	7048-04-6		Reviewed by	Manager Technical
Manufacturer Name	PanReac AppliChem		Version no.	CLYZO/PAN/A1702/01

Sr. No.	Test	Manufacturer COA	Pharmacopeial Specifications		
		Complies Ph. Eur., USP	USP 2022	EP Version 11.0	JP 18
1	Description	Solid	Clear, colorless, mobile, volatile liquid. Has a characteristic odor and produces a burning sensation on the tongue. Is readily volatilized even at low temperatures, and boils at about 78°. Is flammable.	White or almost white, crystalline powder or colourless crystals	White, crystals or crystalline powder
2	Solubility	Soluble in water	Miscible with water and with practically all organic solvents.	Freely soluble in water, slightly soluble in ethanol (96 %)	It is very soluble in water, and soluble in ethanol (99.5). It dissolves in 6M HCl
3	Identification 1	Passes the test	The Infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with L-Cystein Hydrochloride Hydrate reference standard/working standard	The Infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with L-Cystein Hydrochloride Hydrate reference standard/working standard	The Infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with L-Cystein Hydrochloride Hydrate 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	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	Not mentioned
6	Identification 4	Passes the test	Not mentioned	Should comply by turning solution green	1. The gas evolved should turn moistened KI-starch paper blue 2. Should comply by a white crystalline precipitate formation
7	Identification 5	Passes the test	Not mentioned	Should comply by formation of white crystalline precipitate	Not mentioned
8	Appearance of solution/clarity and color of solution	Passes the test	Not mentioned	Sample solution should be clear and not more intensely coloured than reference solution BY6	Sample solution should be clear and colorless
9	Specific optical rotation	Between +5.5° - +7.0° (In 8% HCl) Between +5.7° and +6.8° (in 6M HCl)	Between +5.7° and +6.8°	Between + 5.5° and + 7.0°	Between +6.0° and + 7.5°
10	pH	Not mentioned	Not mentioned	Not mentioned	Between 1.3 and 2.3
11	Heavy metals	NMT. 0.001 %	Not mentioned	Not mentioned	NMT 10 ppm
12	Residue on Ignition	Not mentioned	NMT 0.4%	Not mentioned	NMT 0.1 %
13	Sulfated ash	NMT 0.1 %	Not mentioned	NMT 0.1%	Not mentioned
14	Loss on drying	Between 8.0% and 12.0 %	Between 8.0% and 12.0 %	Between 8.0% and 12.0 %	Between 8.5% and 12.0 %
15	Ammonium	NMT 0.02 %	Not mentioned	NMT 0.02 %	NMT 0.02%
16	Sulfate	NMT 0.03 %	NMT 0.03%	NMT 300 ppm	NMT 0.021%
17	Iron	NMT 0.002 %	NMT 30 ppm	NMT 20 ppm	NMT 10 ppm

18	Ninhydrin positive substances /related substances	Impurity A: NMT 0.5% Maximum unknown impurity: NMT 0.2% Total impurities: NMT 1.0% By TLC Maximum individual impurity: NMT 0.5% Total impurities: NMT 1.0%	Maximum individual impurity: NMT 0.5% Total impurities: NMT 1.0%	Impurity A: NMT 0.5% Maximum unknown impurity: NMT 0.2% Total impurities: NMT 1.0%	NMT 0.2%
19	Assay (dried subst.)	Between 98.5% and 101.0 %	Between 98.5% and 101.5%	Between 98.5% and 101.0 %	Between 98.5% and 101.0%
	Storage	Keep container tightly closed in a dry and well-ventilated place	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.