



" clyzo " - Monograph Comparison



AS PER CURRENT USP 2022/EP11/JP18

Product Name	L-Cystine (Ph. Eur.) pure, pharma grade		Issue Date	March-23
Product Code	A1703		Prepared by	Sr. Tech Lead
CAS NO.	56-89-3		Reviewed by	Manager Technical
Manufacturer Name	PanReac AppliChem		Version no.	CLYZO/PAN/A1703/01

Sr. No.	Test	Pharmacopeial Specifications			
		Manufacturer COA <i>Complies Ph. Eur</i>	USP 2022	EP Version 11.0	JP 18
1	Description	Solid	Not Mentioned	White or almost white, crystalline powder	White, crystals or crystalline powder.
2	Solubility	Practically insoluble in water	Not Mentioned	Practically insoluble in water and in ethanol (96 %). It dissolves in dilute solutions of alkali hydroxides.	It is practically insoluble in water and in ethanol (99.5%). It dissolves in 1 M HCl
3	Identification 1	Passes The Test	The Infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with L-Cystine reference standard/working standard	The Infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with L-Cystine reference standard/working standard	The Infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with L-Cystine reference standard/working standard
4	Identification 2	Passes The Test	Specific Optical Rotation should be between -225° and -215°	Should comply with specific optical rotation Test	Not mentioned
5	Identification 3	Passes The Test	In RS test, the RF value of the principal spot of the Sample solution corresponds to that of the Standard solution.	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 formation of turbidity or a white precipitate within 3 minutes.	Not mentioned
7	Appearance of solution	passes test	Not Mentioned	Sample solution should be clear and not more intensely coloured than reference solution Y7	Sample solution should be clear and colorless
8	Specific optical rotation	Between -224° and -218°	Not Mentioned	Between -224° and -218°	Between -215° and -225°
9	pH	Not mentioned	Not Mentioned	Not mentioned	Not mentioned
10	Heavy metals	NMT 0.001 %	Not Mentioned	NMT 0.001 %	NMT 10 ppm
11	Residue on Ignition	Not mentioned	NMT 0.1 %	Not mentioned	NMT 0.1%
12	Sulfated ash	NMT 0.1 %	Not Mentioned	NMT 0.1 %	Not mentioned
13	Loss on drying	NMT 0.5 %	NMT 0.2 %	NMT 0.5 %	NMT 0.3 %
14	Ammonium	NMT 0.02 %	Not Mentioned	NMT 0.02 %	NMT 0.02 %
15	Chloride	NMT 0.02 %	NMT 200 ppm	NMT 200 ppm	NMT 0.021%
16	Sulfate	NMT 0.03 %	NMT 200 ppm	NMT 300 ppm	NMT 0.028%
17	Iron	NMT 0.001 %	NMT 10 ppm	NMT 0.002 %	NMT 10 ppm
18	Related substances	Maximum individual impurity : NMT 0.2% Total impurities: NMT 0.5%	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%
19	Assay (dried subst.)	Between 98.5 % and 101.0 %	Between 98.5 % and 101.0 %	Between 98.5 % and 101.0 %	Between 99.0 % and 101.0%
	Storage	Store at room temperature	Preserve in well-closed containers, and store at controlled room temperature.	Protected from light	Tight light resistant 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.