



" clyzo " - Monograph Comparison



AS PER CURRENT USP 2022/EP11/JP18

Product Name	L(+)-Ascorbic Acid (USP, BP, Ph. Eur.) pure, pharma grade	 PanReac AppliChem <small>ITW Reagents</small>	Issue Date	March-23
Product Code	141013		Prepared by	Sr. Tech Lead
CAS NO.	50-81-7		Reviewed by	Manager Technical
Manufacturer Name	PanReac AppliChem		Version no.	CLYZO/PAN/141013/01

Sr. No.	Test	Manufacturer COA		Pharmacopeial Specifications	
		Complies USP, BP, Ph. Eur.	USP 2022	EP Version 11.0	JP 18
1	Description	Small white crystals	White or slightly yellow crystals or powder. On exposure to light it gradually darkens. In the dry state, is reasonably stable in air, but in solution rapidly oxidizes. Melts at about 190°C.	White or almost white, crystalline powder or colourless crystals, becoming discoloured on exposure to air and moisture. Melting point at about 190 °C with decomposition	White crystals or white crystalline powder. It is odourless and has an acid taste. Melting point at about 190 °C with decomposition
2	Solubility	Soluble in water	Freely soluble in water; sparingly soluble in alcohol; insoluble in chloroform, in ether, and in benzene.	Freely soluble in water, sparingly soluble in ethanol (96 per cent).	Freely soluble in water, sparingly soluble in ethanol (95%) practically insoluble in diethyl ether
3	Identification 1	Passes Test	The Infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with Ascorbic acid reference standard/working standard	The Infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with Ascorbic acid reference standard/working standard	The colour of the solution should be discharged immediately in each case
4	Identification 2	Passes Test	Sample solution should reduce alkaline cupri tartarate TS slowly at room temperature but more readily upon heating	UV absorption spectrum of ample solution shows maxima at about 243 nm , Specific absorbance at maximum is between 545 to 585	A blue colour should be develop
5	Identification 3	Passes Test	Not mentioned	pH should be between 2.1 and 2.6	Not mentioned
6	Identification 4	Passes Test	Not mentioned	A grey precipitate should be formed	Not mentioned
7	Optical Rotation	Between +20.5° and +21.5 °	Between +20.5° and +21.5°	Between +20.5° and +21.5 °	Between +20.5° and +21.5 °
8	pH	NA	Not mentioned	Not mentioned	Between 2.2 and 2.5
9	Clarity and colour of solution	Passes Test	Not mentioned	Sample solution should be clear and not more intensely coloured than reference solution BY7	The sample solution should be clear and colourless
10	Heavy metals	0.001%	Not mentioned	Not mentioned	NMT 20 ppm
11	Copper	0.0005 %	Not mentioned	Not mentioned	NMT 5 ppm
12	Iron	0.0002 %	Not mentioned	Not mentioned	NMT 2 ppm
13	Matter insoluble in water	Should comply the test	Not mentioned	Not mentioned	Not mentioned
14	Chloride	NMT 0.025%	Not mentioned	Not mentioned	Not mentioned
15	Sulfate	NMT 0.01%	Not mentioned	Not mentioned	Not mentioned
16	Loss on drying	NA	Not mentioned	Not mentioned	NMT 0.2%
17	Residue on ignition	NMT 0.1%	NMT 0.1%	Not mentioned	NMT 0.1%
18	Sulphated Ash	NMT 0.1%	Not mentioned	NMT 0.1%	Not mentioned
19	Impurity E (Oxalic Acid)	0.2%	Not mentioned	NMT 0.2%	Not mentioned
20	Related substances	Impurity C: NMT 0.1% Impurity D: NMT 0.15% Maximum unspecified impurity NMT- 0.1% Total impurities (Excluding impurity C &D)-0.2%	Not mentioned	Impurity C :NMT 0.15% Impurity D: NMT 0.15% Maximum unspecified impurity NMT- 0.1% Total impurities (Excluding impurity C &D)-0.2%	Not mentioned
21	Assay (dried basis)	Between 99.0% and 100.5%	Between 99.0% and 100.5%	Between 99.0% and 100.5%	NLT 99.0%

22	Elenemtal Impurities		Not mentioned	Not mentioned	Not mentioned
	Cd	0.5 ppm			
	Pb	0.5 ppm			
	As	1.5 ppm			
	Hg	1.5 ppm			
	Co	5 ppm			
	V	10 ppm			
	Ni	20 ppm			
	Tl	5 ppm			
	Au	10 ppm			
	Pd	10 ppm			
	Ir	10 ppm			
	Os	10 ppm			
	Rh	10 ppm			
	Ru	10 ppm			
	Se	15 ppm			
	Ag	15 ppm			
	Pt	10 ppm			
	Li	55 ppm			
	Sb	120 ppm			
Ba	140 ppm				
Mo	25 ppm				
Cu	5 ppm				
Sn	600 ppm				
Cr	25 ppm				
23	Residual solvents	Passes Test	Not mentioned	Not mentioned	Not mentioned
	Storage	Store away from direct sunlight	Store in light resistant tight containers	In a non-metallic container, protected from light.	Store in light resistant 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.