



" clyzo " - Monograph Comparison



AS PER CURRENT USP 2022/EP11/JP18

Product Name	tri-Sodium Citrate 2-hydrate (Ph. Eur, BP, USP) GMP - IPEC grade	 PanReac AppliChem ITW Reagents	Issue Date	March-23
Product Code	631655		Prepared by	Sr. Tech Lead
CAS NO.	6132-04-3		Reviewed by	Manager Technical
Manufacturer Name	PanReac AppliChem		Version no.	CLYZO/PAN/631655/01

Sr. No.	Test	Manufacturer COA	Pharmacopeial Specifications		
		Complies USP, Ph. Eur., BP	USP 2022	EP Version 11.0	JP 18
1	Description	White, Small crystals	Colorless crystals, or white, crystalline powder.	White or almost white, crystalline powder or white or almost white, granular crystals, slightly deliquescent in moist air.	Colorless crystals, or a white crystalline powder. It is odorless, and has a cooling, saline taste
2	Solubility	Soluble in water	Not mentioned	Freely soluble in water, practically insoluble in ethanol (96 per cent)	Freely soluble in water, and practically insoluble in ethanol (95) and in diethyl ether.
3	Identification 1	Passes test	Should comply by a light red color formation	After addition of an excess of concentrated ammonia should produces a violet colour, which turns to violet-blue	(1) After addition of 20 mL of a mixture of pyridine and acetic anhydride (3:1) a redbrown color should develop. 2. After addition of equal volume of H2SO4 and 2/3rd volume of KMnO4 should produce a white precipitate. (3) When boiled with excess CaCl2 solution, should produce a white crystalline precipitate.
4	Identification 2	Passes test	Should comply by a dense white precipitate formation	Should comply by a dense white precipitate formation	1. Should develop yellow coloured flame. 2. Should comply by formation of a white, crystalline precipitate with addition of potassium hexahydroxoantimonate (V) TS.
5	Identification 3	Passes test	Upon ignition it should form an alkaline residue	Not mentioned	Not mentioned
6	Clarity and color of solution	Passes test	Not mentioned	Sample Solution should be clear and colourless	Sample solution should be clear and colorless
7	Acidity or alkalinity	Passes test	After addition of 0.2 ml 0.01N H2SO4 should not produce pink color	Not mentioned	Not mentioned
8	pH	Between 7.5 and 9.0	Not mentioned	Between 7.5 and 8.5	Between 7.9 and 8.4.
9	Chloride	NMT 0.0050 %	Not mentioned	NMT 50 ppm	NMT 0.015%
10	Sulfate	NMT 0.0150 %	Not mentioned	NMT 150 ppm	NMT 0.048%
11	Oxalate	NMT 0.0300 %	Not mentioned	NMT 300 ppm	Sample solution should be clear
12	Tartrate	Passes test	No crystalline precipitate should be formed.	Not mentioned	No crystalline precipitate should be formed
13	Water	Between 11.0% and 13.0 %	Between 10.0% and 13.0 %	Between 11.0% and 13.0 %	Not mentioned
14	Loss on drying	Between 10.0% and 13.0 %	Not mentioned	Not mentioned	Between 10.0% and 13.0 %
15	Readily carbonisable substances	The solution should not be more intensely coloured than reference solution Y2 or GY2	Not mentioned	The solution should not be more intensely coloured than reference solution Y2 or GY2	Sample solution should be less intensely colored than Matching Fluid K
16	Arsenic	Not mentioned	Not mentioned	Not mentioned	NMT 2 ppm
17	Heavy metals	Not mentioned	Not mentioned	Not mentioned	NMT 10 ppm
18	Assay	Between 99.0% and 100.5% (USP) Between 99.0 % and 101.0 % (EP)	Between 99.0% and 100.5%	Between 99.0 % and 101.0 %	Between 99.0 % and 101.0 %
	Elemental Impurities				
	Cd	NMT 0.5 ppm			
	Pb	NMT 5 ppm			
	As	NMT 1.5 ppm			
	Hg	NMT 1.5 ppm			

19	CO	NMT 5 ppm	Not mentioned	Not mentioned	Not mentioned
	V	NMT 10 ppm			
	Ni	NMT 20 ppm			
	Tl	NMT 5 ppm			
	Au	NMT 10 ppm			
	Pd	NMT 10 ppm			
	Ir	NMT 10 ppm			
	Os	NMT 10 ppm			
	Rh	NMT 10 ppm			
	Ru	NMT 10 ppm			
	Se	NMT 15 ppm			
	Ag	NMT 15 ppm			
	Pt	NMT 10 ppm			
	Li	NMT 55 ppm			
	Sb	NMT 120 ppm			
	Ba	NMT 140 ppm			
	Mo	NMT 25 ppm			
	Cu	NMT 250 ppm			
	Sn	NMT 600 ppm			
	Cr	NMT 25 ppm			
20	Residual solvents	passes test	Not mentioned	Not mentioned	Not mentioned
	Storage	Preserve in tight containers.	In an airtight container.	Containers — Tight containers	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.					
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