



# " clyzo " - Monograph Comparison



## AS PER CURRENT USP 2022/EP11/JP18

<b>Product Name</b>	tri-Sodium Citrate 2-hydrate Ph. Eur, USP		<b>Issue Date</b>	July-23
<b>Product Code</b>	140046		<b>Prepared by</b>	Sr. Tech Lead
<b>CAS NO.</b>	6132-04-3		<b>Reviewed by</b>	Manager Technical
<b>Manufacturer Name</b>	CG Chemikalein GmbH & Co KG		<b>Version no.</b>	CLYZO/CG/140046/01

Sr. No.	Test	Pharmacopeial Specifications			
		Manufacturer COA <i>Complies USP, Ph. Eur., BP</i>	USP 2022	EP Version 11.0	JP 18
1	Description	White or almost white, crystalline powder	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	Not mentioned	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	Should comply the test	Should comply by a light red color formation	After addition of an excess of concentrated ammonia should produce 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 reddish-brown color should develop. (2) After addition of equal volume of H <sub>2</sub> SO <sub>4</sub> and 2/3rd volume of KMnO <sub>4</sub> should produce a white precipitate. (3) When boiled with excess CaCl <sub>2</sub> solution, should produce a white crystalline precipitate.
4	Identification 2	Should comply the 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	Should comply the test	Upon ignition it should form an alkaline residue	Not mentioned	Not mentioned
6	Clarity and color of solution	Sample Solution should be clear and colourless	Not mentioned	Sample Solution should be clear and colourless	Sample solution should be clear and colorless
7	Acidity or alkalinity	Should comply the test	After addition of 0.2 ml 0.01N H <sub>2</sub> SO <sub>4</sub> should not produce pink color	Not mentioned	Not mentioned
8	pH	Not mentioned	Not mentioned	Between 7.5 and 8.5	Between 7.9 and 8.4.
9	Chloride	NMT 50 ppm	Not mentioned	NMT 50 ppm	NMT 0.015%
10	Sulfate	NMT 150 ppm	Not mentioned	NMT 150 ppm	NMT 0.048%
11	Oxalate	NMT 300 ppm	Not mentioned	NMT 300 ppm	Sample solution should be clear
12	Tartrate	Should comply the 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	Not mentioned	Not mentioned	Not mentioned	Between 10.0% and 13.0 %
15	Readily carbonisable substances	Should comply the test	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	NMT 10 ppm	Not mentioned	Not mentioned	NMT 10 ppm
18	Assay	Between 99.0% and 100.5%	Between 99.0% and 100.5%	Between 99.0 % and 101.0 %	Between 99.0 % and 101.0 %
19	Microbial limit test Total aerobic microbial count Total yeast and molds count E.Coli Pseudomonas aeruginosa Staphylococcus aureus Salmonella	NMT 100 CFU/g NMT 50 cfu/g Absent/g Absent/g Absent/g Absent/25 g	Not mentioned	Not mentioned	Not mentioned
20	Bacterial Endotoxins	NMT 2.5 IU/g	Not mentioned	Not mentioned	Not mentioned
	Storage	Not mentioned	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.