

" clyzo " - Monograph Comparison



C	ly:	ZO	

	Product Name Product Code	Citric Acid Anhydrous Ph. Eur., USP 140035	CG	Issue Date Prepared by	July-23 Sr. Tech Lead
	CAS NO.	77-92-9	GROUP	Reviewed by	Manager Technical
	Manufacturer Name	CG Chemikalein GmbH & Co KG		Version no.	CLYZO/CG/140035/01
. No.	Test	Manufacturer COA	Pharmacopeial Specifications		
		Complies BP	USP 2022	EP Version 11.0	JP 18
1	Descriprion	White or almost white, crystalline powder, colourless	Colorless, translucent crystals, or white, granular to fine, crystalline powder. Melts at about 153°C, with decomposition.	White or almost white, crystalline powder, colourless crystals or granules, efflorescent. Melting point about 1530C with decomposition	It occurs as colorless crystals, white granul or crystalline powder.
2	Solubility	Not mentioned	Very soluble in water; freely soluble in alcohol; very slightly soluble in ether	Very soluble in water, freely soluble in ethanol (96 per cent)	It is very soluble in water, and freely solub in ethanol (99.5%).
3	Identification 1	Should comply the test	Infrared absorption spectrum obtained with sample (previously dried at 105°C for 2 hours) should be concordant with spectrum obtained with Citric acid Reference standard/working standard	Infrared absorption spectrum obtained with sample (previously dried at 105°C for 2 hours) should be concordant with spectrum obtained with Citric acid Reference standard/working standard	Infrared absorption spectrum obtained wi sample (previously dried at 105°C for 2 hours) should be concordant with spectru obtained with Citric acid Reference standard/working standard
4	Identification 2	Should comply the test	Not mentioned	Solution S should be acidic	Not mentioned
5	Identification 3	Should comply the test	Not mentioned	A red colour should developes Should comply by white precipitate	Not mentioned
6	Identification 4	Should comply the test	Not mentioned	formation	Not mentioned
7	Identification 5	Should comply the test	Not mentioned	Should comply by water content test	Not mentioned
8	Clarity & colour of Solution/Appearance of solution	Should comply the test	The Sample solution shows the same clarity as that of water or its opalescence is not more pronounced than Standard suspension A and not more intensely coloured than standard solutions A,B and C	The sample solution is clear and colourless or not more intensely coloured than reference solution Y7, BY7 or GY7	Sample solution should be clear and colorless or has no more color than the control solutions (1), (2) or (3)
9	Readily carbonisable substances	Should comply the test	The color of the sample solution is not darker than that of a similar volume of Matching Fluid K	The sample solution is not more intensely coloured than a mixture of 1 mL of red primary solution and 9 mL of yellow primary solution	The color of the sample solution is not darker than that of a similar volume of Matching Fluid.
10	Heavy metals	NMT 10 ppm	Not mentioned	Not mentioned	NMT 10 ppm
11	Sulfates	NMT 150 ppm	NMT 0.015%	NMT 150 ppm	NMT 150 ppm
12	Limit of Oxalic acid	NMT 360 ppm	NMT 0.036%	NMT 360 ppm	NMT 360 ppm
13	Water	NMT 1.0%	NMT 1.0%	NMT 1.0%	NMT 1.0%
14	Residue on Ignition	NMT 0.1%	NMT 0.1%	Not mentioned	NMT 0.1%
15	Sulfated Ash	Not mentioned	Not mentioned	NMT 0.1%	Not mentioned
16	Assay (Anhydrous basis) Microbial limit test	Between 99.5%–100.5% NMT 100 CFU/g NMT 50 cfu/g Absent/g Absent/g Absent/g Absent/g	Between 99.5%–100.5%	Between 99.5%–100.5%	Between 99.5%–100.5%
	Storage	Not mentioned	Preserve in tight containers	Airtight containers	Tight containers
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