" clyzo " - Monograph Comparison

AS PER CURRENT USP 2022/EP11/JP18

	Product Name	**EDTA Disodium Salt 2-hydrate (USP, BP, Ph. Eur.) pure, pharma grade**	PanReac AppliChem ITW Reagents	**Issue Date**	March-23
	Product Code	141669		**Prepared by**	Sr. Tech Lead
	CAS NO.	6381-92-6		**Reviewed by**	Manager Technical
	Manufacturer Name	**PanReac AppliChem**		**Version no.**	CLYZO/PAN/141669/01

Sr. No.	Test	Manufacturer COA	Pharmacopeial Specifications		
		Complies USP, BP, Ph. Eur	*USP 2022*	*EP Version 11.0*	*JP 18*
1	Descriprion	White crystalline powder	White, crystalline powder.	White or almost white, crystalline powder.	White crystals or crystalline powder. It is odorless and has a slight, acid taste
2	Solubility	Soluble in water, practically insoluble in ethanol 96%	Soluble in water	Soluble in water, practically insoluble in ethanol (96 per cent).	It is soluble in water, and practically insoluble in ethanol (95%) and in diethyl ether.
3	Identification 1	Passes The Test	Infrared absorption spectrum obtained with sample should be concordant with the spectrum obtained with Disodium Edetate USP RS/ Working standard.	Infrared absorption spectrum obtained with sample should be concordant with the spectrum obtained with Disodium Edetate USP RS/ Working standard.	Should comply by a purple color development
4	Identification 2	Passes The Test	The red color should be discharged, leaving a yellowish solution	No precipitate should be formed	The residue should melt between 2409C and 2449C (with decomposition)
5	Identification 3	Passes The Test	Not mentioned	No precipitate should be formed	Not mentioned
6	Identification 4 sodium	Passes The Test	Should comply by a dense white precipitate formation	1. Should comply by a dense white precipitate formation 2. Should comply no precipitate formed	During flame test , a yellow color flame develops
7	pH	Between 4.0 and 5.0	Between 4.0 and 6.0	Between 4.0 and 5.0	Between 4.3 and 4.7
8	Clarity and colour of solution /Appearance of solution	Passes The Test	Not mentioned	Sample solution is clear and colourless	Sample solution is clear and colourless
9	Cyanide	Not mentioned	Not mentioned	Not mentioned	Sample solution should not be more intensely coloured than standard solution
10	Heavy metals	Not mentioned	Not mentioned	Not mentioned	NMT 10 ppm
11	Arsenic	Not mentioned	Not mentioned	Not mentioned	NMT 2 ppm
12	Calcium	Passes The Test	No precipitate should be formed	Not mentioned	Not mentioned
13	Iron	NMT 0.0005%	Not mentioned	NMT 80 ppm	Not mentioned
14	Loss on drying	Between 8.7% and 11.4%	Between 8.7% and 11.4%	Not mentioned	Not mentioned
15	Residue on ignition	Not mentioned	Not mentioned	Not mentioned	Between 37.0 and 39.0
16	Matter insoluble in water	NMT 0.01%	Not mentioned	Not mentioned	Not mentioned
17	Chloride	NMT 0.02%	Not mentioned	Not mentioned	Not mentioned
18	Sulfate	NMT 0.1%	Not mentioned	Not mentioned	Not mentioned
19	Impurity A (Nitriloacetic acid)	NMT 0.1%	NMT 0.1%	NMT 0.1%	Not mentioned
20	Assay (dried basis(	Between 99.0% and 101.0 %	Between 99.0% and 101.0 %	Between 98.5% and 101.0 %	NLT 98.0%
21	Elemental Impurities		Not mentioned	Not mentioned	Not mentioned
	Cd	NMT 0. 5 ppm			
	Pb	NMT 0.5 ppm			
	As	NMT 1 ppm			
	Hg	NMT 1.5 ppm			
	CO	NMT 5 ppm			
	V	NMT 10 ppm			
	Ni	NMT 20 ppm			
	Tl	NMT 0.8 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			
22	Residual solvents	Passes The Test	Not mentioned	Not mentioned	Not mentioned
	Storage	Storage away from direct light.	Preserve in well-closed containers.	Protected from light.	Well closed containers

Note - If you need any additional testing, you may use our Additional Testing Feature on the product page or contact your Clyzo reprensentive.