" clyzo " - Monograph Comparison

AS PER CURRENT USP 2022/EP11/JP18

	Product Name	**di-Sodium Hydrogen Phosphate 2-hydrate (USP, BP, Ph. Eur.) pure, pharma grade**	PanReac AppliChem ITW Reagents	**Issue Date**	March-23
	Product Code	142507		**Prepared by**	Sr. Tech Lead
	CAS NO.	10028-24-7		**Reviewed by**	Manager Technical
	Manufacturer Name	**PanReac AppliChem**		**Version no.**	CLYZO/PAN/10028-24-7/01

Sr. No.	Test	Manufacturer COA	Pharmacopeial Specifications		
		Complies USP, Ph. Eur., BP	*USP 2022*	*EP Version 11.0*	*JP 18*
1	Description	White Crystals	Colorless or white, granular or caked salt.	white or almost white powder or colourless crystals	
2	Solubility	Soluble in water	Freely soluble in water; very slightly soluble in alcohol.	very soluble in water, very slightly soluble in ethanol (96 %).	
3	Identification 1 (Sodium)	Passes the test	After addition of potassium pyroantimonate solution a dense white precipitate should be formed	1. After addition of potassium pyroantimonate solution a dense white precipitate should be formed 2. After addition of ethoxyphenylacetic reagent a voluminous, white, crystalline precipitate should be formed which dissolve in ammonia .On addition of ammonium carbonate solution . No precipitate is formed	
4	Identification 2 (Phosphate)	Passes the test	1. After addition of AgNO3 TS, should produce a yellow precipitate that is soluble in 2 N HNO3 and in 6 N NH4OH 2. After addition of ammonium molybdate TS, should produce a yellow precipitate that is soluble in 6 N NH4OH	1. After addition of AgNO3 TS, should produce a yellow precipitate that is soluble in 2 N HNO3 and in 6 N NH4OH 2. After addition of molybdovanadic reagent , should produce a yellow precipitate	
5	Identification 3	Passes the test	Not mentioned	Sample Solution is slightly alkaline	
6	Identification 4	Passes the test	Not mentioned	Should comply loss on drying Test	
7	Appearance of solution	Passes the test	Not mentioned	Sample Solution should be clear and colourless	
8	Water Insoluble substances	NMT 0.025 %	NMT 0.4%	Not mentioned	
9	pH	Between 8.7 and 9.4	Not mentioned	Not mentioned	
10	Monosodium phosphate	Passes the test	Not mentioned	NMT 2.5 %	
11	Nitrogen compounds (as N)	NMT 0.003 %	Not mentioned	Not mentioned	
12	Chlorides	NMT 0.003 %	NMT 0.06 %	NMT400 ppm	
13	Sulfate	NMT 0.01 %	NMT 0.2 %	NMT 0.1%	
14	Iron	NMT 0.002 %	Not mentioned	NMT 40 ppm	
15	Arsenic	NMT 0.0001 %	NMT 16 ppm	Not mentioned	
16	Reducing substances	Passes the test	Not mentioned	The colour of the permanganate should not completely discharged.	
17	Loss on drying	Between 19.5 % % and 21.0 %	Between 18.5 % and 21.5 %	Between 19.5 % and 21.0 %	Product Not Official in Japanese pharmacopoeia
18	Assay (dried basis)	Between 98.0 % and 100.5 %	Between 98.0% and 100.5 %	Between 98.0 % and 101.0 %	
19	Residual solvents (Ph.Eur/USP)	passes test	Not mentioned	Not mentioned	
	Elemental Impurities		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			

20	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			
21	Residual solvents (Ph.Eur/USP)	passes test	Not mentioned	Not mentioned	
	Storage	Keep container tightly closed in a dry and well-ventilated place.	Preserve in tight containers		

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