" clyzo " - Monograph Comparison

AS PER CURRENT USP 2022/EP11/JP18

	Product Name	**di-Sodium Hydrogen Phosphate 12-hydrate (USP, BP, Ph. Eur.) pure, pharma grade**	PanReac AppliChem ITW Reagents	**Issue Date**	March-23
	Product Code	141678		**Prepared by**	Sr. Tech Lead
	CAS NO.	10039-32-4		**Reviewed by**	Manager Technical
	Manufacturer Name	**PanReac AppliChem**		**Version no.**	CLYZO/PAN/141678/01

Sr. No.	Test	Manufacturer COA	Pharmacopeial Specifications		
		Complies USP, Ph. Eur., BP	*USP 2022*	*EP Version 11.0*	*JP 18*
1	Description	White Crystals	White powder that readily absorbs moisture	Colourless, transparent crystals, very efflorescent.	Colorless or white crystals. It is odorless. It effloresces in warm, dry air.
2	Solubility	Soluble in water	Freely soluble in water; insoluble in alcohol	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 (Sodium)	Passes the test	After addition of potassium pyroantimonate solution R 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	1. Should comply with a white, crystalline precipitate with addition of potassium hexahydroxoantimonate (V) TS. 2. Should develope yellow coloured flame.
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 R, should produce a yellow precipitate	1. After addition of AgNO3 TS a yellow precipitate should be produced , which dissolves upon addition of dilute HNO3 or ammonia TS. 2. After addition of magnesia TS a white, crystalline precipitate should be produced, which dissolves upon subsequent addition of dilute HCl
5	Identification 3	Passes the test	Not mentioned	Sample Solution is slightly alkaline having pH between 8.0 and 10.0	Should comply by yellow precipitate formation on addition hexaammonium heptamolybdate TS.
6	Identification 4	Passes the test	Not mentioned	Should comply loss on dying Test	Not mentioned
7	Appearance of solution	Passes the test	Not mentioned	Sample Solution should be clear and colourless	Sample solution should be clear and colourless
8	Insoluble substances	NMT 0.025 %	NMT 0.4%	Not mentioned	Not mentioned
9	Monosodium phosphate	NMT 2.5 %	Not mentioned	NMT 2.5 %	Not mentioned
10	Nitrogen compounds (as N)	NMT 0.003 %	Not mentioned	Not mentioned	Not mentioned
11	Chlorides	NMT 0.003 %	NMT 0.06 %	NMT 200 ppm	NMT 0.014%
12	Sulfate	NMT 0.01 %	NMT 0.2 %	NMT 500 ppm	NMT 0.038%
13	Iron	NMT 0.001 %	Not mentioned	NMT 20 ppm	Not mentioned
14	Arsenic	NMT 0.0001 %	NMT 16 ppm	Not mentioned	NMT 2 ppm
15	pH	Between 8.7 and 9.4	Not mentioned	Not mentioned	Between 9.0 and 9.4
16	Heavy metals	Not mentioned	Not mentioned	Not mentioned	NMT 10 ppm
17	Carbonates	Not mentioned	Not mentioned	Not mentioned	The solution should not effervesce.
18	Reducing substances	Passes the test	Not mentioned	The colour of the permanganate should not completely discharged.	Not mentioned
19	Water	Between 57.0% and 61.0 %	Not mentioned	Not mentioned	Not mentioned
20	Loss on drying	Between 57.0% and 61.0 %	Between 55.0 % and 64.0 %	Between 57.0% and 61.0 %	Between 57.0% and 61.0%
21	Assay (dried basis)	Between 98.5 % and 100.5 %	Between 98.0% and 100.5 %	Between 98.5 % and 102.5 %	NLT 98.0%
22	Residual solvents (Ph.Eur/USP)	passes test	Not mentioned	Not mentioned	Not mentioned

23	Elemental Impurities		NA	NA	NA
	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 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			
	Storage	Keep container tightly closed in a dry and well-ventilated place.	Preserve in well-closed containers.	Not mentioned	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.