" clyzo " - Monograph Comparison

AS PER CURRENT USP 2022/EP11/JP18

	Product Name	**Aluminium Potassium Sulfate 12-hydrate (USP, BP, Ph. Eur.) pure, pharma grade**	PanReac AppliChem ITW Reagents	**Issue Date**	March-23
	Product Code	141103		**Prepared by**	Sr. Tech Lead
	CAS NO.	7784-24-9		**Reviewed by**	Manager Technical
	Manufacturer Name	**PanReac AppliChem**		**Version no.**	CLYZO/PAN/141103/01

Sr. No.	Test	Manufacturer COA	Pharmacopeial Specifications		
		Complies (USP, BP, Ph. Eur.)	*USP 2022*	*EP Version 11.0*	*JP 18*
1	Description	Small crystals, White	Large, colorless crystals, crystalline fragments, or white powder.	granular powder or colourless, transparent, crystalline masses	colorless or white, crystals or powder. It is odorless. It has a slightly sweet, strongly astringent taste. 5% solution is acidic
2	Solubility	Freely soluble in water	Very soluble in boiling water; freely soluble in water and in glycerin; insoluble in alcohol.	freely soluble in water, very soluble in boiling water, soluble in glycerol, practically insoluble in ethanol (96 per cent).	It is freely soluble in water, and practically insoluble in ethanol (95) and in diethyl ether.
3	Identification 1 Potassium salts	Passes The Test	A precipitate is formed that dissolves in an excess of the reagent. Ammonia is not evolved	a) Add 1 mL of sodium carbonate solution R and heat. No precipitate is formed. Add to the hot solution 0.05 mL of sodium sulfide solution R. No precipitate is formed. Cool in iced water and add 2 mL of a 150 g/L solution of tartaric acid R. Allow to stand. A white crystalline precipitate is formed. b) Add 1 mL of dilute acetic acid R and 1 mL of a freshly prepared 100 g/L solution of sodium cobaltinitrite R. A yellow or orange-yellow precipitate is formed immediately.	1.Flame Test a pale purple color develops 2.a white, crystalline precipitate with sodium hydrogen tartrate TS. 3.Gives a yellow precipitate with sodium hexanitrocobaltate (III) TS. 4.do not evolve the odor of ammonia, when an excess of sodium hydroxide TS is added and warmed
4	Identification 2	Passes The Test	A violet color is imparted to the flame	Not mentioned	Not mentioned
5	Identification 3	Passes The Test	A white, crystalline precipitate is formed within 30 min	Not mentioned	
6	Identification 4 (Aluminium)	Passes The Test	1. a gelatinous, white precipitate that is insoluble in an excess of 6 N ammonium hydroxide. 2.1 N sodium hydroxide or sodium sulfide TS produces a similar gelatinous, white precipitate, which dissolves in an excess of either of the same reagents.	A gelatinous white precipitate is formed which dissolves on further addition of dilute sodium hydroxide solution R. Gradually add ammonium chloride solution R. The gelatinous white precipitate is re-formed.	1.With ammonium chloride and ammonia, a gelatinous, white precipitate which does not dissolve in an excess of ammonia TS should be produced. 2. when treated with sodium hydroxide TS, yield a gelatinous, white precipitatewhich dissolves in an excess of the reagent. 3.treated with sodium sulfide TS, yield a gelatinous, white precipitate which dissolves in an excess of the reagent. 4. on NH3 addition a gelatinous, white precipitate is produced. The color of the precipitate changes to red upon addition of 5 drops of alizarin red S TS.

7	Identification 5 (Sulfate)	Passes The Test	•A.With barium chloride TS, solutions of sulfates yield a white precipitate that is insoluble in hydrochloric acid and in nitric acid. •B.With lead acetate TS, neutral solutions of sulfates yield a white precipitate that is soluble in ammonium acetate TS. •C.Hydrochloric acid produces no precipitate when added to solutions of sulfates (distinction from thiosulfates).	a) Add 1 mL of dilute hydrochloric acid R and 1 mL of barium chloride solution R1. A white precipitate is formed. b) To the suspension obtained during reaction (a), add 0.1 mL of 0.05 M iodine. The suspension remains yellow (distinction from sulfites and dithionites), but is decolorised by adding dropwise stannous chloride solution R (distinction from iodates). Boil the mixture. No coloured precipitate is formed (distinction from selenates and tungstates).	1.with barium chloride TS a white precipitate, which does not dissolve upon addition of dilute nitric acid. 2.with lead (II) acetate TS a white precipitate, which dissolves upon subsequent addition of ammonium acetate TS. 3. on dilute hydrochloric acid addition no white turbidity , and do not evolve the odor of sulfur dioxide .
8	pH	Between 3.0 and 3.5	Not mentioned	Between 3.0 and 3.5	Not mentioned
9	Appearance of solution	Passes The Test	Not mentioned	Solution Sample is clear and colourless	Not mentioned
10	Chloride (Cl)	NMT 0.01%	Not mentioned	Not mentioned	Not mentioned
11	Ammonium (NH4)	NMT 0.01%	Not mentioned	NMT 0.2%	Not mentioned
12	Iron	NMT 0.002%	No blue color should be produced immediatel	NMT 100 ppm	NMT 20 ppm
13	Arsenic	Not mentioned	Not mentioned	Not mentioned	NMT 3.3 ppm
14	Heavy Metals	Not mentioned	Not mentioned	Not mentioned	NMT 20 ppm
15	Loss on drying at 400°C	Between 43.0% and 46.0 %	Between 43.0% and 46.0 %	Not mentioned	Not mentioned
16	Assay	Between 99.0 % and 100.5 %	Between 99.0 % and 100.5 %	Between 99.0 % and 100.5 %	NLT 99.5 %
17	Elemental Impurities		Not mentioned	Not mentioned	Not mentioned
	Cd	NMT 0.5 ppm			
	Pb	NMT 0.5 ppm			
	As	NMT 1.5 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			
18	Residual solvents (Ph.Eur/USP)	Passes The Test			
	Storage	Storage away from direct light	Preserve in tight containers, and store at room temperature.	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.