



# " clyzo " - Monograph Comparison



## AS PER CURRENT USP 2022/EP11/JP18

<b>Product Name</b>	Potassium di-Hydrogen Phosphate (USP-NF, BP, Ph. Eur.) pure, pharma grade	 ITW Reagents	<b>Issue Date</b>	March-23
<b>Product Code</b>	141509		<b>Prepared by</b>	Sr. Tech Lead
<b>CAS NO.</b>	7778-77-0		<b>Reviewed by</b>	Manager Technical
<b>Manufacturer Name</b>	PanReac AppliChem		<b>Version no.</b>	CLYZO/PAN/141509/01

Sr. No.	Test	Manufacturer COA		Pharmacopeial Specifications	
		Complies USP-NF, BP, Ph. Eur.	USP 2022	EP Version 11.0	JP 18
1	Description	Colourless or White crystalline Powder or crystals,	Colorless crystals or white, granular or crystalline powder. Is odorless, and is stable in air. The pH of 1% solution is about 4.5	White or almost white, crystalline powder or colourless crystals.	
2	Solubility	Freely Soluble in Watre; Practically insoluble in ethanol 96%	Freely soluble in water; practically insoluble in alcohol.	Freely soluble in water, practically insoluble in ethanol (96 %).	
3	Identification 1	Passes test	Addition of sodium bitartrate TS should produce a white crystalline precipitate that is soluble in 6 N NH4OH and in solutions of alkali hydroxides and carbonates.	Should comply by a yellow or orange-yellow precipitate formation	
4	Identification 2	Passes test	1. After addition of AgNO3 TS, should produce a yellow precipitate which is soluble in HNO3 and in NH4OH. 2. Addition of ammonium molybdate TS, should produce a yellow precipitate which is soluble in NH4OH.	Should comply by a yellow colour development	
5	Identification 3	Passes test	Not mentioned	The sample solution should be slightly acidic having pH between 4.0 and 6.0	
6	pH	Between 4.2 and 4.5	Not mentioned	Between 4.2 and 4.5	
7	Appearance/ Appearance of solution	Passes test	Not mentioned	The sample solution should be clear and colourless	
8	Insoluble substances in water	NMT 0.2%	NMT 0.2%	NA	
9	Reducing substances	Passes test	Not mentioned	The colour of the permanganate should not be completely discharged.	
10	Chloride	NMT 0.02%	Not mentioned	NMT 200 ppm	
11	Sulfate	NMT 0.03%	Not mentioned	NMT 300 ppm	
12	Arsenic	NMT 0.0001%	NMT 3 ppm	NMT 2 ppm	
13	Iron	NMT 0.001%	Not mentioned	NMT 10 ppm	
14	Lead	NMT 0.00005%	NMT 5 ppm	Not mentioned	
15	Fluoride	NMT 0.001%	NMT 10 ppm	Not mentioned	
16	Loss on drying	NMT 1.0 %	NMT 1.0 %	NMT 2.0%	
17	Assay (dried basis)	Between 98.0 and 100.5 %	Between 98.0% and 100.5%	Between 98.0% and 100.5%	
	Elemental impurities		Not mentioned		
	Cd	NMT 0.5 ppm			
	Pb	NMT 0.5 ppm			
	As	NMT 1 ppm			
	Hg	NMT 1.5 ppm			

Product Not Official in Japanese pharmacopoeia

18	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		Not mentioned
	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			
19	Residual Solvent	Passes test	Not mentioned	Not mentioned
	Storage	Room Temperature	Preserve in tight containers	In an airtight container

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

**Disclaimer** - The information above is solely for your consideration. We do not recommend or affirm the suitability for any specific end use. We suggest the users should research & verify the specifications in accordance with their intended usage.