

## " clyzo " - Monograph Comparison





## AS PER CURRENT USP 2022/EP11/JP18 di-Potassium Hydrogen Phosphate anhydrous (BP, PanReac AppliChem **Product Name** Issue Date March-23 Ph. Eur.) pure, pharma grade **Product Code** 141512 Sr. Tech Lead Prepared by CAS NO. 7758-11-4 Reviewed by Manager Technical Manufacturer Name PanReac AppliChem Version no. CLYZO/PAN/141512/01 **Pharmacopeial Specifications** Manufacturer COA Sr. No. Test Complies BP, Ph. Eur. USP 2022 EP Version 11.0 JP 18 Colorless or white, somewhat hygroscopic, White or almost white powder or colourless Descriprion Small white crystals granular powder. 5% solution pH should be crystals, very hygroscopic. between 8.5 to 9.6. Very soluble in water, very slightly soluble in Freely soluble in water; very slightly soluble 2 Solubility Soluble in water ethanol (96 per cent) in alcohol Sample solution should be slightly alkaline 3 Identification 1 Passes the test having pH between 8.0 and 10.0 1. Should comply by a yellow color precipitate formation with addition of silver nitrate 2. Identification 2 Passes the test Should comply by a yellow color precipitate Should comply by yellow color development formation with addition of ammonium Should comply by a white crystalline Should comply by a white crystalline precipitate formation after addition of Identification 3 Passes the test precipitate sodium bitartrate 6 Between 8.5 and 9.6 Between 8.5 and 9.6 Not mentioned 7 Sample solution should be clear and colorless Appearance of solution Passes the test Not mentioned 8 Reducing substances Passes the test Not mentioned The solution should remain faintly pink A blue color should be produced, which A blue color should be produced, which should be should be changed to yellow (with a greenish Monopotassium phosphate changed to yellow (with a greenish tinge) by the Not mentioned tinge) by the addition of NMT 0.4 ml of 1 N addition of NMT 0.4 ml of 1 N HCl. Chloride NMT 200 ppm NMT 0.03% mag 002 TMN 10 11 Insoluble substances NMT 0.01% NMT 0.2% Not mentioned Not more than a few bubbles should be 12 Carbonates Not mentioned Not mentioned evolved 13 Not mentioned NMT 3 ppm Not mentioned Arsenic 14 Sulfate NMT 0.05% NMT 0.1% NMT 0.1% Platinum wire imparts should not give a 15 Sodium Not mentioned pronounced yellow color to a nonluminous Not mentioned Product Not Official in Japanese Pharmacopoeia NMT 0.001% 16 Fluoride NMT 0.001% Not mentioned 17 Iron NMT 10 ppm NMT 30 ppm NMT 10 ppm Loss on drying NMT 1.0% NMT 1.0% NMT 2.0% 19 Assay (dried basis) Between 98.0% and 100.5% Between 98.0% and 100.5% Between 98.0% and 101.0% **Elemental Impurities** NMT 0.5 ppm Pb NMT 0.5 ppm NMT 1.5 ppm Assay

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	Hg	NMT 1.5 ppm					
	CO	NMT 5 ppm					
	V	NMT 10 ppm					
	Ni	NMT 20 ppm					
	TI	NMT 0.8 ppm					
	Au	NMT 10 ppm					
	Pd	NMT 10 ppm					
	Ir	NMT 10 ppm					
20	Os	NMT 10 ppm	Not mentioned	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					
	Ва	NMT 140 ppm					
	Мо	NMT 25 ppm					
	Cu	NMT 250 ppm					
	Sn	NMT 600 ppm					
	Cr	NMT 25 ppm					
21	Residual solvent	Passes the test	Not mentioned	Not mentioned			
	Storage	Keep in well closed containers	Keep in well closed 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 reprensentive.

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.