



" clyzo " - Monograph Comparison



AS PER CURRENT USP 2022/EP11/JP18

Product Name	Glycerol (USP, BP, Ph. Eur.) pure, pharma grade	 <small>TTW Reagents</small>	Issue Date	March-23
Product Code	141339		Prepared by	Sr. Tech Lead
CAS NO.	56-81-5		Reviewed by	Manager Technical
Manufacturer Name	PanReac AppliChem		Version no.	CLYZO/PAN/141339/01

Sr. No.	Test	Pharmacopeial Specifications			
		Manufacturer COA <i>Complies USP, BP, Ph. Eur</i>	USP 2022	EP Version 11.0	JP 18
1	Description	Clear, colorless viscous liquid, hygroscopic.	Clear, colorless, syrupy liquid, having a sweet taste. Has not more than a slight characteristic odor, which is neither harsh nor disagreeable. It is hygroscopic. Its solutions are neutral to litmus.	Clear, colourless or almost colourless, very hygroscopic, syrupy liquid, unctuous to the touch.	Clear, colorless and viscous liquid. It has a sweet taste.. It has a sweet taste.
2	Solubility	Miscible with water.	Insoluble in chloroform, in ether, and in fixed and volatile oils. Miscible with water and with alcohol.	Miscible with water and with ethanol (96 %), slightly soluble in acetone, practically insoluble in fatty oils and in essential oils.	It is miscible with water and with ethanol (99.5).
3	Identification 1(FTIR)	Passes The Test	The infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with Glycerine reference standard/working standard	The Infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with Glycerine reference standard/working standard	The Infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with Glycerine reference standard/working standard
4	Identification 2 (Limit of Diethylene Glycol and Ethylene Glycol) GC Chromatography	Passes The Test	Ethylene Glycol: NMT 0.1% Diethylene Glycol: NMT 0.1%	Should comply by refractive index test	Not mentioned
5	Identification 3	Passes The Test	In ethylene & diethylene glycol test the retention time of the glycerin peak of the Sample solution corresponds to that obtained in the Standard solution	Relative density should be between 1.258 and 1.268	Not mentioned
6	Appearance/Colour of Solution	Passes The Test	Sample solution should not be darker than standard	Sample solution should be clear and colourless	Sample should not be more coloured than control solution.
7	Acidity/Alkalinity	Passes The Test	Not mentioned	NMT 0.2 ml of 0.1 M NaOH is required to change the colour of the indicator to pink.	The solution should be neutral.
8	Refractive index	Between 1.470 and 1.475.	Not mentioned	Between 1.470 and 1.475.	NLT 1.470
9	Specific Gravity	NLT 1.249 (at 25°C) Between 1.258 and 1.268 (at 20°C)	NLT 1.249	Not mentioned	NLT 1.258
10	Related Compounds	Maximum individual impurity: NMT 0.1% Total impurities: NMT 1.0% Ethylene Glycol: NMT 0.025% Diethylene Glycol: NMT 0.025% Impurity A: NMT 0.1% Any other impurity: NMT 0.1% Total impurities: NMT 0.5%	Maximum individual impurity: NMT 0.1% Total impurities: NMT 1.0%	Impurity A: NMT 0.1% Any other impurity: NMT 0.1% Total impurities: NMT 0.5%	Ethylene Glycol: NMT 0.1% Diethylene Glycol: NMT 0.1% Any other impurity: NMT 0.1% Total impurities: NMT 1.0%
11	Fatty Acid and Esters	NMT 0.002%	NMT 1 ml of 0.5 N NaOH should be consumed.	Not mentioned	NMT 3.0 ml of 0.1 M NaOH should be consumed
12	Aldehydes	NMT 0.001%	Not mentioned	NMT 10ppm	Not mentioned
13	Esters	Passes The Test	Not mentioned	NLT 8.0 ml of 0.1 M HCl is required to change the colour of the indicator.	Not mentioned
14	Residue on Ignition	NMT 0.01%	NMT 0.01%	Not mentioned	NMT 0.01%
15	Sulfated ash	Not mentioned	Not mentioned	NMT 0.01%	Not mentioned

16	Chloride	NMT 0.001%	NMT 10ppm	NMT 10ppm	NMT 10ppm
17	Sulfate	NMT 0.002%	NMT 20ppm	Not mentioned	NMT 20ppm
18	Ammonium	NMT 0.001%	Not mentioned	Not mentioned	The gas evolved should not change moistened red litmus paper to blue
19	Chlorinated /Halogenated Compound	NMT 0.003%	NMT 30 PPM	NMT 35 PPM	Not mentioned
20	Readily carbonizable substances	Not mentioned	Not mentioned	Not mentioned	The solution should not bomore color than Matching Fluid H.
21	Heavy metals	Not mentioned	Not mentioned	Not mentioned	NMT 5ppm
22	Calcium	Not mentioned	Not mentioned	Not mentioned	The solution should remains unchanged.
23	Arsenic	Not mentioned	Not mentioned	Not mentioned	NMT 2 ppm
24	Color	Passes The Test	Not mentioned	Not mentioned	Not mentioned
25	Acrolein, glucose, and other reducing substances/Sugars	Passes The Test	Not mentioned	The solution remains blue and no precipitate is formed.	The color of the solution should not change, and no turbidity should be produced.
26	Water	NMT 0.5%	NMT 5.0%	NMT 2.0%	NMT 2.0%
27	Assay (anhydrous basis)	Between 99.0% and 101.0%	Between 99.0% and 101.0%	Between 98.0% and 101.0%	Between 98.0% and 101.0%
28	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 0.8 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				
29	Residual solvents	Passes The Test	Not mentioned	Not mentioned	Not mentioned
	Storage	Storage at room temperature	Preserve in tight containers	Airtight containers	Tight containers

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.