



" clyzo " - Monograph Comparison



AS PER CURRENT USP 2022/EP11/JP18

Product Name	Glycerol 87% (BP, Ph. Eur.) pure, pharma grade		Issue Date	March-23
Product Code	142329		Prepared by	Sr. Tech Lead
CAS NO.	56-81-5		Reviewed by	Manager Technical
Manufacturer Name	PanReac AppliChem		Version no.	CLYZO/PAN/142329/01

Sr. No.	Test	Manufacturer COA	Pharmacopeial Specifications		
		Complies BP, Ph. Eur.	USP 2022	EP Version 11.0	JP 18
1	Description	Clear viscous colourless liquid		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. It is hygroscopic
2	Solubility	Miscible with water		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
4	Identification 2 (Limit of Diethylene Glycol and Ethylene Glycol) GC Chromatography	Passes The Test		Should comply by refractive index test	Not mentioned
5	Identification 3	Passes The Test		Relative density should be between 1.221 to 1.232	Not mentioned
6	Appearance/Colour of Solution	Passes The Test		Sample solution should be clear and colourless	Sample should not be more coloured than control solution.
7	Acidity/Alkalinity	Passes The Test		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 1.449 and 1.455		Between 1.449 and 1.455	Between 1.449 – 1.454
9	Specific Gravity	Between 1.224 and 1.232		Not mentioned	Between 1.221 – 1.230
10	Insoluble matter in H2O	Passes The Test		Not mentioned	Not mentioned
11	Readily carbonizable substances	Passes The Test		Not mentioned	The solution has not more color than Matching Fluid H.
12	Sugars	Passes The Test		The solution remains blue and no precipitate is formed	Not mentioned
13	Chloride	NMT 0.001%		NMT10 ppm	NMT 10 ppm
14	Ammonium	NMT 0.001%		Not mentioned	The gas evolved should not change moistened red litmus paper to blue
15	Sulfate	NMT 0.002%		Not mentioned	NMT 20 ppm
16	Chlorinated /Halogenated Compound	NMT 0.003%		NMT 30 PPM	Not mentioned
17	Related Compounds	Passes The Test		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%
18	Aldehydes	NMT 0.001%		NMT 10 ppm.	Not mentioned

19	Esters/Fatty acids and esters	Passes The Test
20	Residue on Ignition	Not mentioned
21	Sulfated ash	NMT 0.01 %
23	Water	Between 12.0 % and 16.0 %
24	Heavy metals	NMT 0.0005%
25	Calcium	Not mentioned
26	Arsenic	Not mentioned
27	Acrolein, glucose, and other reducing substances/Sugars	Passes The Test
28	Assay	Between 83.5% and 88.5 %
29	Elemental Impurities	
	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
	TI	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	
30	Residual solvent	Passes the test
	Storage	Keep container tightly closed in a dry and well-ventilated place.

Product Not Official in US Pharmacopoeia

NLT 8.0 ml of 0.1 M HCl is required to change the colour of the indicator.	NMT 3.0 ml of 0.1 M NaOH should be consumed
Not mentioned	NMT 0.01%
NMT 0.01%	Not mentioned
Between 12.0 % and 16.0 %	Between 13.0 % and 17.0 %
Not mentioned	NMT 5 ppm
Not mentioned	The solution should remains unchanged.
Not mentioned	NMT 2 ppm
Should not produce precipitate	Should not produce turbidity
Between 83.5% and 88.5 %	Between 84.0% and 87.0%
Not mentioned	Not mentioned
Not mentioned	Not mentioned
Not mentioned	Not mentioned
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.