



# " clyzo " - Monograph Comparison



## AS PER CURRENT USP 2022/EP11/JP18

<b>Product Name</b>	Glycerol 99% USP, Ph. Eur.		<b>Issue Date</b>	July-23
<b>Product Code</b>	240106		<b>Prepared by</b>	Sr. Tech Lead
<b>CAS NO.</b>	56-81-5		<b>Reviewed by</b>	Manager Technical
<b>Manufacturer Name</b>	CG Chemikalein GmbH & Co KG		<b>Version no.</b>	CLYZO/CG/240106/01

Sr. No.	Test	Pharmacopeial Specifications			
		Manufacturer COA <i>Complies USP, Ph. Eur.</i>	USP 2022	EP Version 11.0	JP 18
1	Description	Colorless or almost colorless, clear liquid	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	Not mentioned	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	Should comply 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	Not mentioned	Ethylene Glycol: NMT 0.1% Diethylene Glycol: NMT 0.1%	Should comply by refractive index test	Not mentioned
5	Identification 3	Should comply 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	Sample should be clear and colorless	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	NMT 0.2 ml of 0.1 M NaOH is required to change the colour of the indicator to pink.	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	NLT 1.249	Not mentioned	NLT 1.258
10	Related Compounds	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	Not mentioned	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 10 ppm	Not mentioned	NMT 10ppm	Not mentioned
13	Esters	NLT 8.0 ml of 0.1 M HCl is required to change the colour of the indicator.	Not mentioned	NLT 8.0 ml of 0.1 M HCl is required to change the colour of the indicator.	Not mentioned
14	Rsidue 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 10 ppm	NMT 10ppm	NMT 10ppm	NMT 10ppm
17	Sulfate	NMT 20 ppm	NMT 20ppm	Not mentioned	NMT 20ppm
18	Ammonium	Not mentioned	Not mentioned	Not mentioned	The gas evolved should not change moistened red litmus paper to blue
19	Chlorinated /Halogenated Compound	NMT 35 ppm	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	NMT 5 ppm	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	Acrolein, glucose, and other reducing substances/Sugars	Should comply 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.
25	Water	NMT 2.0%	NMT 5.0%	NMT 2.0%	NMT 2.0%
26	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%
27	Microbial limit test	NMT 100 CFU/g	Not mentioned	Not mentioned	Not mentioned
	Total aerobic microbial count	NMT 50 cfu/g			
	Total yeast and molds count	Absent/g			
	E.Coli	Absent/g			
Pseudomonas aeruginosa	Absent/g				
Staphylococcus aureus	Absent/g				
Salmonella	Absent/g				
28	Bacterial Endotoxins	NMT 10 IU/g	Not mentioned	Not mentioned	Not mentioned
	Storage	Not mentioned	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.

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