" clyzo " - Monograph Comparison

AS PER CURRENT USP 2022/EP11/JP18

	Product Name	**Polyethylene Glycol 400 (BP, Ph. Eur.) pure, pharma grade Carbowax 400, Macrogol 400, PEG 400**	PanReac AppliChem ITW Reagents	**Issue Date**	March-23
	Product Code	142436		**Prepared by**	Sr. Tech Lead
	CAS NO.	25322-68-3		**Reviewed by**	Manager Technical
	Manufacturer Name	**PanReac AppliChem**		**Version no.**	CLYZO/PAN/142436/01

Sr. No.	Test	Manufacturer COA	Pharmacopeial Specifications		
		Complies BP, Ph. Eur	*USP 2022*	*EP Version 11.0*	*JP 18*
1	Description	Clear, colorless liquid, hygroscopic.	Clear to slightly hazy, colorless or practically colorless, slightly hygroscopic, viscous liquids, having a slight, characteristic odor and a specific gravity at 25°C: about 1.12. Congealing temperature about 6°C	Clear, viscous,colourless or almost colourless, hygroscopic liquid	Clear, colorless and viscous liquid. It has no odor or a slight, characteristic odor. It is slightly hygroscopic. Congealing point: 4 – 8°C. Specific gravity @ 20°C between 1.110 and 1.140
2	Solubility	Miscible with water	Miscible with water, insoluble in ether and in hexane.	Miscible with water, very soluble in acetone, in ethanol (96 %) and in methylene chloride, practically insoluble in fatty oils and in mineral oils	It is miscible with water, with methanol, with ethanol (95) and with pyridine.It is soluble in diethyl ether
3	Identification 1	Passes The Test	Not mentioned	Should comply with viscosity test	Should comply by yellow-green precipitate formation
4	Identification 2	Passes The Test	Not mentioned	Should comply by an abundant, white, crystalline precipitate formation.	Not mentioned
5	Identification 3	Passes The Test	Not mentioned	Liquid phase should become blue	Not mentioned
6	Completeness and colour of solution/ appearance of solution	Passes The Test	Sample solution should be as clear as water	Solution is clear and not more intensely coloured than reference solution BY6	Not mentioned
7	Average Molecular Weight	Between 380 and 420	Between 380 and 420	Not mentioned	Between 380 and 420
8	Viscosity	Kinematic: Between 94 and 116 mm2·s−1 Dynamic : between 105 and 130 mPa·s	Between 6.8 and 8.0 cST @ 98.9°C	Kinematic: Between 94 and 116 mm2·s−1 Dynamic : between 105 and 130 mPa·s	Not mentioned
9	pH	Between 4.5 and 7.5	Between 4.5 and 7.5	Not mentioned	Between 4.0 and 7.0
10	Hydroxyl value	Between 264 and 300	Not mentioned	Between 264 and 300	Not mentioned
11	Acidity or alkalinity	Passes The Test	Not mentioned	NMT 0.1 mL of 0.1 M NaOH is required to change the colour of the indicator to blue.	After addition of 0.20 ml of 0.1 M NaOH, the solution becomes red in color.
12	Water	NMT 2.0%	Not mentioned	NMT 2.0%	NMT 1.0%
13	Reducing Substance	Passes The Test	Not mentioned	After 5 min the solution is not more intensely coloured than reference solution R3	Not mentioned
14	Residue on ignition	NMT 0.1%	NMT 0.1%	Not mentioned	NMT 0.1%
15	Sulfated Ash	Not mentioned	Not mentioned	NMT 0.2%	Not mentioned
16	Formaldehyde	NMT 0.0015%	Not mentioned	NMT 30 ppm	Not mentioned
17	Free ethylene oxide	NMT 0.0001%	NMT 10 ppm	NMT 1 ppm	Not mentioned
18	Free 1.4-Dioxane	NMT 0.001%	NMT 10 ppm	NMT 10 ppm	Not mentioned
19	Ethylene Glycol and Diethylene glycol	NMT 0.25%	NMT 0.25%	NMT 0.4%	NMT 0.25%
20	Matter insoluble in water	Passes The Test	Not mentioned	Not mentioned	Not mentioned
	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 5 ppm			

21	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			
22	Residual solvents	Passes The Test	Not mentioned	Not mentioned	Not mentioned
	Storage	Storage below 25°C. Storage away from direct light.	Preserve in tight containers	In an airtight container	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 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.