" clyzo " - Monograph Comparison



C	lU	ZO	

	AS PER CORRENT USP 2022/EP11/JP18							
	Product Name	Castor Oil (BP, Ph. Eur.) pure, pharma grade		Issue Date	March-23			
	Product Code	144564	PanReac 🧐	Prepared by	Sr. Tech Lead			
	CAS NO.	8001-79-4		Reviewed by	Manager Technical			
	Manufacturer Name	PanReac AppliChem	AppliChem	Version no.	CLYZO/PAN/144564/01			
	L		ITW Reagents	1				
Sr. No.	Test	Manufacturer COA		Pharmacopeial Specifications				
51. NO.	Test	Complies BP, Ph. Eur	USP 2022	EP Version 11.0	JP 18			
1	Descriprion	Yellow viscous liquid	Pale yellowish or almost colorless, transparent, viscid liquid. It has a faint, mild	Clear, almost colourless or slightly yellow, viscous, hygroscopic liquid. Relative density about 0.958,	Product Not Official in Japanese Pharmacopoeia			
-			odor; is free from foreign and rancid odor; and has a bland, characteristic taste.	Refractive index about 1.479, Viscosity about 1000 mPa·s	-			
2	Solubility	Insoluble in water	Soluble in alcohol. Miscible with dehydrated alcohol, with glacial acetic acid, with chloroform, and with ether.	Slightly soluble in light petroleum, miscible with ethanol (96 per cent) and with glacial acetic acid.				
3	Identification 1	Passes The Test	Distinction from Most Other Fixed Oils: It is only slightly soluble in solvent hexane (distinction from most other fixed oils), but it yields a clear liquid with an equal volume of alcohol (foreign fixed oils)	Sample solution should be clear				
4	Identification 2	Passes The Test	Identification of Refined Castor Oil or Virgin Castor Oil by Using Ultraviolet Absorption: Refined Castor Oil:The absorbance is within the range of 0.7–1.5; Virgin Castor Oil:The absorbance is NMT 0.7	Should comply by specific absorbance test				
5	Identification 3	Passes The Test	NA	A red colour should developes				
6	Identification 4	Passes The Test	Should comply by fatty acid composition test	Should comply by fatty acid composition test				
7	Appearance	Passes The Test	NA	The sample should be clear and not more intensely coloured than reference solution BY3 or Y3				
8	Specific Gravity	Passes The Test	Between 0.957 and 0.961	NA	1			
9	Optical Rotation	Between + 3.5° to + 6.0°.	Not mentioned	Between + 3.5° to + 6.0°.				
10	Specific absorbance	About 0.7	Not mentioned	Between 0.7 and 1.5 at absorption maximum at 270 nm				
11	Acid Value	NMT 1.5	NMT 2.0	NMT 0.8				
12	Hydroxyl Value	Not mentioned	Between 160 and 168	NMT 160				
13	Peroxide value	NMT 5.0	NMT 10.0	NMT 5.0				
14	Unsaponifiable matter	NMT 0.8%	NMT 0.8%	NMT 0.8%				
15	Oil obtained by extraction & adulteration	Not mentioned	Not mentioned	The sample solution is less intensely coloured than a freshly prepared standard mixture				
16	Composition of fatty acids	Palmitic acid: NMT 2.0 % Stearic acid: NMT 2.5 % Oleic acid and isomer: 2.5% to 6.0 % Linoleic acid: 2.5% to 7.0 % Linolenic acid: NMT 1.0 % cs 11-Eicosenoic acid: NMT 1.0 % Ricinoleic acid: 85.0 % to 92.0 % cis-11-Octadecenoic acid or any other unidentified fatty acid- NMT 1.0 %.	Palmitic acid: NMT 2.0 % Stearic acid: NMT 2.5 % Oleic acid and isomer: 2.5% to 6.0 % Linoleic acid: 2.5 % to 7.0 % Linolenic acid: NMT 1.0 % cs 11-Eicosenoic acid: NMT 1.0 % Ricinoleic acid: 85.0 % to 92.0 % cis-11-Octadecenoic acid or any other unidentified fatty acid- NMT 1.0 %.	Palmitic acid: NMT 2.0 % Stearic acid: NMT 2.5 % Oleic acid and isomer: 2.5% to 6.0 % Linoleic acid: 2.5% to 7.0 % Linolenic acid: NMT 1.0 % cs 11-Eicosenoic acid: NMT 1.0 % Ricinoleic acid: 85.0 % to 92.0 % cis-11-Octadecenoic acid or any other unidentified fatty acid- NMT 1.0 %.				
17	Saponification value	Between 176 and 187	Not mentioned	Not mentioned	ļ			
18	Iodine value	Between 82 and 90	Not mentioned	Not mentioned	ļ			
19	Refractive Index	Between 1.477 and 1.481	Not mentioned	Not mentioned	ļ			
20	Foreign fatty substances	Passes The Test	Not mentioned	Not mentioned	ļ			
21	Water	NMT 0.3%	NMT 0.3%	NMT 0.3%	1			

22	Assay	NLT 99.5%	NLT 90.0% of the triglyceride of ricinoleic acid	NA	
	Elemental Impurities		Not mentioned	Not mentioned	
	Cd	NMT 0. 5 ppm			
	Pb	NMT 5 ppm			
	As	NMT 1.5 ppm			
	Hg	NMT 1.5 ppm			
	со	NMT 5 ppm			
	V	NMT 10 ppm			
	Ni	NMT 20 ppm			
	тΙ	NMT 5 ppm			
	Au	NMT 10 ppm			
	Pd	NMT 10 ppm	7		
	lr	NMT 10 ppm			
23	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			
	Ва	NMT 140 ppm			
	Mo	NMT 25 ppm			
	Cu	NMT 250 ppm			
	Sn	NMT 600 ppm	1		
	Cr	NMT 25 ppm			
24	Residual solvents	Passes The Test	Not mentioned	Not mentioned	
	Storage	Storage below 25°C. Storage away from direct light.	Preserve in tight containers, avoid exposure	In an airtight, well-filled container, protected from	
			to excessive heat	light.	
		Note - If you need any additional testing, you n	nay use our Additional Testing Feature on the produ	ct 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					