



" clyzo " - Monograph Comparison



AS PER CURRENT USP 2022/EP11/JP18

Product Name	Oleic Acid (Ph. Eur.) pure, pharma grade		Issue Date	March-23
Product Code	142659		Prepared by	Sr. Tech Lead
CAS NO.	112-80-1		Reviewed by	Manager Technical
Manufacturer Name	PanReac AppliChem		Version no.	CLYZO/PAN/142659/01

Sr. No.	Test	Manufacturer COA	Pharmacopeial Specifications		
		<i>Complies Ph. Eur.</i>	<i>USP 2022</i>	<i>EP Version 11.0</i>	<i>JP 18</i>
1	Description	Light Yellow oily liquid	Colorless to pale yellow, oily liquid when freshly prepared, but on exposure to air it gradually absorbs oxygen and darkens.as a characteristic, lard-like odor and taste. When strongly heated in air, it is decomposed with the production of acrid vapors.	clear, yellowish or brownish, oily liquid. Relative densiry about 0.892	
2	Solubility	Insoluble in Water	Practically insoluble in water. Miscible with alcohol, with chloroform, with ether, with benzene, and with fixed and volatile oils.	practically insoluble in water, miscible with ethanol (96 %) and with methylene chlorid	
3	Identification 1	The Infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with Oleic Acid reference standard/working standard	The Infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with Oleic Acid reference standard/working standard	Should comply by acid value	
4	Identification 2	Passes test	In assay test ,the retention time of the major peak of the Sample solution corresponds to that of the Standard solution	Should comply by iodine value	
5	Identification 3	Passes test	Not	Composition of fatty acids Margaric acid: NMT 0.2% (vegetable origin) and NMT 4.0 % (animal origin)	
6	Appearance	Passes test	Not mentioned	The substance to be examined is not more intensely coloured than reference solution Y1 or	
7	Mineral Acid	NA	The filtrate should not reddened by the addition of 1 drop of methyl orange TS.	Not mentioned	
8	Congeaing Temperature	Not mentioned	Between 3° and 10° C (animal sources), Between 10° and 16°C (vegetable source)	Not mentioned	
9	Acid Value	Between 195 and 204	Between 196 and 204	Between 195 and 204	
10	Peroxide value	NMT 10.0	NMT 10.0	NMT 10.0.	
11	Iodine Value	Between 89 and 105	Between 85 and 105	Between 89 and 105.	
12	Water	Not mentioned	NMT 0.4%	Not mentioned	

13	Composition of fatty acids	Myristic acid: NMT 5.0% Palmitic acid: NMT 16.0% Palmetoleic acid: NMT 8.0% Stearic acid: NMT 6.0% Linoleic acid: NMT 18.0% Linolinic acid: NMT 4.0% Fatty acid of chain length more than C18: NMT 4.0% Margaric acid: NMT 4.0% (Animal origin)	C14 with zero double bonds: NMT 5.0% C16 with zero double bonds: NMT 16.0% C16 with one double bonds: NMT 8.0% C18 with zero double bonds: NMT 6.0% C18 with one double bonds: NMT 18.0% C18 with two double bonds: NMT 4.0% C18 with three double bonds NMT 4.0% C20+ C22: NMT 4.0% (Animal origin)	Myristic acid: NMT 5.0% Palmitic acid: NMT 16.0% Palmetoleic acid: NMT 8.0% Stearic acid: NMT 6.0% Linoleic acid: NMT 18.0% Linolinic acid: NMT 4.0% Fatty acid of chain length more than C18: NMT 4.0% Margaric acid: NMT 4.0% (Animal origin)	Product not official in Japanese pharmacopoeia
14	Residue on Ignition	NMT 0.1%	NMT 0.01%	NMT 0.1 %	
15	Assay	Between 65.0% and 88.0%	NLT 65.0%	Between 65.0 % and 88.0 %	
16	Residual Solvent	Passes test	Not mentioned	Not mentioned	
17	Elemental impurities				
	Cd	NMT 0.5 ppm			
	Pb	NMT 2 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			
	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			
	Storage	Store at room temperature	Preserve in well-closed containers, protected from light. Store at room temperature, and avoid exposure to excessive heat.	In an airtight, well-filled container, protected from light.	
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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