



# " clyzo " - Monograph Comparison



## AS PER CURRENT USP 2022/EP11/JP18

<b>Product Name</b>	Polysorbate 80 USP/NF, Ph. Eur.		<b>Issue Date</b>	July-23
<b>Product Code</b>	240108		<b>Prepared by</b>	Sr. Tech Lead
<b>CAS NO.</b>	9005-65-6		<b>Reviewed by</b>	Manager Technical
<b>Manufacturer Name</b>	CG Chemikalein GmbH & Co KG		<b>Version no.</b>	CLYZO/CG/240108/01

Sr. No.	Test	Pharmacopeial Specifications			
		Manufacturer COA <i>Complies USP, BP, Ph. Eur</i>	USP 2022	EP Version 11.0	JP 18
1	Description	Colourless to brownish yellow, clear liquid or slightly opalescent liquid	Lemon- to amber-colored, oily liquid having a faint, characteristic odor and a warm, somewhat bitter taste.	Oily, colourless or brownish-yellow, clear or slightly opalescent liquid. Relative density about 1.1, viscosity about 400 mPa·s@ 25°C	Colorless or brownish yellow, clear or slightly opalescent, oily liquid. Relative density about 1.1, viscosity about 400 mPa·s@ 25°C
2	Solubility	Not mentioned	Very soluble in water, producing an odorless and practically colorless solution; soluble in alcohol and in ethyl acetate; insoluble in mineral oil.	Dispersible in water, in anhydrous ethanol, in ethyl acetate and in methanol, practically insoluble in fatty oils and in liquid paraffin	It is miscible with water, with methanol, with ethanol (99.5%) and with ethyl acetate. It is practically insoluble in fatty oils and in liquid paraffin.
3	Identification 1	Should comply the test	The Infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with Polysorbate 80 reference standard/working standard.	The Infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with Polysorbate 80 reference standard/working standard.	Sample should meet the requirements for Composition of Fatty Acids
4	Identification 2	Should comply the test	Should comply by fatty acid composition	Should comply by hydroxyl value	Not mentioned
5	Identification 3	Should comply the test	Not mentioned	Should comply by Saponification test	Not mentioned
6	Identification 4	Should comply the test	Not mentioned	Should comply by fatty acid composition	Not mentioned
7	Identification 5	Should comply the test	Not mentioned	Sample solution should turn blue	Not mentioned
8	Acid value	NMT 2.0	NMT 2.0	NMT 2.0	NMT 2.0
9	Hydroxyl value	Between 65 and 80	Between 65 and 80	Between 65 and 80	Between 65 and 80
10	Peroxide value	NMT 10.0	NMT 10.0	NMT 10.0	NMT 10.0
11	Saponification value	Between 45 and 55	Between 45 and 55	Between 45 and 55	Between 45 and 55
12	Specific gravity	Between 1.06 and 1.09	Between 1.06 and 1.09	Not mentioned	Not mentioned
13	Viscosity	Between 300 and 500 strokes @ 25°C	Between 300 and 500 strokes @ 25°C	Not mentioned	Not mentioned
14	Heavy metals	NMT 10 ppm	Not mentioned	Not mentioned	NMT 20 ppm
15	Residue on ignition	NMT 0.25%	Not mentioned	Not mentioned	NMT 0.25%
16	Total Ash	Not mentioned	NMT 0.25%	NMT 0.25%	Not mentioned
17	Ethylene oxide	NMT 1 ppm	NMT 1 ppm	NMT 1 ppm	NMT 1 ppm
18	Dioxane	NMT 10 ppm	NMT 10ppm	NMT 10ppm	NMT 10ppm
19	Water	NMT 3.0%	NMT 3.0%	NMT 3.0%	NMT 3.0%
20	Composition of fatty acids	Myristic acid: NMT 5.0 % Palmitic acid: NMT 16.0 % Palmitoleic acid: NMT 8.0 % Stearic acid: NMT 6.0 % Oleic acid: NLT 58.0 % Linoleic acid: NMT 18.0 % Linolenic acid: NMT 4.0 %	Myristic acid: NMT 5.0 % Palmitic acid: NMT 16.0 % Palmitoleic acid: NMT 8.0 % Stearic acid: NMT 6.0 % Oleic acid: NLT 58.0 % Linoleic acid: NMT 18.0 % Linolenic acid: NMT 4.0 %	Myristic acid: NMT 5.0 % Palmitic acid: NMT 16.0 % Palmitoleic acid: NMT 8.0 % Stearic acid: NMT 6.0 % Oleic acid: NLT 58.0 % Linoleic acid: NMT 18.0 % Linolenic acid: NMT 4.0 %	Myristic acid: NMT 5.0 % Palmitic acid: NMT 16.0 % Palmitoleic acid: NMT 8.0 % Stearic acid: NMT 6.0 % Oleic acid: NLT 58.0 % Linoleic acid: NMT 18.0 % Linolenic acid: NMT 4.0 %
21	Microbial limit test Total aerobic microbial count Total yeast and molds count E.Coli Pseudomonas aeruginosa Staphylococcus aureus Salmonella	NMT 100 CFU/g NMT 50 cfu/g Absent/g Absent/g Absent/g Absent/25 g	Not mentioned	Not mentioned	Not mentioned
22	Bacterial Endotoxins	NMT 2.5 IU/g	Not mentioned	Not mentioned	Not mentioned
	Storage	Not mentioned	Preserve in tight containers, protected from light and moisture. Store at room temperature	In an airtight container, protected from light.	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.