



# " clyzo " - Monograph Comparison



## AS PER CURRENT USP 2022/EP11/JP18

<b>Product Name</b>	Tween® 80 (USP-NF, BP, Ph. Eur.) pure, pharma grade		<b>Issue Date</b>	March-23
<b>Product Code</b>	142050		<b>Prepared by</b>	Sr. Tech Lead
<b>CAS NO.</b>	9005-65-6		<b>Reviewed by</b>	Manager Technical
<b>Manufacturer Name</b>	PanReac AppliChem		<b>Version no.</b>	CLYZO/PAN/142050/01

Sr. No.	Test	Manufacturer COA				Pharmacopeial Specifications			
		Complies USP, BP, Ph. Eur		USP 2022	EP Version 11.0	JP 18			
1	Description	Clear, yellow to brownish 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	Soluble in water		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	Passes 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	Passes The Test		Should comply by fatty acid composition	Should comply by hydroxyl value	Not mentioned			
5	Identification 3	Passes The Test		Not mentioned	Should comply by Saponification test	Not mentioned			
6	Identification 4	Passes The Test		Not mentioned	Should comply by fatty acid composition	Not mentioned			
7	Identification 5	Passes 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	Iodine Value	Between 18 and 24		Not mentioned	Not mentioned	Not mentioned			
13	Specific gravity	Between 1.06 and 1.09		Between 1.06 and 1.09	Not mentioned	Not mentioned			
14	Viscosity	Between 300 and 500 strokes @ 25°C		Between 300 and 500 strokes @ 25°C	Not mentioned	Not mentioned			
15	Heavy metals	NMT 0.001%		Not mentioned	Not mentioned	NMT 20 ppm			
16	Residue on ignition	NMT 0.2%		Not mentioned	Not mentioned	NMT 0.25%			
17	Total Ash	NMT 0.25%		NMT 0.25%	NMT 0.25%	Not mentioned			
18	Ethylene oxide	NMT 0.0001%		NMT 1 ppm	NMT 1 ppm	NMT 1 ppm			
19	Dioxane	NMT 0.001%		NMT 10ppm	NMT 10ppm	NMT 10ppm			
20	Water	NMT 3.0%		NMT 3.0%	NMT 3.0%	NMT 3.0%			
21	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: Between 58.0 % and 85.0% 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 %			
	Elemental Impurities			Not mentioned	Not mentioned	Not mentioned			
	Cd	NMT 0.5 ppm							
	Pb	NMT 0.5 ppm							

22	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				
23	Residual solvents	Passes The Test	Not mentioned	Not mentioned	Not mentioned
	Storage	Storage away from direct light.	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.