



# " clyzo " - Monograph Comparison



## AS PER CURRENT USP 2022/EP11/JP18

<b>Product Name</b>	Tween ® 20 (USP-NF, BP, Ph. Eur.) pure, pharma grade		<b>Issue Date</b>	March-23
<b>Product Code</b>	142312		<b>Prepared by</b>	Sr. Tech Lead
<b>CAS NO.</b>	9005-64-5		<b>Reviewed by</b>	Manager Technical
<b>Manufacturer Name</b>	PanReac AppliChem		<b>Version no.</b>	CLYZO/PAN/142312/01

Sr. No.	Test	Pharmacopeial Specifications			
		Manufacturer COA <i>Complies USP, BP, Ph. Eur</i>	USP 2022	EP Version 11.0	JP 18
1	Description	Clear yellow to brownish liquid	Lemon to amber liquid having a faint characteristic odor	Oily, yellow or brownish-yellow, clear or slightly opalescent liquid. Relative density about 1.1, viscosity about 400 mPa·s@ 250C	
2	Solubility	Soluble in water	Soluble in water, in alcohol, in ethyl acetate, in methanol, and in dioxane; insoluble in mineral oil	Soluble in water, in anhydrous ethanol, in ethyl acetate and in methanol, 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 20 reference standard/working standard.	The Infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with Polysorbate 20 reference standard/working standard.	
4	Identification 2	Passes The Test	Should comply by fatty acid composition	Should comply by hydroxyl value	
5	Identification 3	Passes The Test	Not mentioned	Should comply by saponification test	
6	Identification 4	Passes The Test	Not mentioned	Should comply by fatty acid composition	
7	Identification 5	Passes The Test	Not mentioned	Sample solution should be clear and colourless	
8	Acid value	NMT 2.0	NMT 2.0	NMT 2.0	
9	Hydroxyl value	Between 96 and 108	Between 96 and 108	Between 96 and 108	
10	Peroxide value	NMT 10.0	NMT 10.0	NMT 10.0	
11	Saponification value	Between 40 and 50	Between 40 and 50	Between 40 and 50	
12	Residue on ignition	NMT 0.2%	Not mentioned	Not mentioned	
13	Total ash	NMT 0.25%	NMT 0.25%	NMT 0.25%	
14	Reducing impurities	Passes The Test	Not mentioned	Not mentioned	
15	Heavy metals	NMT 0.001%	Not mentioned	Not mentioned	
16	Ethylene oxide	NMT 0.,0001%	NMT 1 ppm	NMT 1 ppm	
17	Dioxane	NMT 0.001%	NMT 10 ppm	NMT 10 ppm	
18	Water	NMT 3.0%	NMT 3.0%	NMT 3.0%	
19	Composition of fatty acids	1)Caproic acid: NMT 1.0 per cent 2)Caprylic acid: NMT 10.0 per cent 3) Capric acid: maximum 10.0 per cent 4) Lauric acid: 40.0 per cent to 60.0 per cent 5)myristic acid: 14.0 per cent to 25.0 per cent 6) palmitic acid: 7.0 per cent to 15.0 per cent 7) stearic acid: NMT 7.0 per cent 8) oleic acid: NMT 11.0 per cent 9) Linoleic acid: NMT 3.0%	1) C6 no double bond-NMT 1.0% 2) C8 no double bond- NMT 10.0% 3) C10 no double bond-NMT 10.0% 4) C12 no double bond- Between 40.0-60.0% 5) C14 no double bond- Between 14.0-25.0% 6) C16 no double bond-7.0-15.0% 7) C18 no double bond-NMT 11.0% 8) C18 with 1 double bond-NMT 11.0% 9) C18 with 2 double bond- NMT 3.0%	1)Caproic acid: NMT 1.0 per cent 2)Caprylic acid: NMT 10.0 per cent 3) Capric acid: maximum 10.0 per cent 4) Lauric acid: 40.0 per cent to 60.0 per cent 5)myristic acid: 14.0 per cent to 25.0 per cent 6) palmitic acid: 7.0 per cent to 15.0 per cent 7) stearic acid: NMT 7.0 per cent 8) oleic acid: NMT 11.0 per cent 9) Linoleic acid: NMT 3.0%	Product Not Official in Japanese Pharmacopoeia
	Elemental Impurities				
	Cd	NMT 0.5 ppm			
	Pb	NMT 0.5 ppm			

20	As	NMT 1 ppm	Not mentioned	Not mentioned
	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			
21	Residual solvents	Passes The Test	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.

**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.