



" clyzo " - Monograph Comparison



AS PER CURRENT USP 2022/EP11/JP18

Product Name	Polyoxyl (40) Stearate, CHP, USP	 南京威尔药业股份有限公司 威尔药业 威尔化工	Issue Date	March-23
Product Code	NAN-017		Prepared by	Sr. Tech Lead
CAS NO.	9004-99-3		Reviewed by	Manager Technical
Manufacturer Name	Nanjing Well Pharmaceutical Group Co Ltd		Version no.	CLYZO/NAN/NAN-017/01

Sr. No.	Test	Manufacturer COA		Pharmacopeial Specifications	
		Complies USP-NF, Ph. Eur.	USP 2022	EP Version 11.0	JP 18
1	Description	This product is white waxy solid, and it is colorless or have a soft color, similar to the grease, Soluble in water, alcohol, ether and acetone; insoluble in mineral and vegetable oils.	Waxy, white to light tan solid. Is odorless or has a faint, fat-like odor	Not official in EP	white to light yellow, waxy solid or powder.
2	Solubility		Soluble in water, in alcohol, in ether, and in acetone; insoluble in mineral oil and in vegetable oils.		It is soluble in water, in ethanol (95) and in diethyl ether.
3	Identification 1	Infrared absorption spectrum should be the same with reference	The Infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with Polyoxy (40)Stearate reference standard/working standard		
4	Identification 2		It meets the requirements of the test for Content of Stearic Acid and Palmitic Acid.		
5	Melting point	46-51°C			
6	Congealing Temperature	37-47°C	37°-47°		39.0 – 44.0 °C
7	Congealing point of the fatty acid				Not below 53°C.
8	Water Determination	NMT 3.0%	NMT 3.0%		
9	Clarity and color of solution				the solution is clear and colorless.
10	Limit of Ethylene Oxide and Dioxane				
I	Ethylene oxide	NMT1ppm	1 ppm		
II	Dioxane	NMT380ppm	380 ppm		
11	Alkalinity	The solution color should not be red	The solution does not turn red.		
12	Fats and Fixed Oils, Acid Value	USP	NMT 6.0		NMT 1.0
13	Fats and Fixed Oils, Hydroxyl Value	25-40	25-40		
14	Fats and Fixed Oils, Iodine Value	NMT 3.0	NMT 3.0		
15	Fats and Fixed Oils, Peroxide Value	NMT 10.0	NMT 10.0		
16	Fats and Fixed Oils, Saponification Value	25-35	25-35		25 – 35
17	Articles of Botanical Origin, Total Ash	NMT 0.3%	NMT 0.3%		
18	Heavy metals	NMT 10ppm			NMT 10ppm
19	Arsenic				NMT 3ppm
20	Residue on ignition				NMT 0.1%
21	Assay				

I	Content of Stearic Acid and Palmitic Acid	Stearic acid:40.0%-60.0%	Stearic Acid: 40.0%–60.0%; sum of Palmitic and Stearic acids: NLT 90.0%		
II	Content of Free Polyethylene Glycols	17-27%	17%–27% of free polyethylene glycols for Polyoxyl 40 Stearate only		
	Storage		Preserve in tight containers, and store at room temperature. Protect from light and moisture		Containers—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.