



" clyzo " - Monograph Comparison



AS PER CURRENT USP 2022/EP11/JP18

Product Name	Paraffin M.P. 51-53°C pellets (USP-NF, BP, Ph. Eur.) pure, pharma grade		Issue Date	March-23
Product Code	143209		Prepared by	Sr. Tech Lead
CAS NO.	8002-74-2		Reviewed by	Manager Technical
Manufacturer Name	PanReac AppliChem		Version no.	CLYZO/PAN/143209/01

Sr. No.	Test	Pharmacopeial Specifications			
		Manufacturer COA <i>Complies USP-NF, BP, Ph. Eur.</i>	USP 2022	EP Version 11.0	JP 18
1	Description	White Pellets	Colorless or white, more or less translucent mass showing a crystalline structure. Is odorless and tasteless, and is slightly greasy to the touch	White or almost white, translucent, soft unctuous mass, transparent in thin layers even after cooling to 0°C	Colorless or white, more or less transparent, crystalline mass. It is odorless and tasteless. Specific gravity @ 20°C is about 0.92
2	Solubility	Insoluble in Water	Freely soluble in chloroform, in ether, in volatile oils, and in most warm fixed oils; slightly soluble in dehydrated alcohol; insoluble in water and in alcohol	Practically insoluble in water, slightly soluble in methylene chloride, practically insoluble in ethanol (96 %) and in glycerol.	It is sparingly soluble in diethyl ether and practically insoluble in water, in ethanol (95%) and in ethanol (99.5%).
3	Identification 1	passes test	Should comply with congealing temperature test	Drop point should be between 35 °C and 70 °C	Burns with a bright flame and odour of paraffin is perceptible
4	Identification 2	passes test	The Infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with Paraffin reference standard/working standard.	The Infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with Paraffin reference standard/working standard.	Odor of hydrogen sulfide should be perceptible
5	Identification 3	passes test	NA	Violet pink or brown colour should be observed in upper layer	Not mentioned
6	Identification 4	passes test	NA	Should comply with appearance test	Not mentioned
7	Melting Range/Congeealing temperature	Between 51°C and 55°C	Between 47°C and 65°C	Not mentioned	Between 50°C and 70°C
8	Appearance	Not mentioned	Not mentioned	Melted sample should not be more intensely coloured than standard solution	Not mentioned
9	Acidity or alkalinity	passes test	NMT 1.0 mL of 0.01 M NaOH is required to change the color of the indicator to pink	NMT 0.5 mL of 0.01 M NaOH is required to change the color of the indicator to pink	After addition of 0.2ml of 0.02M NaOH , solution should produce red colour
10	Alkalinity	passes test	Sample solution is yellow coloured, NMT 0.5 mL of 0.01 M HCl is required to change the color of the indicator to red.	Not mentioned	Not mentioned
11	Darkened Substances by H2SO4/Readily Carbonizable Substances	passes test	Sample solution should be less intensely coloured than the standard	Not mentioned	The color of the sulfuric acid layer should not be darker than that of the control solution
12	Sulfur Compounds	passes test	No dark brown color should develop	Not mentioned	No dark brown color should develop in aqueous layer
13	Polycyclic Aromatic Hydrocarbons	passes test	The absorbance at any wavelength in the specified range should not be greater than one-third of the absorbance, at 278 nm, of the Standard solution.	NMT 75 ppm	Not mentioned
14	Heavy metals	Not mentioned	Not mentioned	Not mentioned	NMT 10ppm
15	Arsenic	Not mentioned	Not mentioned	Not mentioned	NMT 2ppm

16	Residue on Ignition	NMT 0.05%	Not mentioned	Not mentioned	
17	Sulfated Ash	Not mentioned	Not mentioned	NMT 0.05 %	Not mentioned
18	Sulfate	NMT 0.015%	Not mentioned	Not mentioned	
19	Insoluble matter in Ethylbenzene	passes test	Not mentioned	Not mentioned	
20	Reaction	passes test	Not mentioned	Not mentioned	
21	Elemental impurities(ICH Q3D)		Not mentioned	Not mentioned	Not mentioned
	Cd	NMT 25 ppm			
	Pb	NMT 25 ppm			
	As	NMT 1.5 ppm			
	Hg	NMT 25 ppm			
	Co	NMT 25 ppm			
	V	NMT 25 ppm			
	Ni	NMT 25 ppm			
	Tl	NMT 25 ppm			
	Au	NMT 25 ppm			
	Pd	NMT 25 ppm			
	Ir	NMT 25 ppm			
	Os	NMT 25 ppm			
	Rh	NMT 25 ppm			
	Ru	NMT 25 ppm			
	Se	NMT 25 ppm			
	Ag	NMT 25 ppm			
	Pt	NMT 25 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				
22	Residual Solvents(Ph.Eur/USP)	passes test	NA	NA	NA
	Storage	Keep container tightly closed in a dry and well-ventilated place.	Preserve in light resistant, well-closed containers, avoid exposure to excessive heat.	Protected from light	Well-closed 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.