



# " clyzo " - Monograph Comparison



## AS PER CURRENT USP 2022/EP11/JP18

<b>Product Name</b>	1,1,1-Trichloro-2-Methyl-2-Propanol 1/2-hydrate (BP, Ph. Eur.) pure, pharma grade		<b>Issue Date</b>	March-23
<b>Product Code</b>	145300		<b>Prepared by</b>	Sr. Tech Lead
<b>CAS NO.</b>	57-15-8		<b>Reviewed by</b>	Manager Technical
<b>Manufacturer Name</b>	PanReac AppliChem		<b>Version no.</b>	CLYZO/PAN/145300/01

Sr. No.	Test	Manufacturer COA	Pharmacopeial Specifications		
		Complies BP, Ph. Eur.	USP 2022	EP Version 11.0	JP 18
1	Description	crystalline powder, White	Colorless to white crystals, having a characteristic, somewhat camphoraceous, odor and taste. Melting point: NLT 76°C.	white or almost white, crystalline powder or colourless crystals, sublimes readily. Melting point about 95 °C	Colorless or white crystals. It has a camphoraceous odour. It slowly volatilizes in air. Melting point: NLT 76°C.
2	Solubility	Slightly soluble in water, soluble in alcohol	Freely soluble in alcohol, in ether, in chloroform, and in volatile oils; soluble in glycerin; slightly soluble in water.	slightly soluble in water, very soluble in ethanol (96 per cent), soluble in glycerol (85 %)	It is very soluble in methanol, in ethanol (95%) and in diethyl ether, slightly soluble in water.
3	Identification 1	Passes Test	The infrared absorption spectrum obtained with sample should be concordant with the spectrum obtained with Chlorobutanol hemihydrate RS/WS	The infrared absorption spectrum obtained with sample should be concordant with the spectrum obtained with Chlorobutanol RS/WS	Should comply by yellow precipitate formation and the odor of iodoform should be perceptible.
4	Identification 2	Passes Test	In the test of assay, the retention time of the chlorobutanol peak of the Sample solution corresponds to that of the	Should comply by water test	The disagreeable odor of phenyl isocyanide (poisonous) should be perceptible
5	Acidity (Reaction)	Passes Test	The solution should be neutral.	NMT 1.0 mL of 0.01 M NaOH is required to change the colour of the indicator to blue.	The solution should be neutral.
6	Appearance of solution	Passes Test	Not mentioned	Sample solution is not more opalescent than reference suspension II and not more intensely coloured than reference solution BY5	Not mentioned
7	Chloride	NMT 0.01%	NMT 0.07%	NMT 100 ppm	NMT 0.071%
8	Insoluble matter ethanol (96%)	Passes Test	Not mentioned	Not mentioned	Not mentioned
9	Trichloromethane	NMT 0.006%	Not mentioned	NMT 60 ppm	Not mentioned
10	Acetone	NMT 0.1%	Not mentioned	NMT 0.10 %	Not mentioned
11	Residue on ignition		Not mentioned	NA	NMT 0.1%
12	Sulphated Ash	NMT 0.1%	Not mentioned	NMT 0.1%	Not mentioned
13	Water	Between 4.5 % and 5.5 %	NMT 6.0%	between 4.5% and 5.5%	NMT 6.0%
14	Assay (Anhydrous basis)	Between 98.0% and 101.0%	Between 98.0 % and 100.5%	Between 98.0 % and 101.0%	NLT 98.0 %
	Elemental impurities				
	Cd	NMT 0.5 ppm			
	Pb	NMT 0.5 ppm			
	As	NMT 1.5 ppm			
	Hg	NMT 1.5 ppm			
	Co	NMT 5 ppm			
	V	NMT 10 ppm			
	Ni	NMT 20 ppm			

15	Tl	NMT 0.8 ppm	Not mentioned	Not mentioned	Not mentioned
	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				
16	Residual Solvent	Passes test	NA	NA	NA
	Storage	Store between 8 deg. And 15 deg.	Preserve in Tight containers.	Air tight 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.					