



" clyzo " - Monograph Comparison



AS PER CURRENT USP 2022/EP11/JP18

Product Name	Acetone (USP, BP, Ph. Eur.) pure, pharma grade		Issue Date	March-23
Product Code	141007		Prepared by	Sr. Tech Lead
CAS NO.	67-64-1		Reviewed by	Manager Technical
Manufacturer Name	PanReac AppliChem		Version no.	CLYZO/PAN/141007/01

Sr. No.	Test	Manufacturer COA		Pharmacopeial Specifications	
		Complies USP, BP, Ph. Eur	USP 2022	EP Version 11.0	JP 18
1	Description	Liquid	Transparent, colorless, mobile, volatile liquid, having a characteristic odor. 50% solution is neutral to litmus	Volatile, clear, colourless liquid	
2	Solubility	Miscible with water and most organic solvent. Soluble in water	Miscible with water, with alcohol, with ether, with chloroform, and with most volatile oils	Miscible with water and with ethanol (96 %).	
3	Identification 1	Passes the Test	The Infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with Acetone reference standard/ working standard	Should comply with relative density test.	
4	Identification 2	Passes the Test	In assay test, the retention time of the Sample corresponds to that of standard	Should comply by an intense red colour development which becomes violet with the addition acetic acid	
5	Identification 3	Passes the Test	Not mentioned	Should comply by a greenish-blue colour development	
6	Appearance of solution	Passes the Test	Not mentioned	Sample solution should be clear and colourless	
7	Acidity or alkalinity	Passes the Test	Not mentioned	After addition of 0.7 mL of 0.01 M HCL and methyl red indicator, the solution should be red or orange.	
8	Relative density	Between 0.790 and 0.793 (at 20°C) NMT 0.789 (at 25°C)	NMT 0.789	Between 0.790 and 0.793	
9	Water	NMT 0.3%	NMT 0.5%	NMT 0.3%	
10	Nonvolatile Residue	NMT 0.004%	NMT 0.004%	NMT 50 ppm	
11	Readily Oxidizable substances	Passes the Test	The permanganate color of the mixture does not completely disappear within 15 min.	Not mentioned	
12	Reducing substances	NMT 0.1 %	Not mentioned	The mixture should not be completely decolourised on addition of KMnO4 solution	
13	Related substances	Methanol: NMT 0.05% 2-Propanol: NMT 0.05% Benzene: NMT 2 ppm Any other impurity : NMT 0.05% Ethanol: NMT 500 ppm	Not mentioned	Impurity A: NMT 0.05% Impurity B: NMT 0.05% Impurity C: NMT 2 ppm other impurity : NMT 0.05%	Any
14	Matter insoluble in water	Passes the Test	Not mentioned	Sample solution should be clear	
15	Assay	NLT 99.5%	NLT 99.0% (anhydrous basis)	Not mentioned	
16	Elemental impurities (according to ICH Q3D)		Not mentioned	Not mentioned	
	Cd	NMT 0.5 ppm			
	Pb	NMT 5 ppm			
	As	NMT 1.5 ppm			
	Hg	NMT 1.5 ppm			
	CO	NMT 5 ppm			
	V	NMT 10 ppm			

Product Not Official in Japanese Pharmacopoeia

	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		
17	Residual solvents	Passes the Test	Not mentioned	Not mentioned
	Storage	Storage away from direct light	Preserve in tight containers, remote from fire.	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.