



" clyzo " - Monograph Compari



AS PER CURRENT USP 2022/EP11/JP18

Product Name	Formaldehyde 37-38% w/w stabilized with methanol (USP, BP, Ph. Eur.) pure, pharma grade		Issue Date	March-23
Product Code	141328		Prepared by	Sr. Tech Lead
CAS NO.	50-00-0		Reviewed by	Manager Technical
Manufacturer Name	PanReac AppliChem		Version no.	CLYZO/PAN/141328/01

Sr. No.	Test	Pharmacopeial Specifications			
		Manufacturer COA <i>Complies USP, BP, Ph. Eur.</i>	USP 2022	EP Version 11.0	JP 18
1	Descripion	Clear, colorless liquid	Clear, colorless or practically colorless liquid, having a pungent odor. The vapor from it irritates the mucous membrane of the throat and nose. On long standing, especially in the cold, it may become cloudy because of the separation of paraformaldehyde. This cloudiness disappears when the solution is warmed.	Clear, Colourless Liquid. It may be cloudy after storage	Clear, colorless liquid. Its vapor is irritating to the mucous membrane. When stored for a long time, especially in a cold place, it may become cloudy
2	Solubility	Miscible with water	Miscible with water and with alcohol.	Miscible with water and with ethanol (96 %)	Miscible with water and with ethanol (95)
3	Identification 1	Passes the Test	Should comply by grey precipitate or a silver mirror formation	Should comply by grey precipitate or a silver mirror formation	Should comply by grey precipitate or a silver mirror formation
4	Identification 2	Passes the Test	Should comply by dark red color development	Should comply by dark red color development	Should comply by dark red color development
5	Identification 3	Passes the Test	Not mentioned	Should comply by a violet-blue or violet-red colour development	Not mentioned
6	Identification 4	Passes the Test	Not mentioned	Should comply with the limits of Assay	Not mentioned
7	Appearance of solution	Passes the Test	Not mentioned	Sample should be colourless	Not mentioned
8	Acidity	Passes test (free HCOOH: NMT 0.03%)	NMT 10.0 ml of 0.1 N NaOH is consumed	NMT 0.4 ml of 0.1 M NaOH is required to change the colour of the indicator to red	After addition of 5.0 ml 0.1M NaOH and 2 drops of bromothymol blue should develop a blue color
9	Residue on ignition	NMT 0.05%	Not mentioned	Not mentioned	NMT 0.06%
10	Sulphated Ash	Not mentioned	Not mentioned	NMT 0.1%	Not mentioned
11	Methanol	Between 9.0 % and 15.0 %	Between 9.0 % and 15.0 %	Between 9.0 % and 15.0 %	Between 5 % and 13 %
12	Matter insoluble in water	Passes the Test	Not mentioned	Not mentioned	Not mentioned
13	Chloride	NMT 0.001%	Not mentioned	Not mentioned	Not mentioned
14	Sulfate	NMT 0.005%	Not mentioned	Not mentioned	Not mentioned
15	Iron	NMT 0.0005%	Not mentioned	Not mentioned	Not mentioned
16	Assay	Between 37.0% and 38.0%	NLT 34.5%	Between 34.5% and 38.0 %	Between 35.0% and 38.0 %
17	Residual solvent	Passes the Test	Not mentioned	Not mentioned	Not mentioned
18	Elemental impurities (according to ICH Q3D)		Not mentioned	Not mentioned	Not mentioned
	Cd	NMT 0.5 ppm			
	Pb	NMT 0.5 ppm			
	Assay	NMT 1.5 ppm			
	Hg	NMT 1.5 ppm			
	CO	NMT 5 ppm			
	V	NMT 10 ppm			
	Ni	NMT 20 ppm			
	Tl	NMT 0.8 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			
Storage	Storage away from direct light. Storage between 15 and 25°C	Preserve in tight containers, and preferably store at a temperature not below 15°C	Protected from light, at a temperature of 15°C to 25°C	Tight light resistant containers
Note - If you need any additional testing, you may use our Additional Testing Feature on the product page or contact your Clyzo representative.				
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