" clyzo " - Monograph Comparison

AS PER CURRENT USP 2022/EP11/JP18

	Product Name	**L(+)-Lactic Acid (BP, Ph. Eur.) pure, pharma grade**	PanReac AppliChem ITW Reagents	**Issue Date**	March-23
	Product Code	141034		**Prepared by**	Sr. Tech Lead
	CAS NO.	79-33-4		**Reviewed by**	Manager Technical
	Manufacturer Name	**PanReac AppliChem**		**Version no.**	CLYZO/PAN/141034/01

Sr. No.	Test	Manufacturer COA	Pharmacopeial Specifications		
		Complies BP, Ph. Eur.	*USP 2022*	*EP Version 11.0*	*JP 18*
1	Description	Clear viscous Colorless liquid	Colorless or yellowish, practically odorless, syrupy liquid. Is hygroscopic. When it is concentrated by boiling, lactic acid lactate is formed. Specific gravity is about 1.20	Colourless or slightly yellow, syrupy liquid.	A clear, colorless or light odor yellow, viscous liquid. It is odorless or has a faint, unpleasant odor. It is hygroscopic.Specific gravity @ 20^0 C: about 1.20
2	Solubility	Miscible with water	Insoluble in chloroform. Miscible with water, with alcohol, and with ether.	Miscible with water & with ethanol (96 %).	It is miscible with water, with ethanol (95%) and with diethyl ether
3	Identification 1	passes test	Should comply by a blue color formation	The sample solution is strongly acidic having pH below 4.0	1. 2% solution turn blue litmus to red 2. When heated with KMnO4 TS should evolve the odor of acetaldehyde. Lead salt
4	Identification 2	Relative density should be between 1.20 and 1.21	Not mentioned	Relative density should be between 1.20 and 1.21	2% solution when heated with potassium permanganate TS, evolve the odor of acetaldehyde.
5	Identification 3	passes test	Not mentioned	A dark green ring should appear at the junction of the two liquids.	Not mentioned
6	Identification 4	passes test	Not mentioned	complies with the limits of the assay	Not mentioned
7	Appearance	passes test	Not mentioned	Sample solution should not be more intensely coloured than the reference	Not mentioned
8	Ether insoluble substance	passes test	Not mentioned	The solution should not be more opalescent than the solvent used for the test.	Not mentioned
9	Insoluble matter in H2O	passes test	Not mentioned	Not mentioned	Not mentioned
10	Optical rotation	Not mentioned	Not mentioned	Not mentioned	Between -46^0 to -52^0
11	Darkened substances by H2SO4/Readily Carbonizable Substances (JP)	passes test	No dark color develops at the interface of the two acids within 15 min.	Not mentioned	No dark color develops at the zone of contact.
12	Sugars and other reducing substances	passes test	No red precipitate should be formed	No red or greenish precipitate is formed.	No red precipitate should be produced
13	Iron	Not mentioned	Not mentioned	Not mentioned	NMT 5 ppm
14	Residue on ignition	NMT 0.05%	NMT 0.05%	Not mentioned	NMT 0.1%
15	Sulfated ash	NMT 0.05%	Not mentioned	NMT 0.1%	Not mentioned
16	Heavy metals	Not mentioned	Not mentioned	Not mentioned	NMT 10 ppm
17	Chloride	0.002%	No opalescence should be produced immediately.	Not mentioned	NMT 0.036%
18	Citric, Oxalic, Phosphoric and Tartaric acid	passes test	No turbidity is produced.	Sample solution is not more intensely opalescence than the standard mixture	No changes should occur

19	Glycerin and mannitol	Not mentioned	Not mentioned	Not mentioned	No turbidity is produced.
20	Volatile fatty acids	passes test	Not mentioned	Not mentioned	Sample solution does not produce any acetic acid-like or butyric acid-like odor
21	Cyanide	Not mentioned	Not mentioned	Not mentioned	Sample solution has no more color than the control solution
22	Calcium	NMT 0.02%	Not mentioned	NMT 200 ppm	Not mentioned
23	Sulfate	NMT 0.002%	No turbidity should be produced.	NMT 200 ppm	NMT 0.010%
24	Assay	Between 88.0% and 92.0% NLT 95.0% (S enantiomer)	Between 88.0% and 92.0%	Between 88.0% and 92.0% NLT 95.0% (S enantiomer)	Between 85.0% and 92.0%
25	Residual solvent (Ph.Eur)	passes test	Not mentioned	Not mentioned	Not mentioned
26	Elemental impurities		NA	NA	NA
	Cd	NMT 0.5 ppm			
	Pb	NMT 0.5 ppm			
	As	NMT 1 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	Keep containers tightly closed in a dry, cool and well-ventilated place. Protect from moisture. Store	Preserve in tight containers.	NA	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 reprensentive.