



" clyzo " - Monograph Comparison



AS PER CURRENT USP 2022/EP11/JP18

Product Name	Tris (USP, BP, Ph. Eur.) pure, pharma grade		Issue Date	March-23
Product Code	141940		Prepared by	Sr. Tech Lead
CAS NO.	77-86-1		Reviewed by	Manager Technical
Manufacturer Name	PanReac AppliChem		Version no.	CLYZO/PAN/141940/01

Sr. No.	Test	Manufacturer COA	Pharmacopeial Specifications		
		<i>Complies USP, BP, Ph. Eur.</i>	<i>USP 2022</i>	<i>EP Version 11.0</i>	<i>JP 18</i>
1	Description	White crystalline powder	White, crystalline powder, having a slight, characteristic odor.	A white or almost white, crystalline powder, or colourless crystals.	
2	Solubility	Soluble in water	Freely soluble in water.	Freely soluble in water, sparingly soluble in ethanol (96 %), very slightly soluble in ethyl acetate.	
3	Identification 1	Passes the test	The Infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with Tromethamine reference standard/ working standard.	Sample solution is strongly alkaline having pH above 10.0	
4	Identification 2	Passes the test	Should comply by a yellow colorformation	Melting range should be between 168 °C and 174 °C.	
5	Identification 3	Passes the test	The color should change from light yellow to orange.	The Infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with Tromethamine reference standard/ working standard.	
6	Identification 4	Passes the test	Not mentioned	By TLC: The principal spot in the chromatogram obtained with test solution is similar in position, colour and size to the principal spot in the chromatogram obtained with reference solution.	
7	Appearance of solution	Passes the test	Not mentioned	Sample solution should be clear and colourless	
8	Melting range	Between 168° and 172°C	Between 168° and 172°C	Not mentioned	
9	pH	Between 10.0 and 11.5	Between 10.0 and 11.5	Between 10.0 and 11.5	
10	Insoluble matter in H2O	NMT 0.025%	Not mentioned	Not mentioned	
11	Related substances	Passes the test	Not mentioned	NMT 1.0%	
12	Chloride	NMT 0.003%	Not mentioned	NMT 100 ppm	
13	Iron	NMT 0.001%	Not mentioned	NMT 10 ppm	
14	Arsenic	NMT 0.0001%			
15	Heavy Metals	NMT 0.001%	Not mentioned	Not mentioned	
16	Loss on drying	NMT 0.5%	NMT 1.0 %	NMT 0.5 %	
17	Residue on ignition	NMT 0.1%	NMT 0.1 %	Not mentioned	
18	Sulfated ash	Not mentioned	Not mentioned	NMT 0.1 %	
19	Assay (Dried basis)	Between 99.0% and 100.5 %	Between 99.0% and 101.0 %	Between 99.0% and 100.5 %	
20	Residual Solvents	Passes the test	Not mentioned	Not mentioned	
	Elemental Impurities		Not mentioned	Not mentioned	

Product Not Official in Japanese pharmacopoeia

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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		
Tl	NMT 2 ppm		
Au	NMT 10 ppm		
Pd	NMT 10 ppm		
Ir	NMT 10 ppm		
Os	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	Closed Conditions	Preserve in tight containers.	Not mentioned
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.			