



" clyzo " - Monograph Comparison



AS PER CURRENT USP 2022/EP11/JP18

Product Name	Triethyl Citrate (Ph. Eur., USP-NF) pure, pharma grade		Issue Date	March-23
Product Code	147039		Prepared by	Sr. Tech Lead
CAS NO.	77-93-0		Reviewed by	Manager Technical
Manufacturer Name	PanReac AppliChem		Version no.	CLYZO/PAN/147039/01

Sr. No.	Test	Manufacturer COA		Pharmacopeial Specifications	
		Complies Ph. Eur., USP-NF	USP 2022	EP Version 11.0	JP 18
1	Description	Liquid	Practically colorless, oily liquid.	Clear, viscous, colourless or almost colourless, hygroscopic liquid.	Product Not Official in Japanese Pharmacopoeia
2	Solubility	Not mentioned	Soluble in water. Miscible with alcohol and with ether.	Soluble in water, miscible with ethanol (96 per cent), slightly soluble in fatty oils.	
3	Identification 1	Passes test	The infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with Triethyl Citrate reference/working standard.	The infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with Triethyl Citrate reference/working standard.	
4	Identification 2	Passes test	The retention time of the major peak of the sample solution corresponds to that of a similar preparation of USP Triethyl Citrate RS, as obtained in the assay.	Should comply by refractive index test	
5	Identification 3	Passes test	Not mentioned	It should produce a violet colour, turning to violet-blue.	
6	Identification 4	Passes test	Not mentioned	It should produce a violet colour, turning to violet-blue.	
7	Appearance of solution	Passes test	Not mentioned	Sample should be clear and not more intensely coloured than reference solution BY6	
8	Specific gravity	Not mentioned	Between 1.135 and 1.139	Not mentioned	
9	Acidity	Not mentioned	NMT 1.0 mL of 0.10 N NaOH is required.	NMT 0.3 mL of 0.1 M NaOH is required to change the colour of the indicator to blue.	
10	Acidic reaction test	Passes test	Not mentioned	Not mentioned	
11	Water	NMT 0.25 %	NMT 0.25 %	NMT 0.25 %	
12	Refractive index	Between 1.439 and 1.441 (at 250C) Between 1.440 and 1.4461 (at 200C)	Between 1.439 and 1.441	Between 1.440 and 1.446	
13	Density	Between 1.135 and 1.139	Not mentioned	Not mentioned	
14	Related substances	Passes test	Not mentioned	Maximum individual impurity: NMT 0.2% Total impurities: NMT 0.5%	
15	Sulfated ash	NMT 0.1 %	Not mentioned	NMT 0.1%	
16	Assay (anhydrous basis)	Between 98.5% and 101.0% (by Titrimetry) Between 99.0% and 101.0% (by GC)	Between 99.0% and 100.5%	Between 98.5% and 101.0%	
	Storage	Store at room temperature	Preserve in tight containers.	In an airtight container.	

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.