



" clyzo " - Monograph Comparison



AS PER CURRENT USP 2022/EP11/JP18

Product Name	n-Propyl Gallate (Ph. Eur., USP-NF) pure, pharma grade	 PanReac AppliChem <small>ITW Reagents</small>	Issue Date	March-23
Product Code	141962		Prepared by	Sr. Tech Lead
CAS NO.	121-79-9		Reviewed by	Manager Technical
Manufacturer Name	PanReac AppliChem		Version no.	CLYZO/PAN/141962/01

Sr. No.	Test	Manufacturer COA		Pharmacopeial Specifications	
		Complies Ph. Eur., USP-NF	USP 2022	EP Version 11.0	JP 18
1	Description	Solid	White, crystalline powder having a very slight, characteristic odor.	White or almost white, crystalline powder.	Product Not Official in Japanese Pharmacopoeia
2	Solubility	Not mentioned	Freely soluble in alcohol; slightly soluble in water	Very slightly soluble in water, freely soluble in ethanol (96 %). It dissolves in dilute solutions of alkali hydroxides.	
3	Identification 1	Passes the test	The UV absorption spectrum obtained with sample matches with standard and should exhibit maxima at the same wavelength	Melting point should be between 148 °C and 151 °C.	
4	Identification 2	Passes the test	The Infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with propyl gallate reference standard/working standard.	The Infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with propyl gallate reference standard/working standard.	
5	Identification 3	Passes the test	Not mentioned	In TLC test, the principal spot in the chromatogram obtained with the test solution is similar in position, colour and size to the principal spot in the chromatogram obtained with the reference solution.	
6	Identification 4	Passes the test	Not mentioned	Should comply by bright yellow precipitate formation.	
7	Appearance of Solution	Passes the test	Not mentioned	Solution should be clear and not more intensely coloured than reference solution BY5	
8	Related Substance	Each unspecified impurity-NMT 0.10% Total impurities-NMT 0.15%	Not mentioned	Maximum unspecified impurity: NMT 0.10% Total impurities: NMT 0.15%	
9	Total Chlorine	NMT 0.02%	Not mentioned	NMT 200 ppm	
10	Chlorides	NMT 0.01%	Not mentioned	NMT 100 ppm	
11	Zinc	NMT 0.0025%	Not mentioned	NMT 25 ppm	
12	Loss on Drying	NMT 0.5%	NMT 0.5%	NMT 0.5%	
13	Residue on ignition	Not mentioned	NMT 0.1%	Not mentioned	
14	Sulfated Ash	NMT 0.1%	Not mentioned	NMT 0.1%	
15	Melting Range or Temperature	Between 146°C and 150°C	Between 146°C and 150°C	Not mentioned	
16	Assay (dried basis)	By HPLC: Between 98.0% and 102.0% By UV: Between 98.0% and 102.0%	Between 98.0% and 102.0%	Between 98.0% and 102.0%	
	Storage condition	Protect from exposure to the light.	Preserve in tight containers, protected from light, and avoid contact with metals.	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.