



" clyzo " - Monograph Comparison



AS PER CURRENT USP 2022/EP11/JP18

Product Name	Butylhydroxytoluene (BP, Ph. Eur.) pure, pharma grade		Issue Date	March-23
Product Code	142825		Prepared by	Sr. Tech Lead
CAS NO.	128-37-0		Reviewed by	Manager Technical
Manufacturer Name	PanReac AppliChem		Version no.	CLYZO/PAN/142825/01

Sr. No.	Test	Pharmacopeial Specifications			
		Manufacturer COA <i>Complies BP, Ph. Eur</i>	USP 2022	EP Version 11.0	JP 18
1	Description	Small white crystals	White, crystalline solid, having a faint, characteristic odor.	A white or yellowish-white, crystalline powder.	Product Not Official in Japanese Pharmacopoeia
2	Solubility	Insoluble in water, soluble in alcohol and acetone	Freely soluble in alcohol, in chloroform, and in ether; insoluble in water and in propylene glycol.	Practically insoluble in water, very soluble in acetone, freely soluble in ethanol (96 per cent) and in vegetable oils.	
3	Identification 1	Passes The Test	Not mentioned	Should comply by freezing point test	
4	Identification 2	Passes The Test	In the test of assay, the retention time of the BHT peak of the Sample solution corresponds to that of the Standard solution.	The solution shows an absorption maximum at 278 nm and the specific absorbance at the maximum is 80 to 90	
5	Identification 3	Passes The Test	The infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with Butylated Hydroxytoluene reference standard/working standard.	The infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with Butylated Hydroxytoluene reference standard/working standard.	
6	Identification 4	Passes The Test	Not mentioned	A blue colour should develop.	
7	Appearance of solution	Passes The Test	Not mentioned	Sample solution should be clear and not more intensely coloured than reference solution Y5 or BY5	
8	Freezing point	Between 69°C and 70°C	Not mentioned	Between 69°C to 70°C	
9	Sulfated Ash	Not mentioned	Not mentioned	NMT 0.1%	
10	Matter insoluble in methanol	Passes The Test			
11	Residue on Ignition	NMT 0.002%	NMT 0.002%	Not mentioned	
12	Organic Impurities/related substances (HPLC/TLC)	Passes The Test	1.) p-Cresol or m-cresol- NMT 0.1% 2.) 3-tert-Butyl-4-hydroxyanisole (BHA)- NMT 0.1% 3.) 3,5-Di-tert-butyl-4-hydroxybenzoic acid- NMT 0.1% 4.) 2-tert-Butyl-4-methylphenol or 2-tert-butyl-5-methylphenol- NMT 0.1% 5.) 3,5-Di-tert-butyl-4-hydroxy benzaldehyde- NMT 0.1% 6.) 4,6-Di-tert-butyl-m-cresol- NMT 0.1% 7.) 2,6-Di-tert-butyl-phenol-NMT 0.1% 8.) Individual impurity-NMT 0.1% 9.) Total impurities-NMT 0.7%	NMT 0.5%	
13	Assay	NLT 99.0%	Between 99.0% and 101.5%	Not mentioned	
	Elemental Impurities		Not mentioned	Not mentioned	
	Cd	NMT 0.5 ppm			
	Pb	NMT 5 ppm			
	As	NMT 1.5 ppm			
	Hg	NMT 1.5 ppm			
	CO	NMT 5 ppm			
	V	NMT 10 ppm			
	Ni	NMT 20 ppm			

14	Tl	NMT 5 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			
15	Residual solvents	Passes The Test	Not mentioned	Not mentioned
	Storage	Storage at room temperature	Preserve in well closed 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.