



" clyzo " - Monograph Comparison



AS PER CURRENT USP 2022/EP11/JP18

Product Name	Butylhydroxyanisole (USP-NF, BP, Ph. Eur.) pure, pharma grade		Issue Date	March-23
Product Code	144233		Prepared by	Sr. Tech Lead
CAS NO.	25013-16-5		Reviewed by	Manager Technical
Manufacturer Name	PanReac AppliChem		Version no.	CLYZO/PAN/144233/01

Sr. No.	Test	Pharmacopeial Specifications			
		Manufacturer COA <i>Complies USP, BP, Ph. Eur</i>	USP 2022	EP Version 11.0	JP 18
1	Description	Waxy aspect, white colour or slightly yellow-pink. Could form lumps easily	White or slightly yellow, waxy solid, having a faint, characteristic odor.	A white, yellowish or slightly pinkish, crystalline powder	Product Not Official in Japanese Pharmacopoeia
2	Solubility	Insoluble in water	Freely soluble in alcohol, in propylene glycol, in chloroform, and in ether; insoluble in water.	Practically insoluble in water, very soluble in methylene chloride, freely soluble in ethanol (96 %) and in fatty oils. It dissolves in dilute solutions of alkali hydroxides.	
3	Identification 1	Passes The Test	The infrared absorption spectrum obtained with sample should show all peak within 5 cm ⁻¹ of those determined from 3-tert-Butyl-4-Hydroxyanisole.	By TLC: In related substances test, the principal spot in the chromatogram obtained with test solution (b) is similar in position, colour and size to the principal spot in the chromatogram obtained with reference solution (a)	
4	Identification 2	Passes The Test	In HPLC test, the retention time of the main peak of the sample solution corresponds to that of the Standard solution.	Organic layer should become red	
	Identification 3	Passes The Test	Not mentioned	Red color should develop	
5	Appearance of solution	Passes The Test	Not mentioned	Sample solution should be clear and not more intensely colored than intensity 5 of the reference solution	
6	Melting Point	About 50°C	Not mentioned	Not mentioned	
7	Related substances	3-(1,1-dimethylethyl)-4-methoxyphenol): NMT 10.0% Any other impurity: NMT 0.2% Total impurities: NMT 0.5%	Not mentioned	3-(1,1-dimethylethyl)-4-methoxyphenol): NMT 10.0% Any other impurity: NMT 0.2% Total impurities: NMT 0.5%	
8	Sulfated ash	Not mentioned	Not mentioned	NMT 0.1%	
9	Matter insoluble in ethanol	Passes The Test			
10	Residue on ignition	NMT 0.01%	NMT 0.01%	Should comply by the entire sulfuric acid layer turning violet.	
11	Assay	Isomer mixture: NLT 98.5% 3-ter-butyl-4-hydroxyanisole: NMT 90.0% ter-butyl-4-Hydroxyanisole: NMT 10.0%	NLT 98.5%	Sample solution should be clear and colourless	
12	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			
	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		
13	Residual solvents	Passes The Test	Not mentioned	Not mentioned
	Storage	Storage away from direct light.	Preserve in well-closed containers.	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.