

## " clyzo " - Monograph Comparison





## AS PER CURRENT USP 2022/EP11/JP18

AS FER CORRENT OSF 2022/EF11/3F10						
	Product Name	4-Chloro-3-Methylphenol (USP-NF, BP, Ph. Eur.) pure, pharma grade	PanReac AppliChem	Issue Date	March-23	
	Product Code	145226	AppliChom	Prepared by	Sr. Tech Lead	
	CAS NO.	59-50-7	Applichem	Reviewed by	Manager Technical	
	Manufacturer Name	PanReac AppliChem	IIW Reagents	Version no.	CLYZO/PAN/145226/01	
Sr. No.	Test	Manufacturer COA		Pharmacopeial Specifications		
	December 1	Complies (USP-NF, BP, Ph. Eur.) White crystalline powder or compact crystalline masses,	USP 2022 Colorless or practically colorless crystals or	EP Version 11.0  White or almost white, crystalline powder or compacted crystalline	JP 18 Product Not Official in Japanese pharmacopoeia	
1	Description	supplied as pellets.	crystalline powder, having a characteristic, nontarry odor.	masses supplied as pellets or colourless or white crystals.	Product Not Official in Japanese pharmacopoela	
2	Solubility	Slightly soluble in water	Very soluble in alcohol; soluble in ether, in	slightly soluble in water, very soluble in ethanol (96 %), freely soluble in	1	
	,	3 1, 11 11 11	terpenes, in fixed oils, and in solutions of alkali hydroxides;	fatty oils. It dissolves in solutions of alkali hydroxides.		
			slightly soluble in water and more soluble in hot water			
3	Identification 1	Passes The Test	A blue color should develop.	Melting point should be between 64 °C and 67 °C.		
4	Identification 2	Passes The Test	A white precipitate should be formed	Residue should melt between 85°C and 88°C		
5	Identification 3	Passes The Test	Not mentioned	A bluish colour should be produced.		
6	Melting Range	Between 64 °C and 66 °C.	Between 63°and 66°C	Not mentioned		
7	Appearance of solution	Passes The Test	Not mentioned	Sample solution should be clear and not more intensely coloured than		
	A + 1%	Dance The Test		reference solution BY6	-	
8	Acidity	Passes The Test	Not mentioned	NMT 0.2 m of 0.01 M NaOH is required to produce a pure yellow colour.	_	
9	Insoluble matter in CH3CH2OH	Passes The Test	Not mentioned	Not mentioned	-	
10 11	Completeness of Solution Related Substances	Maximum individual unknown impurity: NMT 0.10 %; Tota	Sample solution should be complete.  Not mentioned	Not mentioned  Maximum individual unknown impurity: NMT 0.10 %; Total impurities:	-	
11	Related Substances	impurities: NMT 1.0%	Not mentioned	NMT 1.0%		
12	Non-volatile matter	NMT 0.1 %	NMT 0.1%	NMT 0.1 %		
13	Assay	Between 99.0 % and 101.0 %	Between 99.0 % and 101.0 %	Between 98.0 % and 101.0 %		
14	Elemental Impurities		Not mentioned	Not mentioned		
	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				
	TI	NMT 1 ppm				
	Au	NMT 10 ppm				
	Pd	NMT 10 ppm	-			
	Ir	NMT 10 ppm	-			
	Os	NMT 10 ppm	1			
	Rh	NMT 10 ppm	1			
	Ru	NMT 10 ppm	1			
	Se	NMT 15 ppm	†			
<b>—</b>	Ag	NMT 15 ppm	1			
	Pt	NMT 10 ppm	1			
-	Li	NMT 55 ppm	1			
-	Sb	NMT 120 ppm	1			
$\vdash$	Ba	NMT 140 ppm	1			
$\vdash$	Mo	NMT 25 ppm	1			
-	Cu	NMT 250 ppm	-			
-	Sn	NMT 600 ppm	-			
<u> </u>	Cr	NMT 25 ppm	-			
15	Residual solvents	Passes The Test	Not mentioned	Not mentioned	-	
12	Storage	Storage away from direct light	Preserve in tight, light-resistant containers.	Protected from light.	1	