



" clyzo " - Monograph Comparison



AS PER CURRENT USP 2022/EP11/JP18

Product Name	Maleic Acid (BP, Ph. Eur.) pure, pharma grade		Issue Date	March-23
Product Code	141882		Prepared by	Sr. Tech Lead
CAS NO.	110-16-7		Reviewed by	Manager Technical
Manufacturer Name	PanReac AppliChem		Version no.	CLYZO/PAN/141882/01

Sr. No.	Test	Manufacturer COA		Pharmacopeial Specifications	
		Complies BP, Ph. Eur	USP 2022	EP Version 11.0	JP 18
1	Description	Small white crystals	white, crystalline powder.	A white or almost white, crystalline powder	Product Not Official in Japanese Pharmacopoeia
2	Solubility	Soluble in water	Freely soluble in water and in alcohol; sparingly soluble in ether.	Freely soluble in water and in ethanol (96%)	
3	Identification 1	Passes The Test	The infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with Maleic Acid, NF reference standard/working standard	The pH of the dilution should be less than 2.0	
4	Identification 2	Passes The Test	In the assay test, the retention time of the maleic acid peak of the Sample solution corresponds to that of the Standard solution.	In the fumaric acid test, The principal spot in the chromatogram obtained with test solution (b) is similar in position & size to the principal spot in the chromatogram obtained with reference solution (a).	
5	Identification 3	Passes The Test	Not mentioned	A violet-pink colour should be developed	
6	Water	NMT 1.5%	NMT 0.5 %	NMT 2.0%	
7	Appearance of solution	Passes The Test	Not mentioned	Sample solution should be clear and not more intensely coloured than reference solution Y7	
8	Fumaric acid	Passes The Test	NMT 1.0%	NMT 1.5%	
9	Malic acid	Not mentioned	NMT 0.5%	Not mentioned	
10	Iron	NMT 0.0005%	NMT 5 ppm	NMT 5 ppm	
11	Residue on Ignition/Sulphated ash	NMT 0.1%	NMT 0.1%	NMT 0.1%	
12	Matter insoooble in water	Passes The Test	Not mentioned	Not mentioned	
13	Heavy metals	NMT 0.001%	Not mentioned	Not mentioned	
14	Assay (anhydrous basis)	Between 99.0% and 101.0%	Between 98.0% and 102.0%	Between 99.0% and 101.0%	
15	Elemental Impurities		Not mentioned	Not mentioned	
	Cd	NMT 0.5 ppm			
	Pb	NMT 2 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 0.8 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				
16	Residual solvents	Passes The Test	Not mentioned	Not mentioned	

	Storage	Storage away from direct light	Preserve in tight glass containers, protected from light. Store at room temperature.	Store in a glass container, protected from light.	
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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.