



" clyzo " - Monograph Comparison



AS PER CURRENT USP 2022/EP11/JP18

Product Name	Fumaric Acid (USP-NF) pure, pharma grade		Issue Date	March-23
Product Code	142344		Prepared by	Sr. Tech Lead
CAS NO.	110-17-8		Reviewed by	Manager Technical
Manufacturer Name	PanReac AppliChem		Version no.	CLYZO/PAN/142344/01

Sr. No.	Test	Pharmacoepial Specifications			
		Manufacturer COA	Pharmacoepial Specifications		
		<i>Complies USP</i>	<i>USP 2022</i>	<i>EP Version 11.0</i>	<i>JP 18</i>
1	Description	White small crystals	White, odorless granules or crystalline powder.	Product Not Official in European Pharmacopoeia	Product Not Official in Japanese Pharmacopoeia
2	Solubility	Slightly soluble in water	Soluble in alcohol; slightly soluble in water and in ether; very slightly soluble in		
3	Identification 1	Passes The Test	The Infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with Fumaric Acid reference standard/working standard		
4	Identification 2	Passes The Test	In the assay test, the retention time of the principal peak in the sample solution corresponds to that of the standard solution		
5	Water	NMT 0.5%	NMT 0.5%		
6	Residue on Ignition	NMT 0.1%	NMT 0.1%		
7	Related substances	Maleic acid: NMT 0.1%	Malic acid: NMT 1.5% Maleic acid: NMT 0.5%		
8	Chloride	NMT 0.005%	Not mentioned		
9	Sulfate	NMT 0.01%	Not mentioned		
10	Iron	NMT 0.001%	Not mentioned		
11	Matter insoluble in water	NMT 0.05%	Not mentioned		
12	Assay (Anhydrous Basis)	Between 99.5% and 100.5%	Between 98.0% and 102.0%		
13	Elemental Impurities		Not mentioned		
	Cd	NMT 0.5 ppm			
	Pb	NMT 0.5 ppm			
	As	NMT 1 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				
14	Residual solvents	Passes The Test	Not mentioned		

	Storage	Storage below 25°C. Storage away from direct light.	Preserve in well-closed containers.		
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.					