



" clyzo " - Monograph Comparison



AS PER CURRENT USP 2022/EP11/JP18

Product Name	Folic acid crystalline (Ph. Eur., USP) pure, pharma grade		Issue Date	March-23
Product Code	A7092		Prepared by	Sr. Tech Lead
CAS NO.	59-30-3		Reviewed by	Manager Technical
Manufacturer Name	PanReac AppliChem		Version no.	CLYZO/PAN/A7092/01

Sr. No.	Test	Manufacturer COA	Pharmacopeial Specifications		
		Complies USP, Ph. Eur	USP 2022	EP Version 11.0	JP 18
1	Description	Solid	Yellow, yellow-brownish, or yellowish-orange, odorless, crystalline powder.	Yellowish or orange, crystalline powder.	Yellow to orange-yellow crystalline powder. It is odorless. It is slowly affected by light.
2	Solubility	Not mentioned	Soluble in hot, 3 N HCl, in hot, 2 N H2SO4, in HCl, and in H2SO4, yielding very pale yellow solutions; very slightly soluble in water; insoluble in alcohol, in acetone, in chloroform, and in ether. It readily dissolves in dilute solutions of alkali hydroxides and carbonates	Practically insoluble in water and in most organic solvents. It dissolves in dilute acids and in alkaline solutions.	It is practically insoluble in water, in methanol, in ethanol (95), in pyridine and in diethyl ether. It dissolves in HCl, in H2SO4, in dilute NaOH TS and in a 1% solution of sodium carbonate decahydrate and these solutions are yellow in color.
3	Identification 1	Passes The Test	UV absorption spectrum obtained with sample shows maxima at 256 and 365 nm, ratio of absorbance at 256 to 365 nm is between 2.8 and 3.0	Specific optical rotation should be between +18° to +22°	UV absorption spectrum obtained with sample shows maxima at the same wavelength as of standard
4	Identification 2	Passes The Test	Not mentioned	The infrared absorption spectrum obtained with sample should be concordant with spectrum obtained with Folic acid RS/WS	Should comply by blue fluorescence formation
5	Identification 3	Passes The Test	Not mentioned	By TLC, the principal spot in the chromatogram obtained with the test solution is similar in position, fluorescence and size to the principal spot in the chromatogram obtained with the reference solution.	Not mentioned
6	Identification 5	Passes The Test	Not mentioned	Should comply with water content test	Not mentioned
7	Clarity and colour of solution	Not mentioned	Not mentioned	Not mentioned	Sample solution should be clear and yellow in color
8	Free Amines	Not mentioned	Not mentioned	Not mentioned	NMT 1.0%
9	Related Compounds/substances	NMT 2.0%	NMT 2.0%	Impurity A: NMT 0.5% Impurity D: NMT 0.4% Impurity C,E,G: NMT 0.3% each Impurity H, I: NMT 0.15% each Maximum unknown impurity: NMT 0.1% Total impurities: NMT 1.2%	Not mentioned
10	Water	Between 5.0% and 8.5%	NMT 8.5%	Between 5.0% and 8.5%	NMT 8.5%
11	Sulfated ash	NMT 0.2%	Not mentioned	NMT 0.2%	Not mentioned
12	Residue on ignition	Not mentioned	NMT 0.3%	Not mentioned	NMT 0.5%
13	Assay (Anhydrous basis)	Between 97.0% and 102.0%	Between 97.0% and 102.0%	Between 96.0% and 102.0%	Between 98.0% and 102.0%
	Storage	Store protected from light	Preserve in well-closed, light-resistant containers	Protected from light, under inert gas.	Tight light resistant 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.