



Sri Krishna Pharma
Trusted partners for life's journey

CERTIFICATE OF ANALYSIS

PRODUCT		FOLIC ACID HYDRATE BP (IH.W.STD)		
BATCH No.		WS/FA/003/24-25	DATE OF PREPARATION	31.08.2024
BATCH SIZE		250 gm	VALID UP TO	30.08.2025
AR/WSD/No.		AR/WSD/0011/24-25	ISSUE DATE	31.08.2024
S.No.	TESTS PERFORMED	RESULTS	SPECIFICATIONS	METHOD
01	Characters :			
	Appearance	Yellowish crystalline powder.	Yellowish or orange, crystalline powder.	BP
	Solubility	Complies	Practically insoluble in water and in most organic solvents. It dissolves in dilute acids and in alkaline solutions.	
02	Identification			
	A. Specific optical rotation (anhydrous substance)	+20.6°	+18° to +22°	BP 2.2.7
	B. Infrared absorption Spectrophotometry .	Conforms	The I.R. absorption Spectrum should be concordant with the reference spectrum of folic acid IH.W.STD.	BP 2.2.24
	C. Thin-Layer chromatography.	Conforms	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.	BP 2.2.27
	D. Water	8.0%	5.0% to 8.5%	BP 2.5.12
03	Related substances (Liquid chromatography)			BP 2.2.29
	Impurity A (p-ABGA)	0.1%	Not more than 0.5%	
	Impurity D (Pteric acid)	0.3%	Not more than 0.4%	
	Impurity C	0.1%	Not more than 0.3%	
	Impurity E	Below reporting threshold	Not more than 0.3%	
	Impurity G	Below reporting threshold	Not more than 0.3%	
	Impurity H	0.09%	Not more than 0.15%	
	Impurity I	0.09%	Not more than 0.15%	
	Unspecified impurities	0.07%	Not more than 0.10%	
04	Total impurities			BP 2.5.12
	8.0%			
05	5.0% to 8.5%			BP 2.2.29
	Assay (Liquid chromatography)			
05	99.8%			BP 2.2.29
	Assay (As is basis by Liquid chromatography)			
05	91.73%			BP 2.2.29

REMARKS: The material CONFORMS to the specifications of BP 2024

PREPARED BY: <u>A</u>	CHECKED BY: <u>G. Sathish</u>	APPROVED BY: <u>K. J</u>
Sr. Executive-QC/Designate	Head-QC/Designate	Head-QA/Designate
DATE: <u>31/08/2024</u>	DATE: <u>31/08/2024</u>	DATE: <u>31/08/2024</u>
ISSUED TO: ---		Qty: ---

Note: STORAGE TEMPERATURE: 2°C to 8°C

EP Ref. Std.: 9.0

QC/GEN/014-F-01/03

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