

Certificate of Analysis

Product name: Acidum folicum
Batch number / Weight: 24K07-B04-012547 / 25 g
Producer / Producer Batch Number: SRI KRISHNA Pharmaceuticals Ltd - Unit 3 / FX09/24-25
Analyzed according to: Ph.Eur 11.7
Number of Analysis / Certificate no.: 24K07-B04 / QO0019066

	Requirement	Result	Unit	Standard remark
Appearance	yellowish or orange, crystalline powder	Conform		
Identification	A,B,D	Conform		
Related substances	Conform	Conform		
Impurity A	<=0,5	0,14	%	
Impurity D	<=0,4	0,26	%	
Impurity C	<=0,3	0,08	%	
Impurity E	<=0,3	<0,05	%	
Impurity G	<=0,3	0,05	%	
Impurity H	<=0,15	0,092	%	
Impurity I	<=0,15	0,129	%	
Any other impurity	<=0,10 for each	0,054	%3	
Total impurities	<=1,2	0,80	%	
Water (Karl Fischer)	5,0 - 8,5	7,86	%	
Sulfated ash	<= 0,2	0,00	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		DP
Residual solvents	CPMP/ICH/82 260/06	Conform		DP
Assay	96,0 - 102,0	98,85	% m/m	
TSE/BSE-statement:	EMA/410/01 guidance compliant – no contamination	Conform		DP

All the manufacturing stages of this batch have been carried out in full compliance with the GMP requirements of the EU and with the national legal requirements.

Analysis performed by the authorized lab FSNE lab

Release:

29-7-2025
 Agnieszka Pszczółka
 Qualified Person

Expiration: 31-7-2029

Conclusion: APPROVED

This document has been produced electronically from our quality system and is valid without signature.