Certificate of Analysis

Product name: **Acidum folicum**

Batch number / Weight: **22G18-B01-220210 / 5 G**

Analysed according to: **Ph.Eur.10.8**

Number of analysis / Inspection Code **22G18-B01 / INS-22-6411**

Reference Code / No.: **V01929 / FX01/22-23**

Tests	Requirement	Result	Unit	Standard remark
Appearance	Yellow or orange, crystalline powder	Conform		
Identification A	+18 - +22	+19,8		
Identification B	Conform	Conform		
Identification D		7,84	%	
Related substances	Conform	Conform		
Impurity A	<=0,5	0,11	%	
Impurity D	<=0,4	0,21	%	
Impurity C	<=0,3	0,06	%	
Impurity E	<=0,3	0,00	%	
Impurity G	<=0,3	<0,05	%	
Impurity H	<=0,15	0,089	%	
Impurity I	<=0,15	0,094	%	
Any other impurity	<=0,10	0,063	%	
Total of other impurities	<=1,2	0,63	%	
Water (Karl Fischer)	5,0 - 8,5	7,84	%	
Sulphated ash	<= 0,2	0,00	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Folic acid	96,0 - 102,0	99,56	%	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Residual solvents				
Methanol		<3000	ppm	
Acetone		<5000	ppm	
Buthanol	<= 5000 ppm	<5000	ppm	
Toluene		0,0	ppm	
Dimethylformamide	<880 ppm	0,0	ppm	
Kwas octowy		158,2	ppm	

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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 Fagron PL lab

Release:
Agnieszka Pszczółka
Qualified Person

14-10-2022

Expiration: 31-03-2027

Conclusion: APPROVED

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