

Certificate of Analysis

Product name: **Troxerutinum (Vitamine P4)**

Batch number / Weight: **22F02-B14-224375 / 100 G**

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

Number of analysis / Inspection Code **22F02-B14 / INS-22-5533**

Reference Code / No.: **V01493 / C002K220401**

Tests	Requirement	Result	Unit	Standard remark
Appearance	Yellow-green, crystalline powder, slightly hygroscopic	Conform		
Identification A	Conform	Conform		
Identification B	Conform	Conform		
Composition	Conform	Conform		
Principal peak	≥ 80	88,85	%	
Any other peak	≤ 5	2,04	%	
1 peak $\leq 10\%$	≤ 10	4,02	%	
Ethylene oxide	≤ 1	0,0	ppm	
Loss on drying	$\leq 5,0$	1,02	%	
Sulphated ash	$\leq 0,4$	0,20	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Troxerutine	95,0 - 105,0	99,52	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

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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:
Ewelina Gadzinowska
Qualified Person

28-10-2022

Expiration: 28-02-2025

Conclusion: APPROVED

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