

Certificate of Analysis

Product name: **Diosminum**
Batch number / Weight: **22B02-B07-224246 / 1 KG**
Analysed according to: **Ph.Eur.10.8**
Number of analysis / Inspection Code **22B02-B07 / INS-22-4041**
Reference Code / No.: **V01493 / C006X211232**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Greyish-)yellow to light yellow powder, hygroscopic	Conform		
Apparent volume	About 0,4	0,66	g/ml	
Identification A	Conform	Conform		
Identification B	Conform	Conform		
Iodine	<=0,1	<0,1	%	
Related substances	Conform	Conform		
Impurity A	<=0,5	<0,10	%	
Impurity B	<=4,0	0,00	%	
Impurity C	<=3,0	1,10	%	
Impurity D	<=0,6	<0,10	%	
Impurity E	<=3,0	1,38	%	
Impurity F	<=2,0	0,65	%	
Unspecified impurities	<=0,4	0,21	%	
Total impurities	<=8,5	3,44	%	
Water (Karl Fischer)	<=6,0	3,68	%	
Sulphated ash	<=0,2	0,00	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		
Residual solvents	CPMP/ICH/82 260/06	Conform		
Assay Diosmin	90,0 - 102,0	95,21	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		
Residual solvents				
Methanol	<= 3000	<3000	ppm	
Ethanol	<= 5000	<5000	ppm	
Pyridine	<= 200	<200	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, Eurofins

Release:
Dominika Soltysik
Qualified Person

26-09-2022

Expiration: 20-12-2025

Conclusion: APPROVED

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