

Certificate of Analysis

Product name: **Diosminum**

Batch number / Weight: **21C23-B02-219360 / 1 KG**

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

Tests	Requirement	Result	Unit	Standard remark
Appearance	powder, hygroscopic (Greyish-)yellow to light yellow	Conform		
Apparent volume	About 0,4	0,63	g/ml	
Identification A	Conform	Conform		IR-spectrum
Identification B	Conform	Conform		HPLC
Iodine	<=0,1	<0,1	%	
Related substances	Conform	Conform		HPLC
Impurity A	<=0,5	<0,10	%	
Impurity B	<=4,0	0,11	%	
Impurity C	<=3,0	2,19	%	
Impurity D	<=0,6	0,0	%	
Impurity E	<=3,0	1,60	%	
Impurity F	<=2,0	0,78	%	
Unspecified impurities	<=0,4	0,39	%	
Total impurities	<=8,5	5,28	%	
Water (Karl Fischer)	<=6,0	4,38	%	
Sulphated ash	<=0,2	0,03	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Diosmin	90,0 - 102,0	91,61	%m/m	HPLC, anhydrous
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized lab.

Release:

Agnieszka Pszczółka

Qualified Person

03-03-2022

Expiration: 06-04-2024

Conclusion: APPROVED

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