

Certificate of Analysis

Product name: **Diosminum**

Batch number / Weight: **21K20-B02-216945 / 1 KG**

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

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Greyish-)yellow to light yellow powder, hygroscopic	Conform		
Apparent volume	About 0,4	0,48	g/ml	
Identification A	Conform	Conform		
Identification B	Conform	Conform		
Iodine	$\leq 0,1$	$< 0,1$	%	
Related substances	Conform	Conform		
Impurity A	$\leq 0,5$	0,11	%	
Impurity B	$\leq 4,0$	$< 0,05$	%	
Impurity C	$\leq 3,0$	0,97	%	
Impurity D	$\leq 0,6$	$< 0,05$	%	
Impurity E	$\leq 3,0$	1,19	%	
Impurity F	$\leq 2,0$	0,70	%	
Unspecified impurities	$\leq 0,4$	0,11	%	
Total impurities	$\leq 8,5$	3,11	%	
Water (Karl Fischer)	$\leq 6,0$	4,02	%	
Sulphated ash	$\leq 0,2$	0,09	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		
Residual solvents	CPMP/ICH/82 260/06	Conform		
Assay Diosmin	90,0 - 102,0	94,5	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		

Analysis performed by the authorized lab.

Release:

Dominika Soltysik

Qualified Person

25-04-2022

Expiration: 26-07-2025

Conclusion: APPROVED

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