

Certificate of Analysis

Product name: **Acidum ascorbicum cryst.**

Batch number / Weight: **22A21-B05-222259 / 1 KG**

Analysed according to: **Ph.Eur.10**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder	Conform		
Identification B	Conform	Conform		
Identification C	2,1 - 2,6	2,34		
Appearance of solution	Clear /<=BY7	Conform		
Specific optical rotation	+20,5 - +21,5	+20,9		
Impurity E	<=0,2	<0,2	%	
Related substances	Conform	Conform		
Impurity C	<=0,15	<0,05	%	
Impurity D	<=0,15	<0,05	%	
Unspecified impurities	<=0,10	<0,05	%	
Total impurities other than C and	<=0,2	<0,05	%	
Iron	<= 2,0	Conform	ppm	
Copper	<= 5,0	Conform	ppm	
Sulphated ash	<= 0,1	0,03	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Ascorbic acid	99,0 - 100,5	99,4	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Residual solvents				
Methanol		<3000	ppm	

Analysis performed by the authorized lab.

Release:
Agnieszka Pszczółka
Qualified Person

17-08-2022

Expiration: 31-10-2024

Conclusion: APPROVED

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