

Certificate of Analysis

Product name:Acidum ascorbicum cryst.Batch number / Weight:21H24-B02-217882 / 100 GAnalysed according to:Ph. Eur.

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder	Conform		
Identification B	Conform	Conform		
Identification C	2,1 - 2,6	2,40		
Appearance of solution	Clear /<=BY7	Conform		
Specific optical rotation	+20,5 - +21,5	+20,7		
Impurity E	<=0,2	<0,2	%	
Related substances	Conform	Conform		
Impurity C	<=0,15	0,096	%	
Impurity D	<=0,15	0,019	%	
Unspecified impurities	<=0,10	0,052	%	
Total impurities other than C and	J <=0,2	0,05	%	
Iron	<= 2,0	Conform	ppm	
Copper	<= 5,0	Conform	ppm	
Sulphated ash	<= 0,1	0,04	%	
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	100,03	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized lab.

Release: Dominika Sołtysik Qualified Person

31-03-2022

Expiration: 30-04-2024

Conclusion: APPROVED

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