

Certificate of Analysis

Product name: **Acidum ascorbicum cryst.**

Batch number / Weight: **23L04-B10-236010 / 250 G**

Analysed according to: **Ph.Eur.11.3**

Number of analysis / Inspection Code **23L04-B10 / INS-24-0969**

Reference Code / No.: **V01336 / 3230123123**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder becoming discoloured on exposure to air and moisture	Conform		
Identification B	Conform	Conform		
Identification C	2,1 - 2,6	2,33		
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	0,072	%	
Impurity D	<=0,15	<0,05	%	
Unspecified impurities	<=0,10	<0,05	%	
Total imp. other than C and D	<=0,2	0,00	%	
Iron	<= 2	<1	ppm	
Copper	<= 5	<1	ppm	
Sulphated ash	<= 0,1	0,02	%	
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	99,77	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

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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 lab

Release:
Ewelina Gadzinowska
Qualified Person

16-02-2024

Expiration: 30-06-2026

Conclusion: APPROVED

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