

Certificate of Analysis

Productname: **Acidum ascorbicum pulv.**
Number of analysis/Inspection Code: 1 / KEUR-184090B
Batchnumber: **20E18-F02-371610**
Reference code / No.: 3645 / TL02004365
Analysed according to: **PH.EUR10.2**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder or colorless crystals,	Conform		
Identification B	Conform	Conform		IR-spectrum
Identification C	2,1 - 2,6	2,3		pH
Appearance of solution	Clear / <=BY7	Conform		5% <i>m/V</i>
Specific optical rotation	+20,5 - +21,5	+20,9	°	
Impurity E	<= 0,2	Conform	%	
Related substances	Conform	Conform		HPLC
Impurity C	<=0,15	0,05	%	
Impurity D	<=0,15	n.d.	%	
Unspecified impurities	<=0,10	<0,05	%	
Total impurities other than C and D	<=0,2	0,1	%	
Copper	<= 5	Conform	ppm	AAS
Iron	<=2	Conform	ppm	AAS
Sulphated ash	<= 0,1	Conform	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
Assay Ascorbic acid	99,0 - 100,5	99,6	% <i>m/m</i>	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized laboratory Proxylabs.

Release:
 Paul Hofman
 Pharmacist - Qualified Person

07/08/20

Expiration: 04-2023

Conclusion: APPROVED

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