

Certificate of Analysis

Product name: **Acidum ascorbicum pulv.**

Batch number / Weight: **22G01-B01-221702 / 250 G**

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

Tests	Requirement	Result	Unit	Standard remark
Appearance	White, crystalline powder crystals, becoming discoloured on exposure to air and moisture	Conform		
Particle size	$\geq 70\% < 180 \mu\text{m}$	Conform	%	
Identification B	Conform	Conform		
Identification C	2,1 - 2,6	2,34		
Appearance of solution	Clear / $\leq \text{BY7}$	Conform		
Specific optical rotation	+20,5 - +21,5	+21,0		
Impurity E	$\leq 0,2$	$< 0,2$		
Related substances	Conform	Conform		
Impurity C	$\leq 0,15$	0,079	%	
Impurity D	$\leq 0,15$	0,000	%	
Unspecified impurities	$\leq 0,10$	0,096		
Total impurities other than C and	$\leq 0,2$	0,10	%	
Copper	≤ 5	< 1	ppm	
Iron	$\leq 2,0$	< 1	ppm	
Sulphated ash	$\leq 0,1$	0,00	%	
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	100,04	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Residual solvents				
Methanol	$< 3000 \text{ ppm}$	< 3000	ppm	

Analysis performed by the authorized lab.

Release:

Agnieszka Pszczółka

Qualified Person

18-08-2022

Expiration: 31-05-2024

Conclusion: APPROVED

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