

Certificate of Analysis

Product name: **Acidum ascorbicum pulv.**

Batch number / Weight: **22G01-B01-226323 / 250 G**

Analysed according to: **Ph.Eur.10.8**

Number of analysis / Inspection Code **22G01-B01 / INS-22-5625**

Reference Code / No.: **V01336 / 220122151**

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	$\leq 0,2$	$\leq 0,2$		
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	

fagron.pl

Fagron Sp. z o.o.
 ul. Armii Krajowej 3
 32-540 Trzebinia, Poland
 e-mail: biuro@fagron.pl

fagron.pl

Fagron sp. z o.o.
 ul. Pasternik 26, 31-354 Kraków, Poland
 tel.: +48 12 3343 512
 e-mail: biuro@fagron.pl

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 FAPL, EISpol, CBMiA

Release:

Agnieszka Pszczółka

Qualified Person

28-12-2022

Expiration: 31-05-2024

Conclusion: APPROVED

This document has been produced electronically from our quality system and is valid without signature.

fagron.pl

Fagron Sp. z o.o.
ul. Armii Krajowej 3
32-540 Trzebinia, Poland
e-mail:biuro@fagron.pl