

Certificate of Analysis

Product name: **Coffeinum**

Batch number / Weight: **22A19-B05-223312 / 25 G**

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

Number of analysis / Inspection Code **22A19-B05 / INS-22-4248**

Reference Code / No.: **V00581 / 21091469**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder	Conform		
Appearance	or silky (almost) white crystals			
Identification A	234 - 239	237,9	°C	
Identification B	Conform	Conform		
Identification E	<= 0,5	Conform	%	
Appearance of solution	Clear and colourless	Conform		
Acidity	Conform	0,05 ml NaO	ml	
Related substances	Conform	Conform		
Unspecified impurities	<=0,10	<0,05		
Total impurities	<=0,10	0,00	%	
Sulphates	<= 500	Conform	ppm	
Loss on drying	<=0,5	0,02	%	
Sulfated ash	<= 0,1	0,03	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		
Residual solvents	CPMP/ICH/82 260/06	Conform		
Assay Caffeine	98,5 - 101,5 (dried substance)	99,49	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		
Residual solvent - chloroform	<= 60	<60	ppm	

fagron.pl Fagron Sp. z o.o.
 ul. Armii Krajowej 3
 32-540 Trzebinia, Poland
 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 FAGRON PL lab

Release:
Ewelina Gadzinowska
Qualified Person

21-10-2022

Expiration: 30-09-2025

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