

Certificate of Analysis

Product name: Cetyl esters wax

Batch number / Weight: 23E17-B01-226311 / 250 G

Analysed according to: USP

Number of analysis / Inspection Code 23E17-B01 / INS-23-4374

Reference Code / No.: V01482 / 0002082472

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, fatty flakes having a crystalline structure and a pearly luster when caked	Conform		
Identification A	Conform	Conform		
Identification B	109-120	114,6		
Total saturated fatty esters	>= 90,0	94,36	%	
Fatty esters CC32	>= 10,0	25,49	%	
Total free fatty alcohols and free fatty acids	<= 10,0	5,09	%	
Melting point	43 - 47	43,8	°C	
Acid value	<=5	0,43		
Iodine value	<=1	0,27		
Paraffines and free acids	Conform	Conform		
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

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 FAGRON PL lab

Release:
Dominika Soltysik
Qualified Person

22-06-2023

Expiration: 10-10-2024

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