

Certificate of Analysis

Product name: Cera alba
Batch number / Weight: 22I21-B06-224048 / 1 KG
Analysed according to: Ph. Eur. 10.8
Number of analysis / Inspection Code 22I21-B06 / INS-22-8617
Reference Code / No.: V01202 / 22-0321

Tests	Requirement	Result	Unit	Standard remark
Appearance	<p>white or yellowish-white pieces or plates, translucent when thin</p> <p>with a fine-grained, matt and non-crystalline fracture</p> <p>matt and non-crystalline fracture, when warmed It has an odour similar to that of yellow beeswax,</p> <p>though fainter and never rancid. It is tasteless and does not stick to the teeth.</p>	Conform		
Odour	Like yellow wax, only faint, never rancid	Conform		
Drop point	61 - 66	61,5	°C	
Acid value	17,0 - 24,0	17,39		
Estervalue	70 - 80	74,5		
Saponification value	87 - 104	91,86		
Ceresine, paraffine and other wa	Conform	Conform		
Glycerol and other polyols	<=0,5	<0,5	%	
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
Density	about 0,960	0,9627		
Total aerobic microbial count (TA	<=10 ³	<10	CFU/g	
Total yeasts and moulds (TYMC)	<=10 ²	<10	CFU/g	

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,CBMiA

Release:

Ewelina Gadzinowska

Qualified Person

21-11-2022

Expiration: 13-07-2025

Conclusion: APPROVED

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