

Certificate of Analysis

Product name: **Cera alba**
Batch number / Weight: **23I12-B02-237792 / 1 KG**
Analysed according to: **Ph.Eur.11.3**
Number of analysis / Inspection Code **23I12-B02 / INS-23-7005**
Reference Code / No.: **V01202 / 23-0367**

Tests	Requirement	Result	Unit	Standard remark
Appearance	white or yellowish-white pieces or plates, translucent when thin	Conform		
Appearance	with a fine-grained, matt and non-crystalline fracture			
Appearance	when warmed in the hand they become soft and malleable.			
	It has an odour similar to that of yellow beeswax,			
	though fainter and never rancid.			
Appearance	It is tasteless and does not stick to the teeth.			
Odour	Like yellow wax, only faint, never rancid			
Drop point	61 - 66	61,0	°C	
Acid value	17,0 - 24,0	18,19		
Estervalue	70 - 80	76,4		
Saponification value	87 - 104	94,61		
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	0,9587		

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Total aerobic microbial count (TA $\leq 10^3$
Total yeasts and moulds (TYMC) $\leq 10^2$

<10 CFU/g
<10 CFU/g

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:

Agnieszka Pszczółka
Qualified Person

13-03-2024

Expiration: 18-07-2026

Conclusion: APPROVED

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

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