

Certificate of Analysis

Product name: **Cetyl esters wax**

Batch number / Weight: **23L28-B08-235194 / 250 G**

Analysed according to: **USP**

Number of analysis / Inspection Code **23L28-B08 / INS-24-1177**

Reference Code / No.: **V01482 / 51608**

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	112,9		
Total saturated fatty esters	>= 90,0	92,33	%	
Fatty esters CC32	>= 10,0	24,99	%	
Total free fatty alcohols and free fatty acids	<= 10,0	7,41	%	
Melting point	43 - 47	43,67	°C	
Acid value	<=5	0,32		
Iodine value	<=1	0,21		
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

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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

28-02-2024

Expiration: 12-06-2025

Conclusion: APPROVED

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