

Certificate of Analysis

Product name: **Alc. cetylicus et stearylicus**

Batch number / Weight: **22C11-B01-222963 / 250 G**

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

Number of analysis / Inspection Code **22C11-B01 / INS-22-3842**

Reference Code / No.: **V01160 / 89800**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, waxy granules or flakes	Conform		
Identification GC	Conform	Conform		
Appearance of solution	Clear / colour <=B6	Conform		
Melting point	49 - 56	52,2	°C	
Acid value	<=1,0	0,03		
Hydroxyl value	208 - 228	220,1		
Iodine value	<=2,0	0,14		
Saponification value	<=2,0	0,10		
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Stearyl alcohol	>= 40,0	48,45	%m/m	
Cetyl alcohol and stearyl alcohol	>= 90,0	99,62	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Residual solvents				
Methanol		<3000	ppm	
Ethanol	not more than 2000 ppm	<5000	ppm	
2-propanol	<= 5000	<5000	ppm	
Heptane	<= 5000	<5000	ppm	
Hexane	<= 290	<290	ppm	
1-Butanol	<= 5000	0,0	ppm	

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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

27-09-2022

Expiration: 31-12-2023

Conclusion: APPROVED

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