

Certificate of Analysis

Product name: **Alcohol cetylicus**
Batch number / Weight: **22E24-B03-220827 / 1 KG**
Analysed according to: **Ph.Eur.10.8**
Number of analysis / Inspection Code **22E24-B03 / INS-22-6412**
Reference Code / No.: **V01252 / 0025742878**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, waxy flakes or granules powder, flakes or granules	Conform		
Identification	Conform	Conform		
Appearance of solution	Clear / $\leq B6$	Conform		
Melting point	46 - 52	50,94	°C	
Acid value	$\leq 1,0$	0,03		
Hydroxyl value	218 - 238	228,4		
Iodine value	$\leq 2,0$	0,25		
Saponification value	$\leq 2,0$	0,14		
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay	$\geq 95,0$	98,41	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Methanol		<3000	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:

Agnieszka Pszczółka

Qualified Person

09-09-2022

Expiration: 22-02-2024

Conclusion: APPROVED

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