

Certificate of Analysis

Product name: **Cetomacrogolum 1000**
Batch number / Weight: **23H29-B04-232063 / 100 G**
Analysed according to: **Ph.Eur.11.2**
Number of analysis / Inspection Code **23H29-B04 / INS-23-6758**
Reference Code / No.: **V01252 / 0027029448**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, waxy flakes or granules microbeads or flakes	Conform		
Solidifies	32 - 52	41,0	° C	
Identification A	Conform	Conform		
Identification B	Conform	Conform		
Identification C	Conform	Conform		
Identification D	Conform	Conform		
Identification E	Conform	Conform		
Appearance of solution	acc to Ph. Eur	Conform		
Alcalinity	Conform	0,00	ml	
Acid value	<=1,0	0,08		
Hydroxyl value	40 - 55	50,3		
Saponification value	<=3,0	1,25		
Iodine value	<=2,0	0,96		
Total ash	<=0,2	0,06	%	
Ethylene oxide and dioxan	<= 1 / 10	0/0	ppm	
Water (Karl Fischer)	<=3,0	0,95	%	
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:

Agnieszka Pszczółka

Qualified Person

05-10-2023

Expiration: 05-03-2025

Conclusion: APPROVED

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