

Certificate of Analysis

Product name: **Cetomacrogolum 1000**

Batch number / Weight: **22G07-B12-220273 / 100 G**

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

Number of analysis / Inspection Code **22G07-B12 / INS-22-6290**

Reference Code / No.: **V01252 / 0026007581**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, waxy flakes or granules	Conform		
Solidifying temperature	32-52	40,0	°C	
Identification A	40 - 55	Conform		
Identification B	<=2,0	Conform		
Identification C	<=3,0	Conform		
Identification D	Conform	Conform		
Identification E	Conform	Conform		
Appearance of solution	<=BY5	Conform		
Alcalinity	Conform	Conform		
Acid value	<=1,0	0,11		
Hydroxyl value	40 - 55	52,6		
Iodine value	<=2,0	0,16		
Saponification value	<=3,0	0,14		
Ethylene oxide	<= 1	0,0	ppm	
Dioxane		0,0	ppm	
Water (Karl Fischer)	<=3,0	0,34	%	
Total ash	<=0,2	0,15	%	
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
Remark	= Macrogoli aether cetostearyllicus 20			

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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:
Ewelina Gadzinowska
Qualified Person

31-08-2022

Expiration: 03-05-2024

Conclusion: APPROVED

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