

Certificate of Analysis

Product name: Cera cetomacrogolis emuls.

Batch number / Weight: 22E16-B07-224286 / 500 G

Analysed according to: British Pharmacopoeia

Number of analysis / Inspection Code 22E16-B07 / INS-22-5773

Reference Code / No.: V01252 / 0025863911

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, waxy flakes or granules	Conform		
Identification A	Conform	Conform		
Identification B	Conform	Conform		
Acid value	$\leq 0,5$	0,06		
Refractive index	1,435 - 1,439	1,437		
Freezing point	45 - 53	48,0	°C	
Alcalinity	Conform	Conform		
Sulphated ash	$\leq 0,1$	0,05	%	
Hydroxyl value	175-192	188,9		
Saponification value	$\leq 2,0$	0,27		
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

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 EL Spol

Release:

Agnieszka Pszczółka

Qualified Person

26-10-2022

Expiration: 23-03-2024

Conclusion: APPROVED

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