

## Certificate of Analysis

**Product name:** **Cera cetomacrogolis emuls.**

**Batch number / Weight:** **23J31-B02-233560 / 500 G**

**Analysed according to:** **British Pharmacopoeia**

**Number of analysis / Inspection Code** **23J31-B02 / INS-24-0001**

**Reference Code / No.:** **V01252 / 0027158686**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, waxy flakes or granules when heated to a clear almost colourless liquid	Conform		
Identification A	Conform	Conform		
Identification B	Conform	0,00	%	
Acid value	$\leq 0,5$	0,03		
Refractive index	1,435 - 1,439	1,439		
Freezing point	45 - 53	48,0	°C	
Alcalinity	Conform	0,00	ml	
Sulphated ash	$\leq 0,1$	0,00	%	
Hydroxyl value	175-192	187,8		
Saponification value	$\leq 2,0$	0,28		
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Metallic residues	CHMP/ICH/353369/2013	Conform		

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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, EI Spol

Release:

Agnieszka Pszczółka

Qualified Person

24-01-2024

Expiration: 17-04-2025

Conclusion: APPROVED

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