

Certificate of Analysis

Product name: Cera cetomacrogolis emuls.

Batch number / Weight: 22K09-B05-221385 / 500 G

Analysed according to: British Pharmacopoeia

Number of analysis / Inspection Code 22K09-B05 / INS-22-9959

Reference Code / No.: V01252 / 0026391733

| 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 | 0,06 | % | |
| Acid value | $\leq 0,5$ | 0,06 | | |
| Refractive index | 1,435 - 1,439 | 1,4390 | | |
| Freezing point | 45 - 53 | 49 | °C | |
| Alcalinity | Conform | Conform | | |
| Sulphated ash | $\leq 0,1$ | 0,06 | % | |
| Hydroxyl value | 175-192 | 191,3 | | |
| Saponification value | $\leq 2,0$ | 0,5 | | |
| 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:
Ewelina Gadzinowska
Qualified Person

18-01-2023

Expiration: 20-08-2024

Conclusion: APPROVED

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