

CERTIFICATE OF ANALYSIS

Batch: 25B05-H100105330
Product: Gebufferde cetomacrogolcrème TMF 1Kg
Production date: 05 FEB 2025
Expiry date: 05 FEB 2027
Analysed according to: HeW Pharma Monograph
Analysis performed on: 07 MAY 2025

PERFORMED ANALYSIS AND RESULTS

Analysis	Specification	Result
Appearance		
Appearance	White, homogenous cream	Complies
Identifications		
Cetomacrogol (TLC)	POSITIVE	POSITIVE
Cetostearylalcohol (TLC)	POSITIVE	POSITIVE
White Vaseline (TLC)	POSITIVE	POSITIVE
Potassium sorbate (HPLC)	POSITIVE	POSITIVE
Phosphates (Reaction)	POSITIVE	POSITIVE
Other tests		
pH (Eur. Ph. 2.2.3)	3.5 – 6.0	4,8
Emulsion type	O/W	O/W
Viscosity (RV7, 10 RPM)	20.000-60.000 mPa.s ⁻¹	23.067 mPa.s ⁻¹
Assay		
Potassium sorbate (HPLC)	0,243 – 0,297 %m/m	0,245 %m/m
Microbiology		
TAMC (Ph. Eur. 2.6.12)	NMT 10 ² CFU/g	< 10 CFU/g
TYMC (Ph. Eur. 2.6.12)	NMT 10 CFU/g	< 10 CFU/g
Exclusion S. aureus (Ph. Eur. 2.6.13)	ABSENT	ABSENT
Exclusion P. aeruginosa (Ph. Eur. 2.6.13)	ABSENT	ABSENT

Conclusion:

The batch complies with the specifications of the performed analysis and is thereby released.

BATCH RELEASED BY:

Dr. Apr. Ammar Kurdi

Responsible Pharmacist

Release date:

07 Mei 2025

