

CERTIFICATE OF ANALYSIS

Batch: 23H08-H100123146

Product: Gebufferde cetomacrogolcrème 1 kg

Production date: 08 AUG 2023

Expiry date: 08 AUG 2025

Analysed according to: HeW Pharma Monograph

Analysis performed on: 13 OCT 2023

Analysis	Specification	Result
Appearance		
Appearance	White, homogenous cream	Complies
Identifications		
Cetomacrogol (TLC)	POSITIEVE	POSITIVE
Cetostearylalcohol (TLC)	POSITIEVE	POSITIVE
White Vaseline (TLC)	POSITIEVE	POSITIVE
Potassium sorbate (HPLC)	POSITIEVE	POSITIVE
Phosphates (Reaction)	POSITIEVE	POSITIVE
Other tests		
pH (Ph. Eur. 2.2.3)	4.5 – 5.5	4.8
Emulsion type	O/W	O/W
Viscosity (RV7, 10 RPM)	20000 – 60000 mPa.s	34800
Assay		
Potassium sorbate (HPLC)	90 – 110% of the declared content	90%
Microbiology		
TAMC (Ph. Eur. 2.6.12)	NMT 100 CFU/g	< 10 CFU/g
TYMC (Ph. Eur. 2.6.12)	NMT 10 CFU/g	< 10 CFU/g
S. aureus (Ph. Eur. 2.6.13)	Absent	Absent
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:

02 NOV 2023

