

CERTIFICATE OF ANALYSIS

Batch: 25B25-H100405309

Product: Hydrofiële Carbomeergel 1Kg

Production date: 25 FEB 2025

Expiry date: 25 FEB 2028

Analysed according to: HeW Pharma Monograph

Analysis performed on: 27 MAR 2025

Analysis	Specification	Result
Appearance	Transparent gel	Complies
Identifications		
Propylene glycol (TLC)	POSITIVE	POSITIVE
Trometamol (TLC)	POSITIVE	POSITIVE
Carbomer 980 (Reaction)	POSITIVE	POSITIVE
EDTA (Reaction)	POSITIVE	POSITIVE
Propyl paraben (HPLC)	POSITIVE	POSITIVE
Methyl paraben (HPLC)	POSITIVE	POSITIVE
Other tests		
pH (Eur. Ph. 2.2.3)	6.0 – 8.0	7.0
Viscosity (RV7, 10 RPM)	40.000 – 60.000 mPa.s-1	46.800
Assay		
Methyl paraben (HPLC)	0.063 – 0.077 %	0.077
Propyl paraben (HPLC)	0.0162 – 0.0198 %	0.0183
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: 23 APR 2025

