

CERTIFICATE OF ANALYSIS

Batch: 21B26-H100401308

Product: Carbomeergel 1 kg

Expiry date: 26 FEB 2023

Analysed according to: HeW Pharma Monograph

PERFORMED ANALYSIS AND RESULTS

Analysis	Specification	Result
Characters		
Clear, colourless gel	CONFORM	CONFORM
Odourless	CONFORM	CONFORM
Identifications		
Propylene glycol (TLC)	POSITIVE	POSITIVE
Carbomer 980 (reaction)	POSITIVE	POSITIVE
EDTA (reaction)	POSITIVE	POSITIVE
Trometamol (TLC)	POSITIVE	POSITIVE
Propyl paraben (HPLC)	POSITIVE	POSITIVE
Methyl paraben (HPLC)	POSITIVE	POSITIVE
Other tests		
Ph (Ph. Eur. 2.2.3)	6,0 - 8,0	7,3
Viscosity		46133
Assay:		
Assay Propyl paraben (HPLC)	0,0162 - 0,0198 % m/m	0,018 % m/m
Assay Methyl paraben (HPLC)	0,062 - 0,077 % m/m	0,072 % m/m
Microbiology		
TAMC (Ph. Eur. 2.6.12)	NMT 10 ² CFU/g	<5 CFU/g
TYMC (Ph. Eur. 2.6.12)	NMT 10 CFU/g	<5 CFU/g
Exclusion P. aeruginosa (Ph. Eur. 2.6.13)	ABSENT	ABSENT
Exclusion S. aureus (Ph. Eur. 2.6.13)	ABSENT	ABSENT

RELEASE:

Conclusion: Conform

Date: 01 APR 2021

BATCH RELEASED BY:

Xavier Van Eecke

Responsible Pharmacist

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