

CERTIFICATE OF ANALYSIS

Batch: 21H10-H100111143

Product: Gebufferde cetomacrogolcrème 1 kg

Expiry date: 10 AUG 2022

Analysed according to: HeW Pharma Monograph

PERFORMED ANALYSIS AND RESULTS

Analysis	Specification	Result
Characters		
White, smooth, homogeneous cream	CONFORM	CONFORM
Odourless	CONFORM	CONFORM
Identifications		
Cetomacrogol (TLC)	POSITIVE	POSITIVE
Cetostearylalcohol (TLC)	POSITIVE	POSITIVE
Potassium sorbate (HPLC)	POSITIVE	POSITIVE
Paraffine/Vaseline (TLC)	POSITIVE	POSITIVE
Sodium Phosphates (reaction)	POSITIVE	POSITIVE
Other tests		
Emulsion type	O/W or W/O	O/W
Ph (Ph. Eur. 2.2.3)	4,5 - 5,5	4,9
Viscosity		24733
Assay:		
Assay Potassium Sorbate (HPLC)	0,243 - 0,297 % m/m	0,256 % 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: 20 SEP 2021

BATCH RELEASED BY:

Lieze CERULUS

Responsible Pharmacist

