

CERTIFICATE OF ANALYSIS

Batch: 21C01-H100201305

Product: Hydrofiele anionische crème 0,9 kg

Expiry date: 01 MAR 2022

Analysed according to: HeW Pharma Monograph

PERFORMED ANALYSIS AND RESULTS

Analysis	Specification	Result
Characters		
White, homogeneous cream, greasy, spreads out easily	CONFORM	CONFORM
Odourless	CONFORM	CONFORM
Identifications		
Glycerol (TLC)	POSITIVE	POSITIVE
Cetostearyl alcohol (TLC)	POSITIVE	POSITIVE
Sodium lauryl sulphate (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	6,8
Viscosity (Ph. Eur.)		45367
Emulsion type	O/W or W/O	O/W
Assay:		
Assay Propyl paraben (HPLC)	0,0144 - 0,0176 % m/m	0,016 % m/m
Assay Methyl paraben (HPLC)	0,0567 - 0,0693 % m/m	0,065 % 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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