

CERTIFICATE OF ANALYSIS

**HEW PHARMA
Vaartkaai 52F
2170 Merksem
BELGIUM**

Date of application : 18/08/2023
Date of reception : 21/08/2023
Date start of analysis : 22/08/2023
Date of end of analysis : 13/10/2023

Product : Cetomacrogol gebufferd
Customer product number : N/A
Customer reference : N/A

Test Method : ANA-Q-0135/2
Spec Reference : Customer

PERFORMED ANALYSIS AND RESULTS

Analysis	Specification	Result
F23/1743-01 - 78670 - Lot number : 23H08-H100123146		
Aspect		
Appearance	White, homogenous cream.	Complies
Identifications		
Identification Cetomacrogol en cetostearylalcohol (TLC)	POSITIVE	POSITIVE
Identification Paraffine/Vaseline (TLC)	POSITIVE	POSITIVE
Identification Potassium sorbate (HPLC)	POSITIVE	POSITIVE
Identification C (reaction)	1mL of this mixture gives reaction (b) of phosphates (2.3.1)	POSITIVE
Other tests		
pH (Ph.Eur.2.2.3)	4.5 to 5.5	4.8
Emulsion type	oil in water	oil in water emulsion
Viscosity		
Viscosity (Ph.Eur)	20 00 to 65 000 mPa.s	34800.0
Instrument		RV
Spindle		7
Assays		
Assay Potassium sorbate (HPLC)	90 to 110% of the declared content +/-0,2 7%	0.216 %

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PERFORMED ANALYSIS AND RESULTS

Analysis	Specification	Result
Microbiology		
TAMC (Ph.Eur.2.6.12)	NMT 10 ² CFU/g	<10 CFU/g
TYMC (Ph.Eur.2.6.12)	NMT 10 CFU/g	<10 CFU/g
Exclusion P. aeruginosa (Ph.Eur.2.6.13)	ABSENT	Absent
Exclusion S. aureus (Ph.Eur.2.6.13)	ABSENT	Absent

F23/1743-02 - 80358 - Lot number : 23H08-H100123146

Assays

Assay Potassium sorbate (HPLC)	90 to 110% of the declared content +/-0,2 7%	0.243 %
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Method not validated

Issued By: Ingrid Van den Broeck

Patsy Peeters

Office Manager/HR

Industrial Pharmacist, QP

Date of Issue: 13/10/2023

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Replaces report 35,866 Date: 6/10/2023 11:18:54 By: RAV