

Certificate of Analysis No. G 856

Page: 1 / 1

Analysis required by : HeW Pharma BV, Vaartkaai 52F, 2170 Merksem, Belgium

Sample delivery date: 4/22/2025

Analysis finalization date: 5/5/2025

Purchase Order: **22.4.2025**

Sample description: **Waterhoudende Vaseline met sorbitansesquioleaat TMF**

Batch No.: **25D01-H102205275**

Specification: **Specification supplied by customer**

Results:

Test	Limit	Found	Unit	Method
Appearance	White, homogenous lipophilic cream.	complies		Visually
ID - Paraffin, white soft	complies	complies		Ph. Eur. 2.2.27
pH value	3,5 - 5,5	4,0		Ph. Eur. 2.2.3
Emulsion type	Water in oil	complies		Ph. Eur.
Water	350 - 450	368	ml/kg	Ph. Eur. 2.2.13

Responsible persons : Kabzanová Marie

Edited by: Holaňová Aneta

CONCLUSION : The sample complies with the specifications of the performed analysis.

Ostrava, 5/5/2025

Head of the laboratory: Ing. Jiří Pavelka

Distribution list:

1x HeW Pharma BV

1x Laboratory EKOCENTRUM OVALAB, s.r.o.

CERTIFICATE OF ANALYSIS

Our Ref. : F25/0933-01

Our Sample Id. : 98777

**Hew pharma
Vaartkaai 52F
2170 Merksem
BELGIUM**

Product :	Waterhoudende vaseline sorbitansequeioleaat TMF	Date of application :	03/04/2025
Lot number :	25D01-H102205275	Date of reception :	04/04/2025
Customer product number :	N/A	Date start of analysis :	04/04/2025
Customer reference :	N/A	Date of end of analysis :	09/05/2025

Test Method : ANA_Q_237/1

Spec Reference : ANA_Q_237/1

PERFORMED ANALYSIS AND RESULTS

Analysis	Specification	Result
Aspect		
Appearance	White, homogenous lipophilic cream	Complies
Identifications		
ID Sorbic acid	POSITIVE	POSITIVE
ID Paraffin, white soft	POSITIVE	POSITIVE
Other tests		
Emulsifying type	water in oil (W/O)	Complies
pH (Ph.Eur.)	3.5 - 5.5	4.9
Water (Ph.Eur.2.2.13)	351-440ml/kg (5 grams ointment)	418 mL/kg
Assays		
Assay Sorbic acid	0.135 - 0.165 % w/w	0.154 % w/w
Assay Sorbic acid	90 - 110 %	102 %
Microbiology		
TAMC	NMT 100 CFU/g	<10 CFU/g
TYMC	NMT 10 CFU/g	<10 CFU/g
Exclusion S. aureus	ABSENT	Absent
Exclusion P. aeruginosa	ABSENT	Absent

CONCLUSION : The sample complies with the specifications of the performed analysis.

Method not validated

CERTIFICATE OF ANALYSIS

Our Ref. : F25/0933-01

Our Sample Id. : 98777

Issued By: Ingrid Van den Broeck

Office Manager/HR

Patsy Peeters

Industrial Pharmacist, QP

Date of Issue: 09/05/2025

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