

CERTIFICATE OF ANALYSIS

Our Ref. : F24/1208-01

Our Sample Id. : 87884

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

Product : Xanthaangom excipients

Lot number : 24E03-F100924243

Customer product number : N/A

Customer reference : N/A

Date of application : 16/05/2024

Date of reception : 16/05/2024

Date start of analysis : 16/05/2024

Date of end of analysis : 07/06/2024

Test Method : ANA-Q-128/2

Spec Reference : Customer

PERFORMED ANALYSIS AND RESULTS

Analysis	Specification	Result
Aspect		
Appearance	Kleurlose viscieuze oplossing	Complies
Identifications		
Identification Methyl paraben (HPLC)	POSITIVE	POSITIVE
Identification Propyl paraben (HPLC)	POSITIVE	POSITIVE
Other tests		
pH (Ph.Eur.2.2.3)	4.5 - 7.5	6.2
Assays		
Assay Methyl paraben (HPLC)	1.34 - 1.64 mg/g	1.43 mg/g
Assay Propyl paraben (HPLC)	0.268 - 0.327 mg/g	0.292 mg/g
Microbiology		
TAMC (Ph.Eur.2.6.12)	NMT 10000 CFU/mL	<1000 CFU/mL
TYMC (Ph.Eur.2.6.12)	NMT 10 ² CFU/mL	<10 CFU/mL
Bile-tolerant gram negative bacteria (Ph.Eur. 2.6.13)	NMT 10 ² CFU/mL	<10 CFU/mL
Exclusion E.coli (Ph.Eur.2.6.13)	ABSENT	Absent
Exclusion Salmonella (Ph.Eur.2.6.13)	ABSENT	Absent
Exclusion S. aureus (Ph.Eur.2.6.13)	ABSENT	Absent

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

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Issued By: Ingrid Van den Broeck

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Patsy Peeters

Industrial Pharmacist, QP

Date of Issue: 07/06/2024

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