

Certificate of Analysis No. G 2786

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

Sample delivery date: 11/6/2024

Analysis finalization date: 11/21/2024

Purchase Order: **1.11.2024**
Sample description: **Xanthaangom Excipiens**
Batch No.: **24J21-F100934071**
Specification: **Specification supplied by customer**

Results:

Test	Limit	Found	Unit	Method
Appearance	Colourless, viscous liquid.	complies		Visually
Identification - methylparaben	complies	complies		HPLC/UV
Identification - propylparaben	complies	complies		HPLC/UV
pH value	5,5 - 8,5	6,0		Ph. Eur. 2.2.3
Methylparaben	1,34 - 1,64	1,40	mg/g	HPLC/UV
Propylparaben	0,268 - 0,327	0,275	mg/g	HPLC/UV

Responsible persons : Valeriánová Zuzana, Žemlová Anna
Edited by: Holoňová Aneta

Ostrava, 11/21/2024

Head of the laboratory: Ing. Jiří Pavelka

Distribution list:

1x HeW Pharma BV

1x Laboratory EKO CENTRUM OVALAB, s.r.o.

CERTIFICATE OF ANALYSIS

Our Ref. : F24/2491-01

Our Sample Id. : 93105

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

Product : Xanthaangom excipients

Lot number : 24J21-F100934071

Customer product number : N/A

Customer reference : N/A

Date of application : 24/10/2024

Date of reception : 28/10/2024

Date start of analysis : 29/10/2024

Date of end of analysis : 05/11/2024

Test Method : ANA-Q-128/3

Spec Reference : Customer

PERFORMED ANALYSIS AND RESULTS

Analysis	Specification	Result
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/mL	Absent
Exclusion Salmonella (Ph.Eur.2.6.13)	Absent/10 mL	Absent
Exclusion S. aureus (Ph.Eur.2.6.13)	Absent/mL	Absent

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

Issued By: Ingrid Van den Broeck

Patsy Peeters

Office Manager/HR

Industrial Pharmacist, QP

Date of Issue: 05/11/2024

This is an electronic signature