



BioPharma
Product Testing

Certificate of Analysis

Page 1 of 2

Analytical Report: AAK73797

Eurofins Sample Number: XS20AA4908-1

Version: 1

TioFarma B.V.
Benjamin Franklinstraat 7-10
Oud-Beijerland, 3261 LW
NL

Client Account Number: A00497345P0Q
Eurofins Quote Number: IOQ62018009406

Eurofins Sample Number XS20AA4908-1			
Original Received Date:	21-Oct-2020		
Description:	Excipient xanthani gummi (2020005598)		
Lot Number:	212B5/B		
Containers Submitted:	1 Unit(s)		
Protocol Reference: Suitability test(s) of method was/were not performed.			
Analysis	Specification	Result	Unit
Total Aerobic Microbial Count - Pour Plate	$\leq 10^4$	< 10	CFU/g
Method: Current Ph Eur (2.6.12); Current USP/NF <61>; Current JP (English) <4.05 I>; Current BP Appendix XVI			
Total Yeast and Mold Count-Pour Plate	$\leq 10^2$	< 10	CFU/g
Method: Current Ph Eur (2.6.12); Current USP/NF <61>; Current JP (English) <4.05 I>; Current BP Appendix XVI			
Escherichia coli-Direct inoculation			
Escherichia coli	Absent	Absent	/1 g
Method: Current Ph Eur (2.6.13); Current USP/NF <62>; Current JP (English) <4.05 II>; Current BP Appendix XVI B			
Staphylococcus aureus-Direct inoculation			
Staphylococcus aureus	Absent	Absent	/1 g
Method: Current Ph Eur (2.6.13); Current USP/NF <62>; Current JP (English) <4.05 II>; Current BP Appendix XVI B			
Salmonella species-Direct inoculation			
Salmonella	Absent	Absent	/10 g
Method: Current Ph Eur (2.6.13); Current USP/NF <62>; Current JP (English) <4.05 II>; Current BP Appendix XVI B			
Bile-Tolerant Gram Negative Bacteria - Direct inoculation - quantitative (MPN)	NMT 10^2	<10 ¹	CFU/g
Method: Current Ph Eur (2.6.13); Current USP/NF <62>; Current JP (English) <4.05 II>; Current BP Appendix XVI B			

06. 11. 2020



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Page 2 of 2

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Sample Compliance Assessment

XS20AA4908-1 meets the requirement(s) for all listed test(s) where specifications were applied.

Contracted Company: Eurofins Bactimm (Nijmegen)

Middenkampweg 19, Nijmegen, 6545 CH The Netherlands
BactimmQC@eurofins.com

Questions about this report should be directed to your project manager or the general email listed above.

Reviewed and electronically signed for Technical Supervisor Approval by
Annet van Merode, Business Unit Manager
for Eurofins Bactimm B.V., on 03-Nov-2020 09:34:14 UTC+01:00

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Final Report

Job No:

P-NLD-UTC-202001290

Report Number:

17178

Date issued:

04-Nov-2020

Applicant: TIOFARMA afdeling Laboratorium
For the attention of: Mrs. H. Van der Hoeven
Address: Hermanus Boerhaavestraat 1
Postal Code: 3261 ME Oud-Beijerland

Article: Xanthan gum excipient
Analysis According: AV03066 version 1.0

Page 1 of 1

Analysis Results Batchnumber: 212B5/B

Date Sample(s) Received:

27-Oct-2020

		Requirement	Result
Characters			
Appearance	Appearance	Almost colourless, viscous solution	Complies
Identification			
HPLC-UV	Methyl parahydroxybenzoate	Complies	Complies
	Propyl parahydroxybenzoate	Complies	Complies
Tests			
pH	pH	5.5 - 8.5	6.3
Assay			
HPLC-UV	1. Methyl parahydroxybenzoate		1.36 mg/g
	2. Methyl parahydroxybenzoate		1.36 mg/g
	Average 1-2 Methyl parahydroxybenzoate	1.24 - 1.52 mg/g	1.36 mg/g
	1. Propyl parahydroxybenzoate		0.270 mg/g
	2. Propyl parahydroxybenzoate		0.269 mg/g
	Average 1-2 Propyl parahydroxybenzoate	0.248 - 0.304 mg/g	0.269 mg/g

Released by:

Eric van Dijk
Technical Support Officer Chemistry