

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

Client Account Number: A00497345P0Q
Eurofins Quote Number: IOQ62018009408

Eurofins Sample Number XS21AA0918-2

Original Received Date: 01-Mar-2021
Description: Excipients xanthani gummi (2021000881)
Lot Number: 21849/B
Containers Submitted: 1 Bottle(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			

reviewed by:

T. Lodder

17 MAR 2021



18.03.2021 SA



BioPharma
Product Testing

Certificate of Analysis

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Analytical Report: AAN02906

Eurofins Sample Number: XS21AA0918-2

Version: 1

Sample Compliance Assessment

XS21AA0918-2 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
Lisette Kuehnen, QA Support officer
for Eurofins Bactimm B.V., on 08-Mar-2021 15:35:23 UTC+01:00