



BioPharma
Product Testing

Certificate of Analysis

Page 1 of 2

Analytical Report: AAG61250

Eurofins Sample Number: XS20AA0928-1

Version: 1

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

Client Account Number: A00497345P0Q
Eurofins Quote Number: IOQ62018009403

Eurofins Sample Number XS20AA0928-1	
Original Received Date:	20-Feb-2020
Description:	Fosfaatbuffer voor xylometazoline (2020001019)
Lot Number:	2079F/1
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	$\leq 10^2$	50	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	$\leq 10^1$	< 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			

Pseudomonas aeruginosa-Direct inoculation			
Pseudomonas aeruginosa	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			

Sample Compliance Assessment	
XS20AA0928-1 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.

09.07.2020

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Page 2 of 2

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Reviewed and electronically signed for Technical Supervisor Approval by
Ilse van Dreumel, QA Officer
for Eurofins Bactimm B.V., on 04-Mar-2020 14:33:11 UTC+01:00