

Certificate of Analysis



STERIS

Final Report

Job No: P-NLD-UTC-202000001
Report Number: 8500
Date Issued: 16-Jan-2020

Applicant: Tiofarma laboratorium
For the attention of: Mrs. H. Van der Hoeven
Address: Hermanus Boerhaavesstraat 1
Postal Code: 3261 ME Oud-Beijerland

Article: Phosphate buffer solution for Xylometazoline
Analysis According: AV05008 version 2.0 date 20-07-2015

Page 1 of 1

Analysis Results Batchnumber: 19L12/D1

Date Sample(s) Received:

03-Jan-2020

		Requirement	Result
Characters			
Appearance	Appearance	Clear, colourless liquid, froths copiously when shaken	Complies
Identification			
A	Benzalkonium chloride	Complies	Complies
B	Chlorides	Complies	Complies
C	Sodium	Complies	Complies
D	Sodium edetate	Complies	Complies
E	Phosphates	Complies	Complies
Tests			
pH	pH	5.8 - 6.2	5.9
Density	Relative density	1.005 - 1.010	1.007
Assay			
HPLC-UV	Benzalkonium chloride	0.090 - 0.110 mg/g	0.099 mg/g

Released by:

dr. Joop C. Hoogvliet
QP/Pharmacist

reviewed by: T. Lodder

17 JAN. 2020

01. 01, 2020

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

Client Account Number: A00497345P0Q
Eurofins Quote Number: IOQ62018009402

Eurofins Sample Number XS19AA3077-1			
Original Received Date:	24-Dec-2019		
Description:	Fosfaatbuffer voor xylometazoline (2019008004)		
Lot Number:	19L12/D1		
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	≤100	< 100	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	≤ 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			
XS19AA3077-1 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 by:

T. Lodder

17 JAN 2020

20. 01. 2020



BioPharma
Product Testing

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Page 2 of 2

Analytical Report: AAF79729

Eurofins Sample Number: XS19AA3077-1

Version: 1

Reviewed and electronically signed for Technical Supervisor Approval by
Ilse van Dreumel, QA Officer
for Eurofins Bactimm B.V., on 07-Jan-2020 11:45:12 UTC+01:00