

Certificate of Analysis



Final Report

Job No: P-NLD-UTC-202100262
Report Number: 20319
Date Issued: 15-Mar-2021

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

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

Page 1 of 1

Analysis Results Batchnumber: 21724/1

Date Sample(s) Received:

23-Feb-2021

		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	0.100 mg/g

Released by:

BS

Dr. Ruud Santing
 QP/Pharmacist

reviewed by:

T. Lodder

7 MAR 2021

17 12 2021 SA

Synergy Health Utrecht B.V., a STERIS company
 Reactorweg 47a, 3542 AD P.O. 8121 3503 RC Utrecht, The Netherlands

E-mail: Utrecht@steris.com
 Phone: +31 (0) 302 84 30 10

GMP Certified

Certificate of Analysis

Page 1 of 2

Analytical Report: AAN05671

Eurofins Sample Number: XS21AA0827-2

Version: 1

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

Client Account Number: A00497345P0Q
Eurofins Quote Number: IOQ62018009407

Eurofins Sample Number: XS21AA0827-2	
Original Received Date:	23-Feb-2021
Description:	Fosfaatbuffer voor Xylometazoline (92021000729)
Lot Number:	21724/1
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	$\leq 10^2$	< 100	CFU/g
Method: Current Ph Eur (2.6.12); Current USP/NF <61>; Current JP (English) <4.05 II>; 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 II>; 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	
XS21AA0827-2 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 by:

T. Lodder

7 MAR. 2021

17.03.2021 SA

Certificate of Analysis

Page 2 of 2
Analytical Report: AAN05671
Eurofins Sample Number: XS21AA0827-2
Version: 1

Reviewed and electronically signed for Technical Supervisor Approval by
Anco Terpstra, QA Engineer
for Eurofins Bactimm B.V., on 09-Mar-2021 15:45:25 UTC+01:00