

Certificate of Analysis

Final Report

Job No:

P-NGC-202100767

Report Number:

28986

Date Issued:

17-Jan-2022

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

Article: Phosphate buffer solution for Xylometazoline
Analysis According: AV04011 version 25-06-2021/1.0

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Analysis Results Batchnumber: 221C0X1

Date Sample(s) Received:

03-Jan-2022

		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	6.1
Density	Relative density	1.005 - 1.010	1.007
Assay			
HPLC-UV	Benzalkonium chloride; Decl. = 0.100 mg/g	90.0 - 110.0 % Decl.	93.7 % Decl.

Released by:



Dr. Ruud Santing
QP

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

Client Account Number: A00497345P0Q
Eurofins Quote Number: IOQ62018009408

Eurofins Sample Number XS21AA6275-2	
Original Received Date:	20-Dec-2021
Description:	Fosfaatbuffer voor xylometasoline (2103612)
Lot Number:	221C0X1
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 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	
XS21AA6275-2 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.

