

Certificate of Analysis



Final Report

Job No: P-NLD-UTC-202001290
Report Number: 17178
Date Issued: 04-Nov-2020

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

Article: Xanthan gum excipient
Analysis According: AV03066 version 1.0

Page 1 of 1

Analysis Results Batchnumber: 212B5/B Date Sample(s) Received: 27-Oct-2020

| | | Requirement | Result |
|-----------------------|--|-------------------------------------|------------|
| Characters | | | |
| Appearance | Appearance | Almost colourless, viscous solution | Complies |
| Identification | | | |
| HPLC-UV | Methyl parahydroxybenzoate | Complies | Complies |
| | Propyl parahydroxybenzoate | Complies | Complies |
| | | | |
| Tests | | | |
| pH | pH | 5.5 - 8.5 | 6.3 |
| Assay | | | |
| HPLC-UV | 1. Methyl parahydroxybenzoate | | 1.36 mg/g |
| | 2. Methyl parahydroxybenzoate | | 1.36 mg/g |
| | Average 1-2 Methyl parahydroxybenzoate | 1.24 - 1.52 mg/g | 1.36 mg/g |
| | 1. Propyl parahydroxybenzoate | | 0.270 mg/g |
| | 2. Propyl parahydroxybenzoate | | 0.269 mg/g |
| | Average 1-2 Propyl parahydroxybenzoate | 0.248 - 0.304 mg/g | 0.269 mg/g |
| | | | |
| | | | |

Released by:

Eric van Dijk
Technical Support Officer Chemistry

TioFarma B.V.
Benjamin Franklinstraat 7-10
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NL

Client Account Number: A00497345P0Q
Eurofins Quote Number: IOQ62018009406

| Eurofins Sample Number XS20AA4908-1 | | | |
|---|---------------------------------------|------------------|-------|
| Original Received Date: | 21-Oct-2020 | | |
| Description: | Excipient xanthani gummi (2020005598) | | |
| Lot Number: | 212B5/B | | |
| 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 | $\leq 10^4$ | < 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 | | | |



BioPharma
Product Testing

Certificate of Analysis

Page 2 of 2

Analytical Report: AAK73797

Eurofins Sample Number: XS20AA4908-1

Version: 1

Sample Compliance Assessment

XS20AA4908-1 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 and electronically signed for Technical Supervisor Approval by
Annet van Merode, Business Unit Manager
for Eurofins Bactimm B.V., on 03-Nov-2020 09:34:14 UTC+01:00