

Certificate of Analysis

Productname: CFB Mann. 99,5% Silic 0,5%
Number of analysis/Inspection Code MON-204986B / KEUR-192234B
Batchnumber: 21H04-F08
Reference code / No.: 3828 / 21H04-F08
Analysed according to: INTERN

| Tests | Requirement | Result | Unit | Standard remark |
|--------------------------------------|----------------------------|---------|---------|------------------|
| Appearance | (Almost) fine white powder | Conform | | |
| Identification | Silicates | Conform | | Silicii dioxidum |
| Identification D (Ph.Eur) | Mannitol | Conform | | TLC |
| Apparent volume | | 0,72 | g/ml | |
| Total aerobic microbial count (TAMC) | $\leq 10^1$ | Conform | CFU / g | |
| Total yeasts and moulds (TYMC) | $\leq 10^1$ | Conform | CFU / g | |
| E. coli | Negative / gram | Conform | | |

Release:
Chantal Nobus
Qualified Person

13-10-21

Expiration: 08-2023

Conclusion: APPROVED

This document has been produced electronically from our quality system and is valid without signature.



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Product Testing

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Analytical Report: AAR13797

Eurofins Sample Number: EB21AA5199-4

Version: 1

Fagron Services B.V.
Molenwerf 13
Uitgeest, 1911 DB
NL

Client Account Number: A00497292BNI
Eurofins Quote Number: WB9XPH21013408

| Eurofins Sample Number EB21AA5199-4 | | | |
|--|--|--------------------|-------|
| Original Received Date: | 16-Sep-2021 | | |
| Description: | CFB Mann. 99,5% Silic 0,5% | | |
| Lot Number: | 21H04-F08 | | |
| Containers Submitted: | 3 Tank(s) | | |
| Protocol Reference: 1-P-LB-WI-9039687 | | | |
| General Method Reference: Current EP 0559 | | | |
| Analysis | Specification | Result | Unit |
| Characters | (Almost) white, fine powder | white, fine powder | ---- |
| Method: Synoptique 1-P-LB-WI-9039687 | | | |
| Analysis Date: 20-Sep-2021 to 20-Sep-2021 | | | |
| Identification per silicates | Within a short time a white ring is rapidly formed around the drop of water | Meets Requirements | ---- |
| Method: Synoptique 1-P-LB-WI-9039687 | | | |
| Analysis Date: 20-Sep-2021 to 20-Sep-2021 | | | |
| Ph Eur Identification D per Thin-layer chromatography (2.2.27) | The principal spot in the chromatogram obtained with the test solution is similar in position, colour and size to the principal spot in the chromatogram obtained with reference solution (a). | Meets Requirements | ---- |
| Method: Current EP 2.2.27 | | | |
| Analysis Date: 29-Sep-2021 to 29-Sep-2021 | | | |
| Bulk density and tapped density of powders | ---- | 0.7154 | g/mL |
| Method: Current EP 2.9.34 | | | |
| Analysis Date: 20-Sep-2021 to 20-Sep-2021 | | | |
| TAMC acc to HM | ≤ 10 | < 10 | CFU/g |
| Method: Current Ph Eur (2.6.12), Not validated Method | | | |
| Analysis Date: 20-Sep-2021 to 25-Sep-2021 | | | |

SPECIFICATIES
GECONTROLEERD
EN CONFORM

DATUM: 041020
PARAAF: [Signature]



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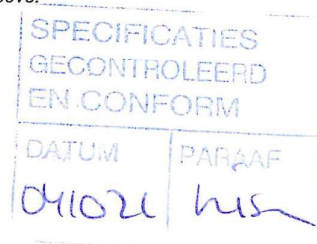
Analytical Report: AAR13797

Eurofins Sample Number: EB21AA5199-4

Version: 1

| Analysis | Specification | Result | Unit |
|--|---|--|-------|
| TYMC acc. to HM | ≤ 10 | < 10 | CFU/g |
| Method: Current Ph Eur (2.6.12), Not Validated Method Analysis Date: 20-Sep-2021 to 25-Sep-2021 | | | |
| Escherichia coli search acc to HM | Absence | Absence | /1 g |
| Method: Current Ph Eur (2.6.13), Not Validated method Analysis Date: 20-Sep-2021 to 25-Sep-2021 | | | |
| Identification per silicates | Within a short time a white ring is rapidly formed around the drop of water | Meets Requirements | ---- |
| Method: Synoptique 1-P-LB-WI-9039687 Analysis Date: 20-Sep-2021 to 20-Sep-2021 | | | |
| Identification per silicates | Within a short time a white ring is rapidly formed around the drop of water | Meets Requirements | ---- |
| Method: Synoptique 1-P-LB-WI-9039687 Analysis Date: 20-Sep-2021 to 20-Sep-2021 | | | |
| Sample Compliance Assessment | | | |
| EB21AA5199-4 meets the requirement(s) for all listed test(s) where specifications were applied. | | | |
| Eurofins BPT Testing Facility | | Test | |
| Eurofins Pharma Quality Control Les Ulis Testing 9 Avenue de Laponie 91978 Les Ulis, Courtaboeuf Cedex FRANCE | | Bulk density and tapped density of powders Characters Identification per silicates Ph Eur Identification D per Thin-layer chromatography (2.2.27) | |
| Eurofins Pharma Quality Control Ste Croix en Plaine 16 Rue Clément Ader 68127 Sainte-Croix-en-Plaine FRANCE | | Escherichia coli search acc to HM TAMC acc to HM TYMC acc. to HM | |
| Contracted Company: Eurofins Pharma Quality Control Les Ulis Testing | | | |
| 9 Avenue de Laponie, Les Ulis, Courtaboeuf Cedex, 91978 France EPQC_ServiceClient@eurofins.com | | | |

Questions about this report should be directed to your project manager or the general email listed above.





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Analytical Report: AAR13797

Eurofins Sample Number: EB21AA5199-4

Version: 1

| | |
|--|------------|
| SPECIFICATIES GECONTROLEERD EN CONFORM | |
| DATUM | PARAAF |
| 04/10/21 <i>WLS</i> | <i>WLS</i> |

Reviewed and electronically signed for Qualified Person Approval by
Anne-Lise BELLI, QA Pharmacist
for Eurofins Pharma Quality Control SAS, on 30-Sep-2021 16:05:25 UTC+02:00