

Certificate of Analysis

Productname: CFB Mann. 99,5% Silic 0,5%
Number of analysis/Inspection Code MON-206758B / KEUR-193951B
Batchnumber: 22A12-F13
Reference code / No.: 3828 / 22A12-F13
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 | | 0,7387 | 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:
Anthony Amoureux
Qualified Person

11-03-22

Expiration: 01-2024

Conclusion: APPROVED

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Product Testing

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Analytical Report: AAU11974

Eurofins Sample Number: EB22AA0604-10

Version: 2

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

Client Account Number: A00497292BNI
Eurofins Quote Number: WB9XPH21016607

| Eurofins Sample Number EB22AA0604-10 | | | |
|--|--|--------------------|-------|
| Original Received Date: | 25-Jan-2022 | | |
| Description: | CFB Mann. 99.5% Silc 0.5% | | |
| Lot Number: | 22A12-F13 | | |
| 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: 03-Feb-2022 to 03-Feb-2022 | | | |
| 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: 04-Feb-2022 to 04-Feb-2022 | | | |
| Bulk density and tapped density of powders | ---- | 0.7387 | g/ml |
| Method: Current EP 2.9.34 | | | |
| Analysis Date: 03-Feb-2022 to 03-Feb-2022 | | | |
| TYMC acc. to HM | ≤ 10 | < 10 | CFU/g |
| Method: Current Ph Eur (2.6.12), Not Validated Method | | | |
| Analysis Date: 31-Jan-2022 to 05-Feb-2022 | | | |
| Escherichia coli search acc to HM | Absence | Absence | /1 g |
| Method: Current Ph Eur (2.6.13), Not Validated method | | | |
| Analysis Date: 31-Jan-2022 to 05-Feb-2022 | | | |



| Analysis | Specification | Result | Unit |
|--|---|--------------------|-------|
| Identification per silicates | Within a short time a white ring is rapidly formed around the drop of water | Meets Requirements | ---- |
| Begin Method: Synoptique 1-P-LB-WI-9039687 Analysis Date: 04-Feb-2022 to 04-Feb-2022 | | | |
| Identification per silicates | Within a short time a white ring is rapidly formed around the drop of water | Meets Requirements | ---- |
| Midden Method: Synoptique 1-P-LB-WI-9039687 Analysis Date: 04-Feb-2022 to 04-Feb-2022 | | | |
| Identification per silicates | Within a short time a white ring is rapidly formed around the drop of water | Meets Requirements | ---- |
| Eind Method: Synoptique 1-P-LB-WI-9039687 Analysis Date: 04-Feb-2022 to 04-Feb-2022 | | | |
| TAMC by inoculation according to EP 2.6.12 / USP <61> | ≤ 10 | < 10 | CFU/g |
| Method: Current Ph Eur (2.6.12), Not validated Method Analysis Date: 22-Feb-2022 to 27-Feb-2022 | | | |
| TYMC by inoculation according to EP2.6.12 / USP <61> | ≤ 10 | < 10 | CFU/g |
| Method: Current Ph Eur (2.6.12), Not Validated Method Analysis Date: 22-Feb-2022 to 27-Feb-2022 | | | |
| Sample Compliance Assessment | | | |
| EB22AA0604-10 meets the requirement(s) for all listed test(s) where specifications were applied. | | | |





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Analytical Report: AAU11974

Eurofins Sample Number: EB22AA0604-10

Version: 2

| 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 by inoculation according to EP 2.6.12 / USP<61> TYMC acc. to HM TYMC by inoculation according to EP2.6.12 / USP <61> |

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.

| | |
|--|--------------------------|
| SPECIFICATIES GECONTROLEERD EN CONFORM | |
| DATE 11/3/22 | SIGNATURE [Signature] |

Reviewed and electronically signed for Qualified Person Approval by
Anne-Lise BELLI, QA Pharmacist
for Eurofins Pharma Quality Control SAS, on 28-Feb-2022 14:42:35 UTC+01:00