



BioPharma
Product Testing

Certificate of Analysis

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Analytical Report: AAU48531

Eurofins Sample Number: EB22AA1696-5

Version: 1

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

Client Account Number: A00497292BNI
Eurofins Quote Number: WB9XPH21016607

| Eurofins Sample Number EB22AA1696-5 | | | |
|--|--|--------------------|-------|
| Original Received Date: | 03-Mar-2022 | | |
| Description: | CFB Mann. 99.5% Silc 0.5% | | |
| Lot Number: | 22B22-F10 | | |
| 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: 08-Mar-2022 to 08-Mar-2022 | | | |
| Identification per silicates | Within a short time a white ring is rapidly formed around the drop of water | Meets Requirements | ---- |
| Elnd | | | |
| Method: Synoptique 1-P-LB-WI-9039687 | | | |
| Analysis Date: 11-Mar-2022 to 11-Mar-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: 08-Mar-2022 to 08-Mar-2022 | | | |
| Bulk density and tapped density of powders | ---- | 0.7320 | g/mL |
| Method: Current EP 2.9.34 | | | |
| Analysis Date: 09-Mar-2022 to 09-Mar-2022 | | | |
| TAMC by inoculation according to EP 2.6.12 / USP<61>, No GMP | ≤ 10 | < 10 | CFU/g |
| Method: Current Ph Eur (2.6.12), Not validated Method | | | |
| Analysis Date: 09-Mar-2022 to 14-Mar-2022 | | | |

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| Analysis | Specification | Result | Unit |
|---|---------------|--------|-------|
| TYMC by inoculation according to EP2.6.12 / USP <61>, No GMP | ≤ 10 | < 10 | CFU/g |

Method: Current Ph Eur (2.6.12), Not Validated Method
Analysis Date: 09-Mar-2022 to 14-Mar-2022

| | | | |
|---|---------|---------|------|
| Escherichia coli search according to EP 2.6.13 / USP<62>, No GMP | Absence | Absence | /1 g |
|---|---------|---------|------|

Method: Current Ph Eur (2.6.13), Not Validated method, No GMP
Analysis Date: 09-Mar-2022 to 14-Mar-2022

| | | | |
|-------------------------------------|---|--------------------|------|
| Identification per silicates | Within a short time a white ring is rapidly formed around the drop of water | Meets Requirements | ---- |
|-------------------------------------|---|--------------------|------|

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Method: Synoptique 1-P-LB-WI-9039687
Analysis Date: 11-Mar-2022 to 11-Mar-2022

| | | | |
|-------------------------------------|---|--------------------|------|
| Identification per silicates | Within a short time a white ring is rapidly formed around the drop of water | Meets Requirements | ---- |
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Method: Synoptique 1-P-LB-WI-9039687
Analysis Date: 11-Mar-2022 to 11-Mar-2022

Sample Compliance Assessment

EB22AA1696-5 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 according to EP 2.6.13 / USP<62>, No GMP TAMC by inoculation according to EP 2.6.12 / USP<61>, No GMP TYMC by inoculation according to EP2.6.12 / USP <61>, No GMP |

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Eurofins Sample Number: EB22AA1696-5

Version: 1

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 | |
| DATUM 18/3/22 | PARAAF |

Reviewed and electronically signed for Qualified Person Approval by
Anne-Lise BELLi, QA Pharmacist
for Eurofins Pharma Quality Control SAS, on 16-Mar-2022 16:36:01 UTC+01:00