



BioPharma
Product Testing

Certificate of Analysis

Page 1 of 3

Analytical Report: AAU74133

Eurofins Sample Number: EB22AA1782-2

Version: 1

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

Client Account Number: A00497292BNI
Eurofins Quote Number: WB9XPH21016608

| Eurofins Sample Number EB22AA1782-2 | | | |
|--|--|--------------------|-------|
| Original Received Date: | 08-Mar-2022 | | |
| Description: | CFB Mann. 99,5% Silic 0,5% | | |
| Lot Number: | 22B22-F12 | | |
| 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: 23-Mar-2022 to 23-Mar-2022 | | | |
| Identification per silicates | Within a short time a white ring is rapidly formed around the drop of water | Meets Requirements | ---- |
| End | | | |
| Method: Synoptique 1-P-LB-WI-9039687 | | | |
| Analysis Date: 23-Mar-2022 to 23-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: 17-Mar-2022 to 17-Mar-2022 | | | |
| Bulk density and tapped density of powders | ---- | 0.7118 | g/ml |
| Method: Current EP 2.9.34 | | | |
| Analysis Date: 25-Mar-2022 to 25-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: 11-Mar-2022 to 16-Mar-2022 | | | |

SPECIFICATIONS

SECURITY/RECORD

IN CONFORM

ATUM

PARAF

30/3/22

[Signature]

Certificate of Analysis

Page 2 of 3

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Version: 1

| 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: 11-Mar-2022 to 16-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 Analysis Date: 11-Mar-2022 to 16-Mar-2022 | | | |
| 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: 23-Mar-2022 to 23-Mar-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: 23-Mar-2022 to 23-Mar-2022 | | | |
| Sample Compliance Assessment | | | |
| EB22AA1782-2 meets the requirement(s) for all listed test(s) where specifications were applied. | | | |

SPECIFICATIES
GECONTROLEERD
EN CONFORM

DATUM: 30/3/22
PARAAAF: 



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Page 3 of 3

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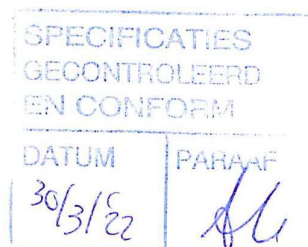
Version: 1

| 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 |

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.



Reviewed and electronically signed for Qualified Person Approval by
Alexandra HAIRON, Valideur
for Eurofins Pharma Quality Control SAS, on 30-Mar-2022 09:45:01 UTC+02:00