



BioPharma
Product Testing

Certificate of Analysis

Page 1 of 2

Analytical Report: AAF57204

Eurofins Sample Number: EB19AA4189-3

Version: 2

Fagron Services B.V.
Molenwerf 13
Uitaeest. 1911 DB
NL

Client Account Number: A00497292BNI
Eurofins Quote Number: K4SEPH19033404

Eurofins Sample Number EB19AA4189-3

Original Received Date: 08-Oct-2019
Description: CFB Mann. 99.5% Silic 0.5%
Lot Number: 19I19-F09
Containers Submitted: 3 Tank(s)

Protocol Reference: 1-P-LB-WI-9039687
General Method Reference: Current EP 0559

| Analysis | Specification | Result | Unit |
|----------|---------------|--------|------|
|----------|---------------|--------|------|

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

Method: Current Ph Eur (2.3.1)
Analysis Date: 07-Nov-2019 to 18-Nov-2019

| | | | |
|---|--|--------------------|------|
| 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: 12-Nov-2019 to 26-Nov-2019

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

Method: Current Ph Eur (2.3.1)
Analysis Date: 07-Nov-2019 to 18-Nov-2019

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

Method: Current Ph Eur (2.3.1)
Analysis Date: 07-Nov-2019 to 18-Nov-2019

| | | | |
|-------------------------------------|--|--------------|------|
| Ph Eur Characters Appearance | White or almost white crystals or powder | White powder | ---- |
|-------------------------------------|--|--------------|------|

Method: Current Ph Eur
Analysis Date: 30-Oct-2019 to 05-Nov-2019

APPROVED
ANALYST
18-12-19
[Signature]

| Analysis | Specification | Result | Unit |
|----------|---------------|--------|------|
|----------|---------------|--------|------|

| | | | |
|---|-----|--------|------|
| Bulk density and tapped density of powders | --- | 0.7196 | g/mL |
|---|-----|--------|------|

Method: Current EP 2.9.34
 Analysis Date: 14-Nov-2019 to 14-Nov-2019

| | | | |
|-----------------------|-----|------|-------|
| TAMC acc to HM | ≤10 | < 10 | CFU/g |
|-----------------------|-----|------|-------|

Method: Current Ph Eur (2.6.12)
 Analysis Date: 27-Nov-2019 to 02-Dec-2019

| | | | |
|------------------------|-----|------|-------|
| TYMC acc. to HM | ≤10 | < 10 | CFU/g |
|------------------------|-----|------|-------|

Method: Current Ph Eur (2.6.12)
 Analysis Date: 27-Nov-2019 to 02-Dec-2019

| | | | |
|--|---------|---------|------|
| Escherichia coli search acc to HM | Absence | Absence | /1 g |
|--|---------|---------|------|

Method: Current Ph Eur (2.6.13)
 Analysis Date: 27-Nov-2019 to 02-Dec-2019

Sample Compliance Assessment

EB19AA4189-3 meets the requirement(s) for all listed test(s) where specifications were applied.

| Eurofins BPT Testing Facility | Test |
|-------------------------------|------|
|-------------------------------|------|

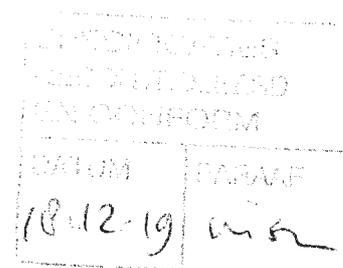
| | |
|---|--|
| Eurofins Pharma Quality Control SAS 9 Avenue de Laponie 91978 Les Ulis, Courtaboeuf Cedex FRANCE | Bulk density and tapped density of powders Identification per Silicates Ph Eur Characters Appearance Ph Eur Identification D per Thin-layer chromatography (2.2.27) |
|---|--|

| | |
|--|--|
| Eurofins Pharma Quality Control SAS 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.



Reviewed and electronically signed for Qualified Person Approval by
 Alexandra HAIRON, Valideur
 for Eurofins Pharma Quality Control SAS, on 17-Dec-2019 12:29:17 UTC+01:00