



BioPharma  
Product Testing

## Certificate of Analysis

Page 1 of 2

Analytical Report: AAF57207

Eurofins Sample Number: EB19AA4189-1

Version: 2

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

Client Account Number: A00497292BNI  
Eurofins Quote Number: K4SEPH19033404

Eurofins Sample Number EB19AA4189-1	
Original Received Date:	08-Oct-2019
Description:	CFB Mann. 99.5% Silic 0.5%
Lot Number:	19I19-F07
Containers Submitted:	3 Tank(s)
Protocol Reference: 1-P-LB-WI-9039687	
General Method Reference: Current EP 0559	

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

ANALYSE  
 GEGEVEN  
 18-12-19  
 NIS

Analysis	Specification	Result	Unit
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<b>Bulk density and tapped density of powders</b>	----	0.7143	g/mL
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Method: Current EP 2.9.34  
Analysis Date: 14-Nov-2019 to 14-Nov-2019

<b>TAMC acc to HM</b>	≤10	< 10	CFU/g
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Method: Current Ph Eur (2.6.12)  
Analysis Date: 27-Nov-2019 to 02-Dec-2019

<b>TYMC acc. to HM</b>	≤10	< 10	CFU/g
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Method: Current Ph Eur (2.6.12)  
Analysis Date: 27-Nov-2019 to 02-Dec-2019

<b>Escherichia coli search acc to HM</b>	Absence	Absence	/1 g
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Method: Current Ph Eur (2.6.13)  
Analysis Date: 27-Nov-2019 to 02-Dec-2019

**Sample Compliance Assessment**

EB19AA4189-1 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.

SPECIFIC DATES  
RECONTROLLED BY  
LAB CONFIRMATION  
DATE: 18-12-19  
SIGNATURE: [Handwritten Signature]

Reviewed and electronically signed for Qualified Person Approval by  
Alexandra HAIRON, Valideur  
for Eurofins Pharma Quality Control SAS, on 17-Dec-2019 12:27:24 UTC+01:00