

## Certificate of Analysis

Productname: **CFB Mann. 99,5% Silic 0,5%**  
Number of analysis/Inspection Code **MON-206553B / KEUR-193757B**  
Batchnumber: **22A12-F17**  
Reference code / No.: **3828 / 22A12-F17**  
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		0,6992	g/ml	
Total aerobic microbial count (TAMC)	$\leq 10^4$	Conform	CFU / g	
Total yeasts and moulds (TYMC)	$\leq 10^4$	Conform	CFU / g	
E. coli	Negative / gram	Conform		

Release:  
Anthony Amoureux  
Qualified Person

23-02-22

Expiration: 01-2024

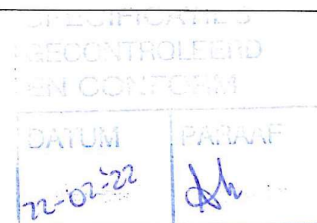
Conclusion: APPROVED

This document has been produced electronically from our quality system and is valid without signature.

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

Client Account Number: A00497292BNI  
Eurofins Quote Number: WB9XPH21016607

<b>Eurofins Sample Number EB22AA0719-4</b>			
<b>Original Received Date:</b>	31-Jan-2022		
<b>Description:</b>	CFB Mann. 99.5% Silic 0.5%		
<b>Lot Number:</b>	22A12-F17		
<b>Containers Submitted:</b>	3 <sup>1</sup> Tank(s) 23-02-22 YS		
Protocol Reference: 1-P-LB-WI-9039687			
General Method Reference: Current EP 0559			
<b>Analysis</b>	<b>Specification</b>	<b>Result</b>	<b>Unit</b>
<b>Characters</b>	(Almost) white, fine powder	White fine powder	----
Method: Synoptique 1-P-LB-WI-9039687			
Analysis Date: 03-Feb-2022 to 03-Feb-2022			
<b>Identification per silicates</b>	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: 03-Feb-2022 to 03-Feb-2022			
<b>Ph Eur Identification D per Thin-layer chromatography (2.2.27)</b>	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			
<b>Bulk density and tapped density of powders</b>	----	0.6992	g/ml
Method: Current EP 2.9.34			
Analysis Date: 03-Feb-2022 to 03-Feb-2022			
<b>TAMC acc to HM</b>	≤10	< 10	CFU/g
Method: Current Ph Eur (2.6.12), Not validated Method			
Analysis Date: 03-Feb-2022 to 08-Feb-2022			



Analysis	Specification	Result	Unit
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<b>TYMC acc. to HM</b>	≤10	< 10	CFU/g
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Method: Current Ph Eur (2.6.12), Not Validated Method

Analysis Date: 03-Feb-2022 to 08-Feb-2022

<b>Escherichia coli search acc to HM</b>	Absence	Absence	/1 g
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Method: Current Ph Eur (2.6.13), Not Validated method

Analysis Date: 03-Feb-2022 to 08-Feb-2022

<b>Identification per silicates</b>	Within a short time a white ring is rapidly formed around the drop of water	Meets Requirements	----
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Begin

Method: Synoptique 1-P-LB-WI-9039687

Analysis Date: 03-Feb-2022 to 03-Feb-2022

<b>Identification per silicates</b>	Within a short time a white ring is rapidly formed around the drop of water	Meets Requirements	----
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Midden

Method: Synoptique 1-P-LB-WI-9039687

Analysis Date: 03-Feb-2022 to 03-Feb-2022

### Sample Compliance Assessment

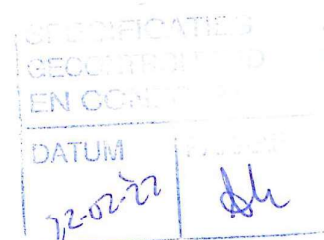
EB22AA0719-4 meets the requirement(s) for all listed test(s) where specifications were applied.

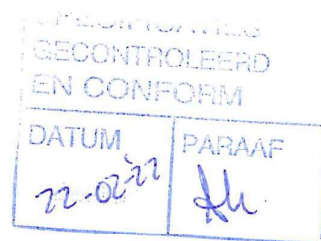
Eurofins BPT Testing Facility	Test
Eurofins Pharma Quality Control Les Ulis Testing 9 Avenue de Laponie 91978 Les Ulis, Courtaboeuf Cedex FRANCE	Bulk density and tapped density of powders Characters Identification per silicates Ph Eur Identification D per Thin-layer chromatography (2.2.27)
Eurofins Pharma Quality Control Ste Croix en Plaine 16 Rue Clément Ader 68127 Sainte-Croix-en-Plaine FRANCE	Escherichia coli search 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  
Anne-Lise BELLI, QA Pharmacist  
for Eurofins Pharma Quality Control SAS, on 17-Feb-2022 10:10:57 UTC+01:00