

Certificate of Analysis

Productname: CFB Mann. 99,5% Silic 0,5%
Number of analysis/Inspection Code MON-206847B / KEUR-194038B
Batchnumber: 22B22-F01
Reference code / No.: 3828 / 22B22-F01
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		0,7259	g/ml	
Total aerobic microbial count (TAMC)	$\leq 10^1$	Conform	CFU / g	
Total yeasts and moulds (TYMC)	$\leq 10^1$	Conform	CFU / g	
E. coli	Negative / gram	Conform		

Release:
Anthony Amoureux
Qualified Person

21-03-22

Expiration: 02-2024

Conclusion: APPROVED

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

Certificate of Analysis

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Analytical Report: AAU48497

Eurofins Sample Number: EB22AA1640-1

Version: 1

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

Client Account Number: A00497292BNI
Eurofins Quote Number: WB9XPH21016607

Eurofins Sample Number EB22AA1640-1

Original Received Date: 02-Mar-2022
Description: CFB Mann. 99.5% Silic 0.5%
Lot Number: 22B22-F01
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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Characters	(Almost) white, fine powder	white fine powder	----
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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	----
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Eind
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	----
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Method: Current EP 2.2.27
Analysis Date: 08-Mar-2022 to 08-Mar-2022

Bulk density and tapped density of powders	----	0.7259	g/mL
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Method: Current EP 2.9.34
Analysis Date: 09-Mar-2022 to 09-Mar-2022



Analysis	Specification	Result	Unit
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: 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	----
midden Method: Synoptique 1-P-LB-WI-9039687 Analysis Date: 11-Mar-2022 to 11-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			
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 Analysis Date: 09-Mar-2022 to 14-Mar-2022			
Sample Compliance Assessment			
EB22AA1640-1 meets the requirement(s) for all listed test(s) where specifications were applied.			

SPECIFICATIES
DECONTROLEERD
EN CONFORM

DATUM
18/3/22

PARAAF
[Signature]



BioPharma
Product Testing

Certificate of Analysis

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Analytical Report: AAU48497

Eurofins Sample Number: EB22AA1640-1

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 16-Mar-2022 16:29:58 UTC+01:00