

Certificate of Analysis

Productname: CFB Mann. 99,5% Silic 0,5%
Number of analysis/Inspection Code MON-206849B / KEUR-194040B
Batchnumber: 22B22-F02
Reference code / No.: 3828 / 22B22-F02
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		0,7202	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

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BioPharma
Product Testing

Certificate of Analysis

Page 1 of 3

Analytical Report: AAU48500

Eurofins Sample Number: EB22AA1640-2

Version: 1

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

Client Account Number: A00497292BNI
Eurofins Quote Number: WB9XPH21016607

Eurofins Sample Number EB22AA1640-2			
Original Received Date:	02-Mar-2022		
Description:	CFB Mann. 99.5% Silic 0.5%		
Lot Number:	22B22-F02		
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: 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	----
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	----
Method: Current EP 2.2.27			
Analysis Date: 08-Mar-2022 to 08-Mar-2022			
Bulk density and tapped density of powders	----	0.7202	g/mL
Method: Current EP 2.9.34			
Analysis Date: 09-Mar-2022 to 09-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			

SPECIFICATIES
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EN CONFORM

DATUM

18/3/22


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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: 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			
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			
Sample Compliance Assessment			
EB22AA1640-2 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 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	

SPECIFICATIES
 GECONTROLEERD
 EN CONFORM

DATUM
 02/3/22

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BioPharma
Product Testing

Certificate of Analysis

Page 3 of 3

Analytical Report: AAU48500

Eurofins Sample Number: EB22AA1640-2

Version: 1

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.

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DATUM 18/3/22	PARAAF 

Reviewed and electronically signed for Qualified Person Approval by
Alexandra HAIRON, Valideur
for Eurofins Pharma Quality Control SAS, on 16-Mar-2022 16:29:59 UTC+01:00