Certificate of Analysis

Productname:	**CFB Mann. 99,5% Silic 0,5%**	
Number of analysis/Inspection Code	MON-202795B	/ KEUR-190081B
Batchnumber:	**21D02-F04**	
Reference code / No.:	3828	/ 21D02-F04
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		0,7371	g/ml	
Total aerobic microbial count (TAMC)	<=10¹	Conform	CFU / g	
Total yeasts and moulds (TYMC)	<=10¹	Conform	CFU / g	
E. coli	Negative / gram	Conform		

Release:
Chantal Nobus
Qualified Person

05-05-21

Expiration: 04-2023

Conclusion: APPROVED

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

eurofins | BioPharma Product Testing

Certificate of Analysis

Analytical Report: AAO08425
Eurofins Sample Number: EB21AA2030-3
Version: 1

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

Client Account Number: A00497292BNI
Eurofins Quote Number: K4SEPH19033498

Eurofins Sample Number EB21AA2030-3

Original Received Date:	14-Apr-2021
Description:	CFB Mann. 99,5% Silic 0,5%
Lot Number:	21D02-F04
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: 20-Apr-2021 to 20-Apr-2021			
Identification per silicates	Within a short time a white ring is rapidly formed around the drop of water	Meets Requirements	----
Method: Synoptique 1-P-LB-WI-9039687 Analysis Date: 20-Apr-2021 to 20-Apr-2021			
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: 20-Apr-2021 to 20-Apr-2021			
Bulk density and tapped density of powders	----	0.7371	g/ml
Method: Current EP 2.9.34 Analysis Date: 20-Apr-2021 to 20-Apr-2021			
TAMC acc to HM	≤ 10	< 10	CFU/g
Method: Current Ph Eur (2.6.12), Not validated Method Analysis Date: 15-Apr-2021 to 20-Apr-2021			

SPECIFICATIES GECONTROLEERD EN CONFORM
DATUM 05-05-21 PARAAF

Analysis	Specification	Result	Unit
TYMC acc. to HM	≤ 10	< 10	CFU/g
Method: Current Ph Eur (2.6.12),Not Validated Method Analysis Date: 15-Apr-2021 to 20-Apr-2021			
Escherichia coli search acc to HM	Absence	Absence	/1 g
Method: Current Ph Eur (2.6.13),Not Validated method Analysis Date: 15-Apr-2021 to 20-Apr-2021			
Identification per silicates	Within a short time a white ring is rapidly formed around the drop of water	Meets Requirements	----
Method: Synoptique 1-P-LB-WI-9039687 Analysis Date: 20-Apr-2021 to 20-Apr-2021			
Identification per silicates	Within a short time a white ring is rapidly formed around the drop of water	Meets Requirements	----
Method: Synoptique 1-P-LB-WI-9039687 Analysis Date: 20-Apr-2021 to 20-Apr-2021			

Sample Compliance Assessment

EB21AA2030-3 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.

SPECIFICATIES GECONTROLEERD EN CONFORM
DATUM 05-05-21 PARAAF