

Certificate of Analysis

Productname: CFB Mann. 99,5% Silic 0,5%
Number of analysis/Inspection Code MON-202793B / KEUR-190079B
Batchnumber: 21D02-F02
Reference code / No.: 3828 / 21D02-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		0,7430	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:
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.



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Analytical Report: AAO08428

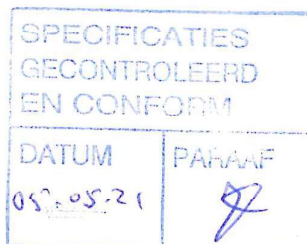
Eurofins Sample Number: EB21AA2030-1

Version: 1

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

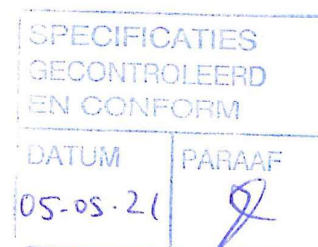
Client Account Number: A00497292BNI
Eurofins Quote Number: K4SEPH19033498

Eurofins Sample Number EB21AA2030-1			
Original Received Date:	14-Apr-2021		
Description:	CFB Mann. 99,5% Silic 0,5%		
Lot Number:	21D02-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: 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	----	0.7430	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			



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			
EB21AA2030-1 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.





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Version: 1

SPECIFICATIES GECONTROLEERD EN CONFORM	
DATUM	PARAAAF
05-05-21	

Reviewed and electronically signed for Qualified Person Approval by
Alexandra HAIRON, Valideur
for Eurofins Pharma Quality Control SAS, on 30-Apr-2021 08:43:29 UTC+02:00