

Certificate of Analysis

Productname: CFB Mann. 99,5% Silic 0,5%
Number of analysis/Inspection Code MON-206758B / KEUR-193951B
Batchnumber: 22A12-F13
Reference code / No.: 3828 / 22A12-F13
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		0,7387	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

11-03-22

Expiration: 01-2024

Conclusion: APPROVED

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



BioPharma
Product Testing

Certificate of Analysis

Page 1 of 3

Analytical Report: AAU11974

Eurofins Sample Number: EB22AA0604-10

Version: 2

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

Client Account Number: A00497292BNI
Eurofins Quote Number: WB9XPH21016607

Eurofins Sample Number EB22AA0604-10			
Original Received Date:	25-Jan-2022		
Description:	CFB Mann. 99.5% Silc 0.5%		
Lot Number:	22A12-F13		
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: 03-Feb-2022 to 03-Feb-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: 04-Feb-2022 to 04-Feb-2022			
Bulk density and tapped density of powders	----	0.7387	g/ml
Method: Current EP 2.9.34			
Analysis Date: 03-Feb-2022 to 03-Feb-2022			
TYMC acc. to HM	≤ 10	< 10	CFU/g
Method: Current Ph Eur (2.6.12), Not Validated Method			
Analysis Date: 31-Jan-2022 to 05-Feb-2022			
Escherichia coli search acc to HM	Absence	Absence	/1 g
Method: Current Ph Eur (2.6.13), Not Validated method			
Analysis Date: 31-Jan-2022 to 05-Feb-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: 04-Feb-2022 to 04-Feb-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: 04-Feb-2022 to 04-Feb-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: 04-Feb-2022 to 04-Feb-2022			
TAMC by inoculation according to EP 2.6.12 / USP <61>	≤ 10	< 10	CFU/g
Method: Current Ph Eur (2.6.12), Not validated Method Analysis Date: 22-Feb-2022 to 27-Feb-2022			
TYMC by inoculation according to EP2.6.12 / USP <61>	≤ 10	< 10	CFU/g
Method: Current Ph Eur (2.6.12), Not Validated Method Analysis Date: 22-Feb-2022 to 27-Feb-2022			
Sample Compliance Assessment			
EB22AA0604-10 meets the requirement(s) for all listed test(s) where specifications were applied.			





BioPharma
Product Testing

Certificate of Analysis

Page 3 of 3

Analytical Report: AAU11974

Eurofins Sample Number: EB22AA0604-10

Version: 2

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 by inoculation according to EP 2.6.12 / USP<61> TYMC acc. to HM TYMC by inoculation according to EP2.6.12 / USP <61>

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	
DATE 11/3/22	SIGNATURE [Signature]

Reviewed and electronically signed for Qualified Person Approval by
Anne-Lise BELLI, QA Pharmacist
for Eurofins Pharma Quality Control SAS, on 28-Feb-2022 14:42:35 UTC+01:00

Roodbordje nr: 8
12-01-22 g.

12-01-22

Prod.-order - Materiaalbehoefte
Fagron Services B.V.

12. januari 2022
Pagina 1
lusom01

Productieorder: Status: Vrijgegeven, Nr.: 526737

Vrijgegeven 526737 CFB Mann. 99,5% Silic 0,5%
Bronnr. 518913
Aantal 50

Oorspr. artikelnr.	Artikelnr.	Omschrijving	Lot No.	Lotnr. Vervaldatum	Hoofdingrediënt	Aantal per Eenheidsco	Resterend Uaantal %	Vestiging
521813	✓ 521813	Mannitolium	21H20-F50	14-05-26	Nee	0,995 KG	49,75	0 BU 01
519334	✓ 519334	Silica colloid. anh. geperst	21E28-F01-526645	07-01-23	Nee	0,02 250G	1	0 BU 01
519205	✓ 519205	Emmer 27,6 liter wit			Nee	0,08 STUK	4	0 BU 01
519213	✓ 519213	Deksel rood emmer 27,6 liter			Nee	0,08 STUK	4	0 BU 01
517073	✓ 517073	Zak 80x120x100mu PE transp.			Nee	0,08 STUK	4	0 BU 01
556075	503625	Tie-wrap verzegeling wit			Nee	0,08 STUK	4	0 BU 01
521086	✓ 521086	Etiket FA 60 x 170 mm PE			Nee	0,16 STUK	10	20 BU 01

12.01.22 p

Fysiek gecontroleerd bordje nr 14 12-01-22 B6