

**Certificate of Analysis**

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Analytical Report: AAR13793

Eurofins Sample Number: EB21AA5199-2

Version: 1

Fagron Services B.V.

Molenwerf 13

Uitgeest, 1911 DB

NL

Client Account Number: A00497292BNI

Eurofins Quote Number: WB9XPH21013408

Eurofins Sample Number EB21AA5199-2			
<b>Original Received Date:</b>	16-Sep-2021		
<b>Description:</b>	CFB Mann. 99,5% Silic 0,5%		
<b>Lot Number:</b>	21H04-F06		
<b>Containers Submitted:</b>	3 Tank(s)		
Protocol Reference: 1-P-LB-WI-9039687			
General Method Reference: Current EP 0559			
Analysis	Specification	Result	Unit
<b>Characters</b>	(Almost) white, fine powder	white, fine powder	----
Method: Synoptique 1-P-LB-WI-9039687			
Analysis Date: 20-Sep-2021 to 20-Sep-2021			
<b>Identification per silicates</b>	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-Sep-2021 to 20-Sep-2021			
<b>Ph Eur Identification D per Thin-layer chromatography (2.2.27)</b>	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: 29-Sep-2021 to 29-Sep-2021			
<b>Bulk density and tapped density of powders</b>	----	0.7153	g/mL
Method: Current EP 2.9.34			
Analysis Date: 20-Sep-2021 to 20-Sep-2021			
<b>TAMC acc to HM</b>	≤ 10	< 10	CFU/g
Method: Current Ph Eur (2.6.12), Not validated Method			
Analysis Date: 20-Sep-2021 to 25-Sep-2021			

 SPECIFICATIES  
GECONTROLEERD  
EN CONFORM

DATUM

PARAAF

041021



Analysis	Specification	Result	Unit
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<b>TYMC acc. to HM</b>	$\leq 10$	< 10	CFU/g
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Method: Current Ph Eur (2.6.12), Not Validated Method

Analysis Date: 20-Sep-2021 to 25-Sep-2021

<b>Escherichia coli search acc to HM</b>	Absence	Absence	/1 g
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Method: Current Ph Eur (2.6.13), Not Validated method

Analysis Date: 20-Sep-2021 to 25-Sep-2021

<b>Identification per silicates</b>	Within a short time a white ring is rapidly formed around the drop of water	Meets Requirements	----
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Method: Synoptique 1-P-LB-WI-9039687

Analysis Date: 20-Sep-2021 to 20-Sep-2021

<b>Identification per silicates</b>	Within a short time a white ring is rapidly formed around the drop of water	Meets Requirements	----
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Method: Synoptique 1-P-LB-WI-9039687

Analysis Date: 20-Sep-2021 to 20-Sep-2021

**Sample Compliance Assessment**

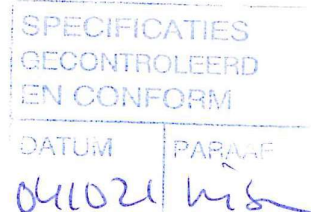
EB21AA5199-2 meets the requirement(s) for all listed test(s) where specifications were applied.

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 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.





BioPharma  
Product Testing

## *Certificate of Analysis*

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Eurofins Sample Number: EB21AA5199-2

Version: 1

SPECIFICATIES GECONTROLEERD EN CONFORM	
DATUM	PARAAF
04/10/21	WJS

Reviewed and electronically signed for Qualified Person Approval by  
Anne-Lise BELLÉ, QA Pharmacist  
for Eurofins Pharma Quality Control SAS, on 30-Sep-2021 16:05:23 UTC+02:00