



BioPharma  
Product Testing

## Certificate of Analysis

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Analytical Report: AAR13798

Eurofins Sample Number: EB21AA5199-3

Version: 1

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

Client Account Number: A00497292BNI  
Eurofins Quote Number: WB9XPH21013408

Eurofins Sample Number EB21AA5199-3	
Original Received Date:	16-Sep-2021
Description:	CFB Mann. 99,5% Silic 0,5%
Lot Number:	21H04-F07
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-Sep-2021 to 20-Sep-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-Sep-2021 to 20-Sep-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: 29-Sep-2021 to 29-Sep-2021			

Bulk density and tapped density of powders	----	0.7241	g/mL
Method: Current EP 2.9.34			
Analysis Date: 20-Sep-2021 to 20-Sep-2021			

TAMC acc to HM	≤ 10	10	CFU/g
Method: Current Ph Eur (2.6.12), Not validated Method			
Analysis Date: 20-Sep-2021 to 25-Sep-2021			

SPECIFICATIES  
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EN CONFORM

DATUM: 04/10/21  
PARAAAF: Wis

Analysis	Specification	Result	Unit
<b>TYMC 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			
<b>Escherichia coli search acc to HM</b>	Absence	Absence	/1 g
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	----
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>Sample Compliance Assessment</b>			
EB21AA5199-3 meets the requirement(s) for all listed test(s) where specifications were applied.			
<b>Eurofins BPT Testing Facility</b>		<b>Test</b>	
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	
<b>Contracted Company: Eurofins Pharma Quality Control Les Ulis Testing</b>			
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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 04/02/21 | *WIS*

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