



BioPharma  
Product Testing

## Certificate of Analysis

Page 1 of 3

Analytical Report: AAU48531

Eurofins Sample Number: EB22AA1696-5

Version: 1

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

Client Account Number: A00497292BNI  
Eurofins Quote Number: WB9XPH21016607

Eurofins Sample Number EB22AA1696-5			
<b>Original Received Date:</b>	03-Mar-2022		
<b>Description:</b>	CFB Mann. 99.5% Silc 0.5%		
<b>Lot Number:</b>	22B22-F10		
<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: 08-Mar-2022 to 08-Mar-2022			
<b>Identification per silicates</b>	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: 11-Mar-2022 to 11-Mar-2022			
<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: 08-Mar-2022 to 08-Mar-2022			
<b>Bulk density and tapped density of powders</b>	----	0.7320	g/mL
Method: Current EP 2.9.34			
Analysis Date: 09-Mar-2022 to 09-Mar-2022			
<b>TAMC by inoculation according to EP 2.6.12 / USP&lt;61&gt;, No GMP</b>	≤ 10	< 10	CFU/g
Method: Current Ph Eur (2.6.12), Not validated Method			
Analysis Date: 09-Mar-2022 to 14-Mar-2022			

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Analysis	Specification	Result	Unit
<b>TYMC by inoculation according to EP2.6.12 / USP &lt;61&gt;, No GMP</b>	≤ 10	< 10	CFU/g
Method: Current Ph Eur (2.6.12), Not Validated Method Analysis Date: 09-Mar-2022 to 14-Mar-2022			
<b>Escherichia coli search according to EP 2.6.13 / USP&lt;62&gt;, No GMP</b>	Absence	Absence	/1 g
Method: Current Ph Eur (2.6.13), Not Validated method, No GMP Analysis Date: 09-Mar-2022 to 14-Mar-2022			
<b>Identification per silicates</b>	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: 11-Mar-2022 to 11-Mar-2022			
<b>Identification per silicates</b>	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: 11-Mar-2022 to 11-Mar-2022			
Sample Compliance Assessment			
EB22AA1696-5 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 according to EP 2.6.13 / USP<62>, No GMP TAMC by inoculation according to EP 2.6.12 / USP<61>, No GMP TYMC by inoculation according to EP2.6.12 / USP <61>, No GMP	

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Page 3 of 3

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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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18/3/22	

Reviewed and electronically signed for Qualified Person Approval by  
Anne-Lise BELLI, QA Pharmacist  
for Eurofins Pharma Quality Control SAS, on 16-Mar-2022 16:36:01 UTC+01:00