



BioPharma  
Product Testing

## Certificate of Analysis

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Analytical Report: AAV80743

Eurofins Sample Number: EB22AA2092-2

Version: 1


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

Client Account Number: A00497292BNI  
Eurofins Quote Number: WB9XPH21016609

Eurofins Sample Number EB22AA2092-2			
Original Received Date:	18-Mar-2022		
Description:	Syrspend SF PH4 Dry		
Lot Number:	22C07-F03		
Containers Submitted:	5 Tank(s)		
Protocol Reference: 1-P-LB-WI-9028625			
General Method Reference: Client Method 15ACE375 - Validated Method N°14-71495			
Analysis	Specification	Result	Unit
Organoleptic description	White powder, after reconstitution it is a hazy white translucent syrups, nearly odorless	Meets Requirements	----
Method: 15ACE375			
Analysis Date: 25-Mar-2022 to 25-Mar-2022			
pH	4.0 to 5.0	4.3	----
Method: 15ACE375			
Analysis Date: 25-Mar-2022 to 25-Mar-2022			
Water Solubility	Dispersible in water	Meets Requirements	----
Method: 15ACE375			
Analysis Date: 25-Mar-2022 to 25-Mar-2022			
Modified Stach, Identification C	Orange-Red to deep blue	Deep blue	----
Method: 15ACE375			
Analysis Date: 28-Mar-2022 to 28-Mar-2022			



Analysis	Specification	Result	Unit
<b>Rheology</b>			
Rheology (6.5% solution in water) at 9.3 sec-1	25 to 275	85	cP
Rheology (6.5% solution in water) at 0.93 sec-1	75 to 450	100	cP
<b>Refer to Laboratory OOS Investigation EXC-EB22AA7612</b>  DV3T Spindle SC4-21 Speed = 100rpm, 10rpm and 1rpm T°C = 25.0°C Tork = 10rpm = 1.7% 1rpm = 0.2% Method: 15ACE375 Analysis Date: 18-May-2022 to 18-May-2022			
<b>TAMC by inoculation according to EP 2.6.12 / USP&lt;61&gt;</b>	≤ 100	< 10	CFU/g
Method: Current Ph Eur (2.6.12), Not validated Method Analysis Date: 24-Mar-2022 to 29-Mar-2022			
<b>TYMC by inoculation according to EP2.6.12 / USP &lt;61&gt;</b>	≤ 10	< 10	CFU/g
Method: Current Ph Eur (2.6.12), Not Validated Method Analysis Date: 24-Mar-2022 to 29-Mar-2022			
<b>Escherichia coli search according to EP 2.6.13 / USP&lt;62&gt;</b>	Absence	Absence	/1 g
Method: Current Ph Eur (2.6.13), Not Validated method Analysis Date: 24-Mar-2022 to 29-Mar-2022			
<b>pH</b>	4.0 to 5.0	4.1	----
Method: 15ACE375 Analysis Date: 25-Mar-2022 to 25-Mar-2022			

SPECIFICATIES  
 GECONTROLEERD  
 EN CONFORM  
 DATUM 23-5-22 PARAAF 



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Analysis	Specification	Result	Unit
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pH	4.0 to 5.0	4.2	----
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Method: 15ACE375

Analysis Date: 25-Mar-2022 to 25-Mar-2022

### Sample Compliance Assessment

EB22AA2092-2 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	Modified Stach, Identification C Organoleptic description pH Rheology Water Solubility
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> TAMC by inoculation according to EP 2.6.12 / USP<61> 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.



Reviewed and electronically signed for Qualified Person Approval by  
Alexandra HAIRON, Valideur  
for Eurofins Pharma Quality Control SAS, on 19-May-2022 16:14:19 UTC+02:00