

Certificate of Analysis

Productname: SyrSpend® SF PH4 Dry
Number of analysis/Inspection Code MON-204917B / KEUR-192178B
Batchnumber: 21H20-F02
Reference code / No.: 3828 / 21H20-F02
Analysed according to: INTERN

Tests	Requirement	Result	Unit	Standard remark
Appearance	White powder	Conform		
Identification	Conform	Conform		Starch
pH	4,0 - 5,0	4,0		
Solubility in water	Dispersible	Conform		
Rheology 9.3 / sec	25 - 275	105	cP	
Rheology 0.93 / sec	75 - 450	150	cP	
Total aerobic microbial count (TAMC)	$\leq 10^2$	Conform	CFU / g	
Total yeasts and moulds (TYMC)	$\leq 10^1$	Conform	CFU / g	
E. coli	Absent/ g	Conform		

Release:
Chantal Nobus
Qualified Person

15-12-21

Expiration: 08-2024

Conclusion: APPROVED

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BioPharma
Product Testing

Certificate of Analysis

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Analytical Report: AAS24775

Eurofins Sample Number: EB21AA4937-3

Version: 2

Fagron Services B.V.

Molenwerf 13

Uitgeest, 1911 DB

NL

Client Account Number: A00497292BNI

Eurofins Quote Number: WB9XPH21013406

Eurofins Sample Number EB21AA4937-3

Original Received Date: 01-Sep-2021
Description: Syrspond SF PH4 Dry
Lot Number: 21H20-F02
Containers Submitted: 3 Tank(s)

Protocol Reference: 1-P-LB-WI -9059454

General Method Reference: 15ACE375

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: 08-Sep-2021 to 08-Sep-2021

pH	4.0 to 5.0	4.0	----
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Begin

Method: 15ACE375

Analysis Date: 07-Sep-2021 to 07-Sep-2021

Water Solubility	Dispersible in water	Meets Requirements	----
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Method: 15ACE375

Analysis Date: 08-Sep-2021 to 08-Sep-2021

Modified Stach, Identification C	Orange-Red to deep blue	Deep blue	----
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Method: 15ACE375

Analysis Date: 09-Sep-2021 to 09-Sep-2021

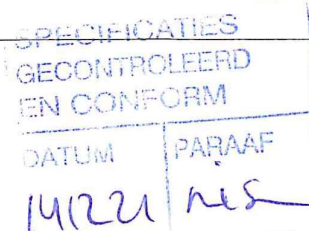
Rheology			
Rheology (6% solution in water) at 9.3 sec-1	25 to 275	105	cP
Rheology (6% solution in water) at 0.93 sec-1	75 to 450	150	cP

Refer to Laboratory OOS Investigation EXC-EB21AB9122

DV3T, spindle SC4-21, 25°C, 9.3sec-1 and 0.93 sec-1


Method: 21ACE971

Analysis Date: 20-Sep-2021 to 23-Sep-2021



Analysis	Specification	Result	Unit
TAMC acc to HM	≤100	< 10	CFU/g
Method: Current Ph Eur (2.6.12), 14-71495 Analysis Date: 06-Sep-2021 to 11-Sep-2021			
TYMC acc. to HM	≤10	< 10	CFU/g
Method: Current Ph Eur (2.6.12), 14-71495 Analysis Date: 06-Sep-2021 to 11-Sep-2021			
Escherichia coli search acc to HM	Absence	Absence	/1 g
Method: Current Ph Eur (2.6.13), 14-71495 Analysis Date: 06-Sep-2021 to 11-Sep-2021			
pH	4.0 to 5.0	4.0	----
Midden Method: 15ACE375 Analysis Date: 07-Sep-2021 to 07-Sep-2021			
pH	4.0 to 5.0	4.1	----
Eind Method: 15ACE375 Analysis Date: 07-Sep-2021 to 07-Sep-2021			
Sample Compliance Assessment			
Test level investigations were conducted for the following:			
EB21AA4937-3			
Meets specification(s) for the following test(s) but an investigation was conducted:			
• Rheology - Laboratory OOS EXC-EB21AB9122			
The Sample meets requirement(s) for all remaining 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 acc to HM TAMC acc to HM TYMC acc. to HM	

SPECIFICATIONS
GECONTROLEERD
EN CONFORM

DATUM 14/12/21 PARAAF 



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Eurofins Sample Number: EB21AA4937-3

Version: 2

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
Anne-Lise BELLI, QA Pharmacist
for Eurofins Pharma Quality Control SAS, on 22-Nov-2021 11:12:36 UTC+01:00