

Certificate of Analysis

Productname: **SyrSpend® SF PH4 Dry**
Number of analysis/Inspection Code MON-197461B / KEUR-184830B
Batchnumber: **20F18-F13**
Reference code / No.: 3828 / 20F18-F13
Analysed according to: **INTERN**

Tests	Requirement	Result	Unit	Standard remark
Appearance	White powder	Conform		
Identification	Conform	Conform		Starch
pH	4,0 - 5,0	4,2		
Solubility in water	Dispersible	Conform		
Rheology 9.3 / sec	25 - 275	95	cP	
Rheology 0.93 / sec	75 - 450	200	cP	
Total aerobic microbial count (TAMC)	<=1000	Conform	CFU / g	
Total yeasts and moulds (TYMC)	<=100	Conform	CFU / g	
E. coli	Absent/ g	Conform		

Release:
Paul Hofman
Pharmacist - Qualified Person

07-08-20

Expiration: 06-2023

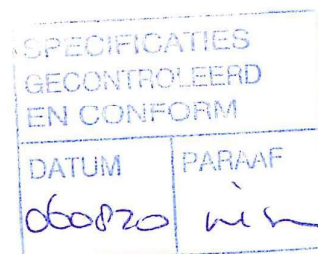
Conclusion: APPROVED

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

Client Account Number: A00497292BNI
Eurofins Quote Number: K4SEPH19033468

Eurofins Sample Number EB20AA3073-4			
Original Received Date:		07-Jul-2020	
Description:		Syrspend SF PH4 dry	
Lot Number:		20F18-F13	
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 harzy white translucent syrups, nearly odorless	Meets Requirements	----
Method: 15ACE375			
Analysis Date: 31-Jul-2020 to 31-Jul-2020			
pH	4.0 to 5.0	4.2	----
End			
Method: 15ACE375			
Analysis Date: 31-Jul-2020 to 31-Jul-2020			
Water Solubility	Dispersible in water	Meets Requirements	----
Method: 15ACE375			
Analysis Date: 31-Jul-2020 to 31-Jul-2020			
Modified Stach, Identification C	Orange-Red to deep blue	Meets Requirements	----
Method: 15ACE375			
Analysis Date: 04-Aug-2020 to 04-Aug-2020			





Analysis	Specification	Result	Unit
Rheology			
Rheology (6.5% solution in water) at 9.3 sec-1	25 to 275	95	cP
Rheology (6.5% solution in water) at 0.93 sec-1	75 to 450	200	cP
Sample tested using DV3T, mobile SC4-21 at 25°C + /-0.2°C.			
Method: 15ACE375			
Analysis Date: 17-Jul-2020 to 21-Jul-2020			
Water Solubility	Dispersible in water	Meets Requirements	----
Method: 15ACE375			
Analysis Date: 31-Jul-2020 to 31-Jul-2020			
Water Solubility	Dispersible in water	Meets Requirements	----
Method: 15ACE375			
Analysis Date: 31-Jul-2020 to 31-Jul-2020			
TAMC acc to HM	≤ 1000	< 10	CFU/g
Method: Current Ph Eur (2.6.12), 14-71495			
Analysis Date: 10-Jul-2020 to 15-Jul-2020			
TYMC acc. to HM	≤ 100	< 10	CFU/g
Method: Current Ph Eur (2.6.12), 14-71495			
Analysis Date: 10-Jul-2020 to 15-Jul-2020			
Escherichia coli search acc to HM	Absence	Absence	/1 g
Method: Current Ph Eur (2.6.13), 14-71495			
Analysis Date: 10-Jul-2020 to 15-Jul-2020			
pH	4.0 to 5.0	4.0	----
Start			
Method: 15ACE375			
Analysis Date: 31-Jul-2020 to 31-Jul-2020			
pH	4.0 to 5.0	4.2	----
Middle			
Method: 15ACE375			
Analysis Date: 31-Jul-2020 to 31-Jul-2020			
Sample Compliance Assessment			
EB20AA3073-4 meets the requirement(s) for all listed test(s) where specifications were applied.			

Eurofins BPT Testing Facility	Test
Eurofins Pharma Quality Control SAS 9 Avenue de Laponie 91978 Les Ulis, Courtaboeuf Cedex FRANCE	Modified Stach, Identification C Organoleptic description pH Rheology Water Solubility
Eurofins Pharma Quality Control SAS 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.

