

Certificate of Analysis

Productname: SyrSpend® SF Alka Unflavoured
Number of analysis/Inspection Code MON-205106B / KEUR-192354B
Batchnumber: 21101-F04
Reference code / No.: 3828 / 21101-F04
Analysed according to: INTERN

Tests	Requirement	Result	Unit	Standard remark
Appearance	White to off-white, free flowing powder	Conform		
Identification	Conform	Conform		Starch
Identification B	Conform	Conform		Carbonate
Identification C	Conform	Conform		Calcium
pH	>= 7,0	9,6		
Solubility in water	Dispersible	Conform		
Assay Calcium carbonate	48,2 - 58,9	49,5	%m/m	
Total aerobic microbial count (TAMC)	<=10 ²	Conform	CFU / g	
Total yeasts and moulds (TYMC)	<=10 ¹	Conform	CFU / g	
E. coli	Absent/ g	Conform		

Release:
Anthony Amoureux
Qualified Person

19-01-22

Expiration: 09-2025

Conclusion: APPROVED

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

Client Account Number: A00497292BNI
Eurofins Quote Number: WB9XPH21013408

Eurofins Sample Number EB21AA5359-4			
Original Received Date:	23-Sep-2021		
Description:	Syrspend SF Alka Unflavoured		
Lot Number:	21I01-F04		
Containers Submitted:	3 Tank(s)		
General Method Reference: 14ACE102 and 1-P-LB-WI-9043482			
Analysis	Specification	Result	Unit
Calcium Carbonate Content	48.2 to 58.9	49.4	%
Begin Method: 14ACE102 Analysis Date: 05-Oct-2021 to 05-Oct-2021			
Calcium Carbonate Content	48.2 to 58.9	49.8	%
Midden Method: 14ACE102 Analysis Date: 05-Oct-2021 to 05-Oct-2021			
Calcium Carbonate Content	48.2 to 58.9	49.4	%
Eind Method: 14ACE102 Analysis Date: 05-Oct-2021 to 05-Oct-2021			
Organoleptic Description	White free flowing powder	Meets Requirements	----
Method: 14ACE102 Analysis Date: 27-Sep-2021 to 27-Sep-2021			
Identification by Iodine reaction	Orange-Red to deep blue	Deep blue	----
Method: 14ACE102 Analysis Date: 27-Sep-2021 to 27-Sep-2021			
Identification of Carbonates	Effervescence is observed	Meets Requirements	----
Method: 14ACE102 Analysis Date: 27-Sep-2021 to 27-Sep-2021			

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Analysis	Specification	Result	Unit
Identification of Calcium	Yellowish-red color to a nonluminous flame	Red color to a nonluminous flame	----
Method: 14ACE102 Analysis Date: 27-Sep-2021 to 27-Sep-2021			
pH	>7.0	9.6	----
Method: 14ACE102 Analysis Date: 27-Sep-2021 to 27-Sep-2021			
Water solubility	The resulting suspension forms a cloudy, viscous liquid	Meets Requirements	----
Method: 14ACE102 Analysis Date: 27-Sep-2021 to 27-Sep-2021			
TAMC acc to HM	≤ 100	220	CFU/g
Refer to Laboratory OOS Investigation EXC-HA21AC0203			
Method: Current Ph Eur (2.6.12), Not validated Method Analysis Date: 27-Sep-2021 to 02-Oct-2021			
TYMC acc. to HM	≤ 10	< 10	CFU/g
Method: Current Ph Eur (2.6.12), Not Validated Method Analysis Date: 27-Sep-2021 to 02-Oct-2021			
Escherichia coli search acc to HM	Absence	Absence	/1 g
Method: Current Ph Eur (2.6.13), Not Validated method Analysis Date: 27-Sep-2021 to 02-Oct-2021			
Séquençage additionnel non-identifié MALDI	----	See Report	----
Method: PR-L-028-BM Analysis Date: 18-Oct-2021 to 10-Nov-2021 Subcontracted to Eurofins IDmyk SAS (FR)			
Proteomic identification of bacteria by MALDI-TOF	----	See Report	----
Method: PR-L-001-MC Analysis Date: 18-Oct-2021 to 29-Oct-2021 Subcontracted to Eurofins IDmyk SAS (FR)			

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Analysis	Specification	Result	Unit
TAMC acc to HM	≤100	< 100 (Container M004)	CFU/g
Method: Current Ph Eur (2.6.12), Not validated Method Analysis Date: 23-Dec-2021 to 28-Dec-2021			
TAMC acc to HM	≤100	<100 (Container M001)	CFU/g
Method: Current Ph Eur (2.6.12), Not validated Method Analysis Date: 29-Dec-2021 to 03-Jan-2022			
TAMC acc to HM	≤100	<100 (Container M002)	CFU/g
Method: Current Ph Eur (2.6.12), Not validated Method Analysis Date: 29-Dec-2021 to 03-Jan-2022			
TAMC acc to HM	≤100	<100 (Container M003)	CFU/g
Method: Current Ph Eur (2.6.12), Not validated Method Analysis Date: 29-Dec-2021 to 03-Jan-2022			
TAMC acc to HM	≤100	<100 (Container M005)	CFU/g
Method: Current Ph Eur (2.6.12), Not validated Method Analysis Date: 29-Dec-2021 to 03-Jan-2022			
Sample Compliance Assessment			
Test level investigations were conducted for the following:			
EB21AA5359-4			
An investigation was conducted for the following test(s):			
• TAMC acc to HM - Laboratory OOS EXC-HA21AC0203			
The Sample meets requirement(s) for all remaining test(s) where specifications were applied.			
Supplemental Information			
Analytical Report Version 5 Comment: Error specification			

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Eurofins BPT Testing Facility	Test
Eurofins Pharma Quality Control Les Ulis Testing 9 Avenue de Laponie 91978 Les Ulis, Courtaboeuf Cedex FRANCE	Calcium Carbonate Content Identification by Iodine reaction Identification of Calcium Identification of Carbonates Organoleptic Description pH 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 Proteomic identification of bacteria by MALDI-TOF (Subcontracted to 'Eurofins IDmyk SAS (FR)') Séquençage additionnel non-identifié MALDI (Subcontracted to 'Eurofins IDmyk SAS (FR)') 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.

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Reviewed and electronically signed for Qualified Person Approval by
 Tugba Ozel, Quality Assistant
 for Eurofins Pharma Quality Control SAS, on 17-Jan-2022 10:13:20 UTC+01:00