

Certificate of Analysis

Productname: **SyrSpend® SF Alka Unflavoured**
Number of analysis/Inspection Code MON-197464B / KEUR-184833B
Batchnumber: **20F18-F16**
Reference code / No.: 3828 / 20F18-F16
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	51,6	%m/m	
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: 06-2024

Conclusion: APPROVED

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

Client Account Number: A00497292BNI
Eurofins Quote Number: K4SEPH19033473

Eurofins Sample Number EB20AA3333-1	
Original Received Date:	15-Jul-2020
Description:	Syrspend SF ALKA unflavoured
Lot Number:	20F18-F16
Containers Submitted:	3 Tank(s)
General Method Reference: 14ACE102 and 1-P-LB-WI-9043482	

Analysis	Specification	Result	Unit
Calcium Carbonate Content	48.6 to 59.5	53.4	%

Start
Method: 14ACE102
Analysis Date: 03-Aug-2020 to 04-Aug-2020

Calcium Carbonate Content	48.6 to 59.5	52.7	%
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Middle
Method: 14ACE102
Analysis Date: 03-Aug-2020 to 04-Aug-2020

Calcium Carbonate Content	48.6 to 59.5	48.6	%
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End
Method: 14ACE102
Analysis Date: 03-Aug-2020 to 04-Aug-2020

Organoleptic Description	White free flowing powder	Meets Requirements	----
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Method: 14ACE102
Analysis Date: 30-Jul-2020 to 30-Jul-2020

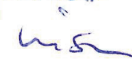
Identification of Carbonates	Effervescence is observed	Meets Requirements	----
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Method: 14ACE102
Analysis Date: 28-Jul-2020 to 28-Jul-2020

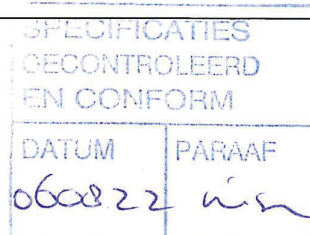
Identification of Calcium	Yellowish-red color to a nonluminous flame	Meets Requirements	----
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Method: 14ACE102
Analysis Date: 28-Jul-2020 to 28-Jul-2020

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EN CONFORM

DATUM 060820 PARAAF 

Analysis	Specification	Result	Unit
Identification by Iodine reaction	Orange-Red to deep blue	The product is colored to deep blue	----
Method: 14ACE102 Analysis Date: 29-Jul-2020 to 29-Jul-2020			
pH	>7.0	9.6	----
Method: 14ACE102 Analysis Date: 30-Jul-2020 to 30-Jul-2020			
Water solubility	The resulting suspension forms a cloudy, viscous liquid	Meets Requirements	----
Method: 14ACE102 Analysis Date: 28-Jul-2020 to 28-Jul-2020			
TAMC acc to HM	≤ 1000	< 10	CFU/g
Method: Current Ph Eur (2.6.12), Not validated Method Analysis Date: 28-Jul-2020 to 02-Aug-2020			
TYMC acc. to HM	≤ 100	< 10	CFU/g
Method: Current Ph Eur (2.6.12), Not Validated Method Analysis Date: 28-Jul-2020 to 02-Aug-2020			
Escherichia coli search acc to HM	Absence	Absence	/1 g
Method: Current Ph Eur (2.6.13), Not Validated method Analysis Date: 28-Jul-2020 to 02-Aug-2020			
Sample Compliance Assessment			
EB20AA3333-1 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		Calcium Carbonate Content Identification by Iodine reaction Identification of Calcium Identification of Carbonates Organoleptic Description pH 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 Testing9 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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DATUM 060822	PARAAF wis