

Certificate of Analysis

Productname: **SyrSpend® SF Alka Unflavoured**
Number of analysis/Inspection Code MON-188369B / KEUR-175834B
Batchnumber: **19F06-B03**
Reference code / No.: 3828 / 19F06-B03
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	10,0		
Solubility in water	Dispersible	Conform		
Assay Calcium carbonate	48,2 - 58,9	50,1	%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:
dr. M.J. Vincenten - van Maanen
Pharmacist - Qualified Person

30-08-19

Expiration: 06-2023

Conclusion: APPROVED

This document has been produced electronically from our quality system and is valid without signature.

Certificate of Analysis

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Analytical Report: AAE15955

Eurofins Sample Number: EB19AA2456-5

Version: 1

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

Client Account Number: A00497292BNI

Eurofins Sample Number EB19AA2456-5

Original Received Date: 12-Jul-2019
Description: SyrSpend SF Alka Unflavoured begin
Lot Number: 19F06-B03
Containers Submitted: 1 Box(es)

General Method Reference: 14ACE102

Analysis	Specification	Result	Unit
Organoleptic Description	White free flowing powder	Meets Requirements	----
Analysis Date: 18-Jul-2019 to 18-Jul-2019			
Identification by Iodine reaction	Orange-Red to deep blue	Meets Requirements	----
Analysis Date: 02-Aug-2019 to 02-Aug-2019			
Identification of Carbonates	Effervescence is observed	Meets Requirements	----
Analysis Date: 02-Aug-2019 to 02-Aug-2019			
Identification of Calcium	Yellowish-red color to a nonluminous flame	Meets Requirements	----
Analysis Date: 02-Aug-2019 to 02-Aug-2019			
pH	>7.0	10.0	----
Analysis Date: 19-Jul-2019 to 19-Jul-2019			
Water solubility	The resulting suspension forms a cloudy, viscous liquid	Meets Requirements	----
Analysis Date: 16-Jul-2019 to 16-Jul-2019			
Calcium Carbonate Content	48.2 to 58.9	50.9	%
Analysis Date: 30-Jul-2019 to 02-Aug-2019			
Sample Compliance Assessment			
EB19AA2456-5 meets the requirement(s) for all listed test(s) where specifications were applied.			

Contracted Company: Eurofins Pharma Quality Control

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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Product Testing

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Analytical Report: AAE15955

Eurofins Sample Number: EB19AA2456-5

Version: 1

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Reviewed and electronically signed for Qualified Person Approval by
Alexandra HAIRON, Valideur
for Eurofins Pharma Quality Control SAS, on 29-Aug-2019 17:50:38 UTC+02:00



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Analytical Report: AAE15956

Eurofins Sample Number: EB19AA2456-6

Version: 1

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

Client Account Number: A00497292BNI

Eurofins Sample Number EB19AA2456-6	
Original Received Date:	12-Jul-2019
Description:	SyrSpend SF Alka Unflavoured midden
Lot Number:	19F06-B03
Containers Submitted:	1 Box(es)
General Method Reference: 14ACE102	

Analysis	Specification	Result	Unit
Organoleptic Description	White free flowing powder	Meets Requirements	----
Analysis Date: 18-Jul-2019 to 18-Jul-2019			
Identification by Iodine reaction	Orange-Red to deep blue	Meets Requirements	----
Analysis Date: 02-Aug-2019 to 02-Aug-2019			
Identification of Carbonates	Effervescence is observed	Meets Requirements	----
Analysis Date: 02-Aug-2019 to 02-Aug-2019			
Identification of Calcium	Yellowish-red color to a nonluminous flame	Meets Requirements	----
Analysis Date: 02-Aug-2019 to 02-Aug-2019			
pH	>7.0	10.0	----
Analysis Date: 19-Jul-2019 to 19-Jul-2019			
Water solubility	The resulting suspension forms a cloudy, viscous liquid	Meets Requirements	----
Analysis Date: 16-Jul-2019 to 16-Jul-2019			
Calcium Carbonate Content	48.2 to 58.9	50.0	%
Analysis Date: 30-Jul-2019 to 02-Aug-2019			
Sample Compliance Assessment			
EB19AA2456-6 meets the requirement(s) for all listed test(s) where specifications were applied.			

Contracted Company: Eurofins Pharma Quality Control

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EPQC_ServiceClient@eurofins.com

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Analytical Report: AAE15956

Eurofins Sample Number: EB19AA2456-6

Version: 1

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Analytical Report: AAE15947

Eurofins Sample Number: EB19AA2456-7

Version: 1

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

Client Account Number: A00497292BNI

Eurofins Sample Number EB19AA2456-7

Original Received Date: 12-Jul-2019
Description: SyrSpend SF Alka Unflavoured eind
Lot Number: 19F06-B03
Containers Submitted: 1 Box(es)

General Method Reference: 14ACE102

Analysis	Specification	Result	Unit
Organoleptic Description	White free flowing powder	Meets Requirements	----
Analysis Date: 18-Jul-2019 to 18-Jul-2019			
Identification by Iodine reaction	Orange-Red to deep blue	Meets Requirements	----
Analysis Date: 02-Aug-2019 to 02-Aug-2019			
Identification of Carbonates	Effervescence is observed	Meets Requirements	----
Analysis Date: 02-Aug-2019 to 02-Aug-2019			
Identification of Calcium	Yellowish-red color to a nonluminous flame	Meets Requirements	----
Analysis Date: 02-Aug-2019 to 02-Aug-2019			
pH	>7.0	10.1	----
Analysis Date: 19-Jul-2019 to 19-Jul-2019			
Water solubility	The resulting suspension forms a cloudy, viscous liquid	Meets Requirements	----
Analysis Date: 16-Jul-2019 to 16-Jul-2019			
Calcium Carbonate Content	48.2 to 58.9	49.3	%
Analysis Date: 30-Jul-2019 to 02-Aug-2019			
Sample Compliance Assessment			
EB19AA2456-7 meets the requirement(s) for all listed test(s) where specifications were applied.			

Contracted Company: Eurofins Pharma Quality Control

9 Avenue de Laponie, Les Ulis, Courtaboeuf Cedex, 91978 France
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Analytical Report: AAE15947

Eurofins Sample Number: EB19AA2456-7

Version: 1

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Analytical Report: AAE15954

Eurofins Sample Number: EB19AA2456-8

Version: 1

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

Client Account Number: A00497292BNI

Eurofins Sample Number EB19AA2456-8

Original Received Date:	12-Jul-2019
Description:	SyrSpend SF Alka Unflavoured pool
Lot Number:	19F06-B03
Containers Submitted:	1 Box(es)

Analysis	Specification	Result	Unit
TAMC acc to HM	≤1000	< 10	CFU/g
Method: Current Ph Eur (2.6.12) Analysis Date: 17-Jul-2019 to 22-Jul-2019			
TYMC acc. to HM	≤100	< 10	CFU/g
Method: Current Ph Eur (2.6.12) Analysis Date: 17-Jul-2019 to 22-Jul-2019			
Escherichia coli search acc to HM	Absence	Absence	/1 g
Method: Current Ph Eur (2.6.13) Analysis Date: 17-Jul-2019 to 22-Jul-2019			

Sample Compliance Assessment

EB19AA2456-8 meets the requirement(s) for all listed test(s) where specifications were applied.

Eurofins BPT Testing Facility	Test
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

9 Avenue de Laponie, Les Ulis, Courtaboeuf Cedex, 91978 France
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Alexandra HAIRON, Valideur
for Eurofins Pharma Quality Control SAS, on 29-Aug-2019 17:50:11 UTC+02:00