

Certificate of Analysis

Productname: SyrSpend® SF Alka Unflavoured
Number of analysis/Inspection Code MON-201664B / KEUR-188965B
Batchnumber: 20L15-F06
Reference code / No.: 3828 / 20L15-F06
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	$\geq 7,0$	9,5		
Solubility in water	Dispersible	Conform		
Assay Calcium carbonate	48,2 - 58,9	48,6	%m/m	
Total aerobic microbial count (TAMC)	$\leq 10^3$	Conform	CFU / g	
Total yeasts and moulds (TYMC)	$\leq 10^2$	Conform	CFU / g	
E. coli	Absent/ g	Conform		

Release:
Paul Hofman
Pharmacist - Qualified Person

01-03-21

Expiration: 12-2024

Conclusion: APPROVED

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Product Testing

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Analytical Report: AAM83455

Eurofins Sample Number: EB21AA0470-5

Version: 1

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

Client Account Number: A00497292BNI
Eurofins Quote Number: K4SEPH19033496

Eurofins Sample Number EB21AA0470-5			
Original Received Date:	27-Jan-2021		
Description:	Syrspend SF ALKA Unflavoured		
Lot Number:	20L15-F06		
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	48.4	%
Begin Method: 14ACE102 Analysis Date: 18-Feb-2021 to 19-Feb-2021			
Calcium Carbonate Content	48.2 to 58.9	49.1	%
Middle Method: 14ACE102 Analysis Date: 18-Feb-2021 to 19-Feb-2021			
Calcium Carbonate Content	48.2 to 58.9	48.4	%
End Method: 14ACE102 Analysis Date: 18-Feb-2021 to 19-Feb-2021			
Organoleptic Description	White free flowing powder	Meets Requirements	----
Method: 14ACE102 Analysis Date: 16-Feb-2021 to 16-Feb-2021			
Identification of Carbonates	Effervescence is observed	Meets Requirements	----
Method: 14ACE102 Analysis Date: 16-Feb-2021 to 16-Feb-2021			
Identification of Calcium	Yellowish-red color to a nonluminous flame	Meets Requirements	----
Method: 14ACE102 Analysis Date: 16-Feb-2021 to 16-Feb-2021			

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EN CONFORM

DATUM

26-02-21

PARAAF

Analysis	Specification	Result	Unit
Identification by Iodine reaction	Orange-Red to deep blue	deep blue	----
Method: 14ACE102 Analysis Date: 16-Feb-2021 to 16-Feb-2021			
pH	>7.0	9.5	----
Method: 14ACE102 Analysis Date: 16-Feb-2021 to 16-Feb-2021			
Water solubility	The resulting suspension forms a cloudy, viscous liquid	Meets Requirements	----
Method: 14ACE102 Analysis Date: 16-Feb-2021 to 16-Feb-2021			
TAMC acc to HM	≤ 1000	< 10	CFU/g
Method: Current Ph Eur (2.6.12), Not validated Method Analysis Date: 05-Feb-2021 to 10-Feb-2021			
TYMC acc. to HM	≤ 100	< 10	CFU/g
Method: Current Ph Eur (2.6.12), Not Validated Method Analysis Date: 05-Feb-2021 to 10-Feb-2021			
Escherichia coli search acc to HM	Absence	Absence	/1 g
Method: Current Ph Eur (2.6.13), Not Validated method Analysis Date: 05-Feb-2021 to 10-Feb-2021			
Sample Compliance Assessment			
EB21AA0470-5 meets the requirement(s) for all listed 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		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 TAMC acc to HM TYMC acc. to HM	





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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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DATUM 26-02-21	PARAARF 

Reviewed and electronically signed for Qualified Person Approval by
Alexandra HAIRON, Valideur
for Eurofins Pharma Quality Control SAS, on 25-Feb-2021 14:55:03 UTC+01:00