

Certificate of Analysis

Productname: **SyrSpend® SF Alka Unflavoured**
Number of analysis/Inspection Code MON-188651B / KEUR-176111B
Batchnumber: **19F12-B05**
Reference code / No.: 3828 / 19F12-B05
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	10,1		
Solubility in water	Dispersible	Conform		
Assay Calcium carbonate	48,2 - 58,9	52,6	%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:
dr. M.J. Vincenten - van Maanen
Pharmacist - Qualified Person

09-09-19

Expiration: 06-2023

Conclusion: APPROVED

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

Client Account Number: A00497292BNI

Eurofins Sample Number EB19AA2702-9	
Original Received Date:	25-Jul-2019
Description:	SyrSpend SF Alka Unflavoured
Lot Number:	19F12-B05
Containers Submitted:	1 Box(es)
Protocol Reference: 1-P-LB-WI-9028625	
General Method Reference: Current EP (Validated method 14-41495)	

Analysis	Specification	Result	Unit
Organoleptic Description	White free flowing powder	Meets Requirements	----
Method: 14ACE102 Analysis Date: 01-Aug-2019 to 02-Aug-2019			
Identification by Iodine reaction	Orange-Red to deep blue	Meets Requirements	----
Method: 14ACE102 Analysis Date: 16-Aug-2019 to 16-Aug-2019			
Identification of Carbonates	Effervescence is observed	Meets Requirements	----
Method: 14ACE102 Analysis Date: 16-Aug-2019 to 16-Aug-2019			
Identification of Calcium	Yellowish-red color to a nonluminous flame	Meets Requirements	----
Method: 14ACE102 Analysis Date: 16-Aug-2019 to 16-Aug-2019			
pH	>7.0	10.1	----
Method: 14ACE102 Analysis Date: 01-Aug-2019 to 02-Aug-2019			
Water solubility	The resulting suspension forms a cloudy, viscous liquid	Meets Requirements	----
Method: 14ACE102 Analysis Date: 16-Aug-2019 to 16-Aug-2019			
Calcium Carbonate Content	48.2 to 58.9	52.6	%
Method: 14ACE102 Analysis Date: 02-Sep-2019 to 02-Sep-2019			

SPECIFICATIONS
RECONTROLLED
IN CONFORM

DATE: 29-Aug-19

PARAF: 1/5

Analysis	Specification	Result	Unit
TAMC acc to HM	≤1000	< 10	CFU/g
Method: Current Ph Eur (2.6.12) Analysis Date: 30-Jul-2019 to 05-Aug-2019			

TYMC acc. to HM	≤100	< 10	CFU/g
Method: Current Ph Eur (2.6.12) Analysis Date: 30-Jul-2019 to 05-Aug-2019			

Escherichia coli search acc to HM	Absence	Absence	/1 g
Method: Current Ph Eur (2.6.13) Analysis Date: 30-Jul-2019 to 05-Aug-2019			

Sample Compliance Assessment

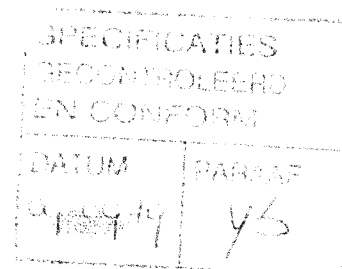
EB19AA2702-9 meets the requirement(s) for all listed test(s) where specifications were applied.

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

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.



Reviewed and electronically signed for Qualified Person Approval by
Alexandra HAIRON, Valideur
for Eurofins Pharma Quality Control SAS, on 09-Sep-2019 11:54:30 UTC+02:00