

Certificate of Analysis

Productname: **SyrSpend® SF Alka Unflavoured**
Number of analysis/Inspection Code MON-173051B / KEUR-160702B
Batchnumber: **18C13-B08**
Reference code / No.: 3828 / 18C13-B08
Analysed according to: **HN**

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	$\geq 7,0$	9,7		
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:
Drs. M.V. Garcia Alia
Pharmacist - QA Manager / QP

24-04-18

Expiration: 03-2022

Conclusion: APPROVED

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



BioPharma
Product Testing

Chimie
9, Avenue de Laponie – Les Ulis
F-91978 Courtabœuf Cedex
Tél : 33 (0)1 69 10 60 32
Fax: 33 (0)1 69 10 60 58
ChimiePharmaControl@eurofins.com

Fagron Services BV

Molenwerf 13

1911 Uitgeest(NETHERLANDS)

A l'attention de : Quality Assurance

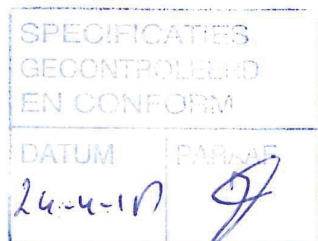
CERTIFICATE OF ANALYSIS

PRODUCT NAME : Syrspend SF alka unflavoured
BATCH NUMBER : 18C13-B08
ANALYTICAL NUMBER :
RECEPTION DATE : 28-Mar-18 2:42:39 PM
ENTRY NUMBER : ACE-2018-00029189
START OF ANALYSIS :

TESTS	SPECIFICATIONS	RESULTS
<u>CHARACTERS</u> Appearance	White free flowing powder	White free flowing powder
<u>IDENTIFICATIONS</u> Colored by iodine Carbonates Calcium	Orange-red to deep blue Effervescence Yellowish-red to flame test	Deep blue (x3) Complies Complies
<u>TESTS</u> pH Water solubility	> 7.0 Dispersible to form cloudy, viscous liquid	9.7 Complies
<u>ASSAYS</u> Calcium carbonate (in the as is basis)	48.2 to 58.9 % (w/v)	51.6 %

NOTE: Analysis performed according to client file "SyrSpend SF Alka: method of analysis", 14ACE102

CONCLUSION : COMPLIES FOR PERFORMED TESTS



Analyst
NL, LB, TB, MAS/JLO, M^{re}

Pharmacist

Certificat validé le 23-Apr-18 4:12:49 PM informatiquement par :

Nicolas BILON Responsable QC



Chimie
9, Avenue de Laponie – Les Ulis
F-91978 Courtabeuf Cedex
Tél : 33 (0)1 69 10 60 32
Fax: 33 (0)1 69 10 60 58
ChimiePharmaControl@eurofins.com

Fagron Services BV
Molenwerf 13

1911 Uitgeest(NETHERLANDS)
A l'attention de : Quality Assurance

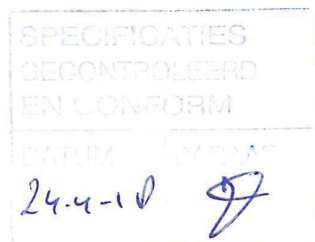
CERTIFICATE OF ANALYSIS

PRODUCT NAME : Syrspend SF alka unflavoured
BATCH NUMBER : 18C13-B08
ANALYTICAL NUMBER :
RECEPTION DATE : 28-Mar-18 2:42:39 PM
ENTRY NUMBER : **ACE-2018-00029189**
START OF ANALYSIS : 31/03/18

TEST:	Method :	Procedures Eurofins Pharma Quality Control:
Total Aerobic Microbial Count	Eur. Ph.9.3, Chap. 2.6.12 + 2.6.13 + Validation report 14-71495	M-PEH + M-FTH
Total Mould and Yeast Count		M-PEH + M-FTH
Detection of E. coli		M-PEH + M-ECH

	Specifications :	Results
TAMC	≤ 1000 cfu / g	10 cfu / g
TMYC	≤ 100 cfu / g	<10 cfu / g
Detection of E. coli	Absence / g	Absence / g

The tested product corresponds to the requirements of the Eur. Ph. 9.3.



Analyst
NL, LB, TB, MAS/JLO, M^{re}

Pharmacist

Certificat validé le 23-Apr-18 4:12:49 PM informatiquement par :

Nicolas BILON Responsable QC