

Certificate of Analysis

Productname: **SyrSpend® SF Alka Unflavoured**
Number of analysis/Inspection Code MON-172411B / KEUR-160070B
Batchnumber: **18B21-B08**
Reference code / No.: 3828 / 18B21-B08
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	52,1	%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:
Drs. M.V. Garcia Alia
Pharmacist - QA Manager / QP

09-04-18

Expiration: 02-2022

Conclusion: APPROVED

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BioPharma
Product Testing

Chimie
9, Avenue de l'aponie - 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 : 18B21-B08
ANALYTICAL NUMBER:
RECEPTION DATE : 14-Mar-18 10:14:53 AM
ENTRY NUMBER : ACE-2018-00024526
START OF ANALYSIS : 22/03/18

TESTS	SPECIFICATIONS	RESULTS
<u>CHARACTERS</u>		
Appearance	White free flowing powder	White free flowing powder
<u>IDENTIFICATIONS</u>		
Colored by iodine	Orange-red to deep blue	Complies (X3)
Carbonates	Effervescence	Complies (X3)
Calcium	Yellowish-red to flame test	Complies (X3)
<u>TESTS</u>		
pH	> 7.0	9.6
Water solubility	Dispersible to form cloudy, viscous liquid	Complies
<u>ASSAYS</u>		
Calcium carbonate (in the as is basis)	48.2 to 58.9 % (w/v)	52.1 %

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

CONCLUSION : COMPLIES FOR ALL PERFORMED TESTS

SPECIFICATIES GECONTROLEERD EN CONFORM	
DATUM 5-4-18	PARAAF

Analysts
EJ, EJN, JBU, ME, ER, ANV

Approbator

Certificat validé le 04-Apr-18 5:09:57 PM informatiquement par :

Antoine Belland Pharmacien responsable



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Product Testing

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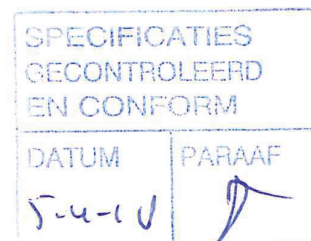
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PRODUCT NAME : SyrSpend SF Alka Unflavoured
BATCH NUMBER : 18B21-B08
ANALYTICAL NUMBER:
RECEPTION DATE : 14-Mar-18 10:14:53 AM
ENTRY NUMBER : ACE-2018-00024526
START OF ANALYSIS : 16/03/18

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.



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