

Certificate of Analysis

Productname: **SyrSpend® SF Alka Unflavoured**
Number of analysis/Inspect **MON-168170B** / **KEUR-155932B**
Batchnumber: **17J30-B04**
Reference code / No.: **3828** / **17J30-B04**
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	$\geq 7,0$	9,3		
Solubility in water	Dispersible	Conform		
Assay Calcium carbonate	48,2 - 58,9	53,0	%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

28-12-17

Expiration: 10-2021

Conclusion: APPROVED

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



BioPharma
Product Testing

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A l'attention de : Quality Assurance

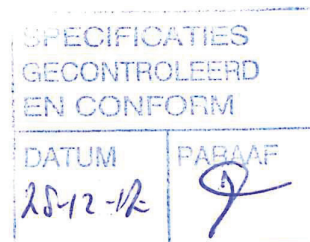
CERTIFICATE OF ANALYSIS

PRODUCT NAME : SyrSpend SF Alka Unflavoured
BATCH NUMBER : 17J30-B04
ANALYTICAL NUMBER :
RECEPTION DATE : 15-Nov-2017 2:17:41 PM
ENTRY NUMBER : **ACE-2017-00141848**
START OF ANALYSIS : 24/11/2017

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	Complies (x3) Complies (x3) Complies (x3)
<u>TESTS</u> pH Water solubility	> 7.0 Dispersible to form cloudy, viscous liquid	9.3 Complies
<u>ASSAYS</u> Calcium carbonate (in the as is basis)	48.2 to 58.9 % (w/v)	53.0%

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

CONCLUSION : COMPLIES FOR PERFORMED TESTS



Analyst
ADY, NAZ, ER, TB

Approbator

Certificat validé le 13-Dec-2017 1:06:30 PM informatiquement par :

Marie Broette Directeur de Site



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CERTIFICATE OF ANALYSIS

PRODUCT NAME : Syrspend SF Alka Unflavoured
BATCH NUMBER : 17J30-B04
ANALYTICAL NUMBER :
RECEPTION DATE : 18-Dec-2017 10:48:11 AM
ENTRY NUMBER : **ACE-2017-00153639**
START OF ANALYSIS : 20/12/17

TEST:	Method :	Procedures Eurofins Pharma Quality Control:
Total Aerobic Microbial Count	Eur. Ph.9.2, 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. 9.2.

Visa Technician: NL



Approbator

Certificat validé le 27-Dec-2017 5:41:47 PM informatiquement par :

Marie Brette Directeur de Site