



Certificate of Analysis

Productname: Fitalite

Inspection No: M10308/1225/536
Batchnumber: 25I02-T10-124174
Expiration date: 30.11.2028
Analysed according to: FSCE-SPEC-0375

Customer: FAGRON a.s.
Sample Unit: 1 x 500 g
Batch Size: 200 x 500 g

Batch no. of vendor: 25I02-T10

	Requirement	Result	Unit	Standard remark
CHARACTERS				
Appearance	Almost white to light yellow, opaque, semi-viscous cream.	Conform		
Fitalite color scale	A, B, C, D, E, F, G, H	B		
Odour	Characteristic odour.	Conform		
IDENTIFICATION				
Identification A	Conform	Conform		Benzoic acid, HPLC
Identification B	Conform	Conform		Sorbic acid, HPLC
TESTS				
pH	3,5 - 5,5	4,8		
Yield value	75 - 200	151	Pa	25+ - 2 °C
Microbiology	Conform	Conform		
TAMC	$\leq 1 \times 10^2$	<10	CFU/g	
TYMC	$\leq 1 \times 10^1$	<10	CFU/g	
Pseudomonas aeruginosa	negative/1g	Conform		
Staphylococcus aureus	negative/1g	Conform		
TSE/BSE	No contamination with TSE/BSE-risk materials.	Conform		
Residual solvents	ICH Q3C	Conform		
Elemental impurities	ICH Q3D	Conform		
Nitrosamines	Risk evaluation	Conform		
ASSAY				
Benzoic acid	0,13 - 0,26	0,20	%	HPLC
Sorbic acid	0,07 - 0,14	0,10	%	HPLC

Performed by: QC Fagron a.s. (CZ)

Responsible: Mgr. Kateřina Špičková, QC
Ing. Martina Zemanová,

Date: 22.12.2025

Conclusion: APPROVED

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