



## Certificate of Analysis

**Productname:** Lavandulae etheroleum

**Inspection No:** K01735/0523/536

**Batchnumber:** 23A12-T02-102627

**Expiration date:** 22.12.2025

**Analysed according to:** ČL 2017-Dopl.2018, Ph.Eur. 11.0

**Original Manuf. Date:** 23.12.2022

**Sample Unit:** 1 x 1 ml

**Batch Size:** 104 x 100 ml

**Identification of producer:** V00201

**Batch no. of vendor:** 1335332

	Requirement	Result	Unit	Standard remark	Insp. Site
CHARACTERS					
Appearance	Colourless or pale yellow, clear liquid.	Conform			Fagron CZ
Odour	Complex, reminiscent of linalyl acetate.	Conform			Fagron CZ
IDENTIFICATION					
Identification B	Conform	Conform		Chromatographic profile, GC	Contract Lab
TESTS					
Relative density	0,878 - 0,892	0,884			Fagron CZ
Refractive index	1,455 - 1,466	1,459			Fagron CZ
Optical rotation	-12,5 - -6,0	-7,4	°		Fagron CZ
Acid value	<=1,0	0,49			Fagron CZ
Chromatographic profile	Conform	Conform		GC	Contract Lab
limonene	<=1,0	0,2	%		Contract Lab
1,8-cineole	<=2,5	1,0	%		Contract Lab
3-octanone	0,1 - 5,0	2,2	%		Contract Lab
camphor	<=1,2	0,2	%		Contract Lab
linalol	20,0 - 45,0	34,0	%		Contract Lab
linalyl-acetate	25,0 - 47,0	36,3	%		Contract Lab
terpinen-4-ol	0,1 - 8,0	3,3	%		Contract Lab
lavandulyl-acetate	>=0,2	2,6	%		Contract Lab
lavandulol	>=0,1	2,1	%		Contract Lab
alfa-terpineol	<=2,0	0,8	%		Contract Lab
Chiral purity	Conform	Conform		GC	Contract Lab
(S)-linalol	<=12	3	%		Contract Lab
(S)-linalyl acetate	<=1	1	%		Contract Lab
Microbiology	Conform	Conform			Contract Lab
TYMC	<=2 x 10 <sup>2</sup>	<10	CFU/g		Contract Lab
TAMC	<=2 x 10 <sup>3</sup>	<10	CFU/g		Contract Lab
TSE/BSE	No contamination with TSE/BSE-risk materials.	Conform			Data Producer
Residual solvents	CPMP/ICH/82 260/2006	Conform			Data Producer
Metallic residues	ICH Q3D on elemental impurities	Conform			Data Producer

Quality: Excipient

<b>Name</b>	Fagron a.s. (CZ)	<b>Address</b>	Holická 1098/31m, Olomouc	<b>Phone No.</b>	+420585222590
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**Performed by:** Ludmila Burianová

**Responsible:** Mgr. Zdeňka Šinclová, QC  
MVDr. Zdenka Borská, QP

**Date:** 22.05.2023

**Conclusion:** **APPROVED**

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