



Certificate of Analysis

Productname: Lavandulae etheroleum

Inspection No: J04604/0422/536

Batchnumber: 22C08-T07-095543

Expiration date: 21.02.2025

Analysed according to: ČL 2017-Dopl.2018, Ph.Eur.10.0

Original Manuf. Date: 22.2.2022

Sample Unit: 1 x 1 ml

Batch Size: 91 x 250 ml

Identification of producer: V00201

Batch no. of vendor: 1297460

	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	1,460			Fagron CZ
Optical rotation	-12,5 - -6,0	-8,8	°		Fagron CZ
Acid value	<=1,0	0,30			Fagron CZ
Chromatographic profile	Conform	Conform		GC	Contract Lab
limonene	<=1,0	0,2	%		Contract Lab
1,8-cineole	<=2,5	1,2	%		Contract Lab
3-octanone	0,1 - 5,0	2,1	%		Contract Lab
camphor	<=1,2	0,2	%		Contract Lab
linalol	20,0 - 45,0	35,1	%		Contract Lab
linalyl-acetate	25,0 - 47,0	36,6	%		Contract Lab
terpinen-4-ol	0,1 - 8,0	3,4	%		Contract Lab
lavandulyl-acetate	>=0,2	2,0	%		Contract Lab
lavandulol	>=0,1	1,7	%		Contract Lab
alfa-terpineol	<=2,0	0,9	%		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 ²	<10	CFU/g		Contract Lab
TAMC	<=2 x 10 ³	<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

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Performed by: Ludmila Stochlebová

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

Date: 02.06.2022

Conclusion: **APPROVED**

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