



Certificate of Analysis

Productname: Lavandulae etheroleum

Inspection No: J02652/0422/536

Batchnumber: 22A14-T03-093717

Expiration date: 22.12.2024

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

Original Manuf. Date: 23.12.2021

Sample Unit: 1 x 1 ml

Batch Size: 294 x 250 ml

Identification of producer: V00201

Batch no. of vendor: 1292721

	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	0,885			Fagron CZ
Refractive index	1,455 - 1,466	1,460			Fagron CZ
Optical rotation	-12,5 - -6,0	-8,5	°		Fagron CZ
Acid value	<=1,0	0,29			Fagron CZ
Chromatographic profile	Conform	Conform		GC	Contract Lab
limonene	<=1,0	0,2	%		Contract Lab
1,8-cineole	<=2,5	1,1	%		Contract Lab
3-octanone	0,1 - 5,0	0,5	%		Contract Lab
camphor	<=1,2	0,2	%		Contract Lab
linalol	20,0 - 45,0	41,1	%		Contract Lab
linalyl-acetate	25,0 - 47,0	32,9	%		Contract Lab
terpinen-4-ol	0,1 - 8,0	3,7	%		Contract Lab
lavandulyl-acetate	>=0,2	2,2	%		Contract Lab
lavandulol	>=0,1	0,2	%		Contract Lab
alfa-terpineol	<=2,0	1,0	%		Contract Lab
Chiral purity	Conform	Conform		GC	Contract Lab
(S)-linalol	<=12	3,0	%		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

Name	Fagron a.s. (CZ)	Address	Holická 1098/31m, Olomouc	Phone No.	+420585222590
	Kontrolní laboratoř č. 536	Post Code	779 00	Fax No.	+420 585 226 521

Performed by: Ing. Petra Drábková

Responsible: Ing. Pavel Mišák, QC
PharmDr. Ivana Urbánková, QA

Date: 22.04.2022

Conclusion: **APPROVED**

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