

Certificate of Analysis

Productname: Lavandulae etheroleum

Inspection No: 104097/0521/536
 Batchnumber: 21D06-T03-084276
 Expiration date: 28.03.2024
 Analysed according to: ČL 2017-Dopl.2018,Ph.Eur.10.0
 Original Manuf. Date: 29.3.2021

Sample Unit: 1 x 1 ml
 Batch Size: 686 x 250 ml

Identification of producer: V00201
 Batch no. of vendor: 1252709

	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	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	-8,7	°		Fagron CZ
Acid value	<=1,0	0,32			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	38,9	%		Contract Lab
linalyl-acetate	25,0 - 47,0	33,2	%		Contract Lab
terpinen-4-ol	0,1 - 8,0	3,7	%		Contract Lab
lavandulyl-acetate	>=0,2	2,5	%		Contract Lab
lavandulol	>=0,1	1,3	%		Contract Lab
alfa-terpineol	<=2,0	0,7	%		Contract Lab
Chiral purity	Conform	Conform		GC	Contract Lab
(S)-linalol	<=12	2,5	%		Contract Lab
(S)-linalyl acetate	<=1	0,8	%		Contract Lab
Microbiology	Conform	Conform			Contract Lab
TYMC	<=2 x 10 ²	Conform	CFU/g		Contract Lab
TAMC	<=2 x 10 ³	Conform	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

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Performed by: Lucie Kubáňová DiS.
Responsible: Ing. Pavel Mišák, QC
PharmDr. Ivana Urbánková, QA
Date: 09.06.2021
Conclusion: **APPROVED**

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