

Certificate of Analysis

Productname: Thymi etheroleum

Inspection No: I08129/1021/536
Batchnumber: 21117-T02-085599
Expiration date: 07.09.2024
Analysed according to: ČL 2017-Dopl.2020,Ph.Eur.10.0
Original Manuf. Date: 8.9.2021

Sample Unit: 1 x 5 ml
Batch Size: 6 x 30 ml

Identification of producer: V00201
Batch no. of vendor: 1275876

	Requirement	Result	Unit	Standard remark	Insp. Site
CHARACTERS					
Appearance	Clear, yellow or very dark reddish-brown, mobile liquid. Odour reminiscent of thymol.	Conform			Fagron CZ
Solubility	Conform	Conform			Fagron CZ
IDENTIFICATION					
B.chromatographic profile	Conform	Conform		GC	Contract Lab
TESTS					
Relative density	0,915 - 0,935	0,931			Fagron CZ
Refractive index	1,490 - 1,505	1,502			Fagron CZ
Chromatographic profile	Conform	Conform		GC	Contract Lab
alfa-thujene	0,2 - 1,5	0,8	%		Contract Lab
beta-myrcene	1,0 - 3,0	1,7	%		Contract Lab
alfa-terpinene	0,9 - 2,6	1,4	%		Contract Lab
p-cymene	14,0 - 28,0	18,8	%		Contract Lab
gama-terpinene	4,0 - 12,0	6,9	%		Contract Lab
linalol	1,5 - 6,5	4,2	%		Contract Lab
terpinen-4-ol	0,1 - 2,5	0,8	%		Contract Lab
carvacrol methyl ether	0,05 - 1,5	0,08	%		Contract Lab
thymol	37,0 - 55,0	52,9	%		Contract Lab
carvacrol	0,5 - 5,5	3,4	%		Contract Lab
Microbiology	Conform	Conform			Contract Lab
TAMC	<=2 x 10 ³	<10	CFU/g		Contract Lab
TYMC	<=2 x 10 ²	<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

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Performed by: Lucie Kubáňová DiS.

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

Date: 27.10.2021

Conclusion: **APPROVED**

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