

Certificate of Analysis

Productname: Eucalypti etheroleum

Inspection No: I02394/0321/536

Batchnumber: 20E18-F01-085628

Expiration date: 06.05.2023

Analysed according to: ČL 2017, Ph.Eur.10.0

Original Manuf. Date: 7.5.2020

Sample Unit: 1 x 1 ml

Batch Size: 96 x 100 ml

Identification of producer: V00201

Batch no. of vendor: 1204970

	Requirement	Result	Unit	Standard remark	Insp. Site
CHARACTERS					
Appearance	Bezbarvá nebo světle žlutá kapalina.	Conform			Fagron
Odour	Reminiscent of 1,8-cineole.	Conform			Fagron
IDENTIFICATION					
Identification B	Conform	Conform		GC	Contract Lab
TESTS					
Relative density	0,906 - 0,927	0,911			Fagron
Refractive Index	1,458 - 1,470	1,461			Fagron
Optical rotation	0 - +10	+2,3	°		Fagron
Solubility in alcohol	Conform	Conform		1,0 ml/2,0 ml ethanol (70% V/V)	Fagron
Aldehydes	Conform	Conform			Fagron
Chromatographic profile	Conform	Conform		GC	Contract Lab
alfa-pinene	0,05 - 10,0	2,5	%		Contract Lab
beta-pinene	0,05 - 1,5	0,3	%		Contract Lab
sabinene	<=0,3	<0,1	%		Contract Lab
alfa-phellandrene	0,05 - 1,5	1,4	%		Contract Lab
limonene	0,05 - 15,0	7,4	%		Contract Lab
1,8-cineole	>=70,0	81,3	%		Contract Lab
Camphor	<=0,1	<0,1	%		Contract Lab
Microbiology	Conform	Conform			Contract Lab
TAMC	<=2 x 10 ³	Conform	CFU/g		Contract Lab
TYMC	<=2 x 10 ²	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

Name Fagron a.s. (CZ)
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Performed by: Lucie Kubáňová DiS.
Responsible: Ing. Mgr. Kateřina Jokešová, QC
PharmDr. Ivana Urbánková, QA
Date: 29.03.2021
Conclusion: **APPROVED**

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