

Certificate of Analysis

Productname: **Eucalypti etheroleum**

Inspection No: I08146/1021/536
 Batchnumber: **21117-T07-089560**
 Expiration date: 07.09.2024
 Analysed according to: Ph.Eur.10.5
 Original Manuf. Date: 8.9.2021

Sample Unit: 1 x 1 ml
 Batch Size: 48 x 100 ml

Identification of producer: V00201
 Batch no. of vendor: 1275879

	Requirement	Result	Unit	Standard remark	Insp. Site
CHARACTERS					
Appearance	Bezbarvá nebo světle žlutá kapalina.	Conform			Fagron CZ
Odour	Reminiscent of 1,8-cineole.	Conform			Fagron CZ
IDENTIFICATION					
Identification B	Conform	Conform		Chromatographic profile, GC	Contract Lab
TESTS					
Relative density	0,906 - 0,927	0,912			Fagron CZ
Refractive Index	1,458 - 1,470	1,461			Fagron CZ
Optical rotation	0 - +10	+3	°		Fagron CZ
Solubility in alcohol	Conform	Conform		10 volumes of ethanol (70% V/V)	Fagron CZ
Aldehydes	Conform	Conform			Fagron CZ
Chromatographic profile	Conform	Conform		GC	Contract Lab
alfa-pinene	0,05 - 10,0	1,68	%		Contract Lab
beta-pinene	0,05 - 1,5	0,21	%		Contract Lab
sabinene	<=0,3	<0,3	%		Contract Lab
alfa-phellandrene	0,05 - 1,5	1,00	%		Contract Lab
limonene	0,05 - 15,0	8,13	%		Contract Lab
1,8-cineole	>=70,0	82,6	%		Contract Lab
Camphor	<=0,1	<0,1	%		Contract Lab
Microbiology	Conform	Conform			Contract Lab
TAMC	<=2 x 103	<10	CFU/g		Contract Lab
TYMC	<=2 x 102	<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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