



Certificate of Analysis

Productname: Eucalypti etheroleum

Inspection No: J10269/1222/536

Batchnumber: 22K02-T03-099545

Expiration date: 23.10.2025

Analysed according to: ČL 2017-Dopl.2021, Ph.Eur.10.5

Original Manuf. Date: 24.10.2022

Sample Unit: 1 x 1 ml

Batch Size: 67 x 250 ml

Identification of producer: V00201

Batch no. of vendor: 1328935

	Requirement	Result	Unit	Standard remark	Insp. Site
CHARACTERS					
Appearance	Colourless or pale yellow liquid.	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	0,911			Fagron CZ
Refractive index	1,458 - 1,470	1,465			Fagron CZ
Optical rotation	0 - +10	+2,5	°		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	3,01	%		Contract Lab
beta-pinene	0,05 - 1,5	0,23	%		Contract Lab
sabinene	<=0,3	<0,05	%		Contract Lab
alfa-phellandrene	0,05 - 1,5	0,66	%		Contract Lab
limonene	0,05 - 15,0	7,56	%		Contract Lab
1,8-cineole	>=70,0	81,9	%		Contract Lab
Camphor	<=0,1	<0,05	%		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	ICH Q3C	Conform			Data Producer
Metallic residues	ICH Q3D	Conform			Data Producer

Quality: Excipient

Performed by: Ing. Petra Drábková

Responsible: Mgr. Zdeňka Šinclová, QC
MVDr. Zdenka Borská, QP

Date: 02.12.2022

Conclusion: **APPROVED**

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