



## Certificate of Analysis

**Productname:** Eucalypti etheroleum

**Inspection No:** K09222/0124/536

**Sample Unit:** 1 x 1 ml

**Batchnumber:** 23J24-T13-108270

**Batch Size:** 44 x 1 l

**Expiration date:** 17.10.2026

**Analysed according to:** ČL 2017-Dopl.2021, Ph.Eur. 11.0

**Original Manuf. Date:** 18.10.2023

**Identification of producer:** V00201

**Batch no. of vendor:** 1372504

	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	0,912			Fagron CZ
Refractive index	1,458 - 1,470	1,461			Fagron CZ
Optical rotation	0 - +10	+4	°		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	3,59	%		Contract Lab
beta-pinene	0,05 - 1,5	0,14	%		Contract Lab
sabinene	<=0,3	<0,05	%		Contract Lab
alfa-phellandrene	0,05 - 1,5	0,64	%		Contract Lab
limonene	0,05 - 15,0	8,39	%		Contract Lab
1,8-cineole	>=70,0	81,5	%		Contract Lab
Camphor	<=0,1	<0,05	%		Contract Lab
Microbiology	Conform	Conform			Contract Lab
TAMC	<=2 x 10 <sup>3</sup>	<10	CFU/g		Contract Lab
TYMC	<=2 x 10 <sup>2</sup>	<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

<b>Name</b>	Fagron a.s. (CZ)	<b>Address</b>	Holická 1098/31m, Olomouc	<b>Phone No.</b>	+420585222590
	Kontrolní laboratoř č. 536	<b>Post Code</b>	779 00	<b>Fax No.</b>	+420 585 226 521

**Performed by:** Ludmila Stochlebová

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

**Date:** 19.12.2023

**Conclusion:** **APPROVED**

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