

Certificate of Analysis

Productname: Eucalypti etheroleum

Inspection No: J05850/0622/536
Batchnumber: 22A03-T18-097527
Expiration date: 07.10.2024
Analysed according to: ČL 2017-Dopl.2021,Ph.Eur.10.5
Original Manuf. Date: 8.10.2021

Sample Unit: 1 x 1 ml
Batch Size: 5 x 250 ml

Identification of producer: V00201
Batch no. of vendor: 1280842

	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	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	1,8	%		Contract Lab
beta-pinene	0,05 - 1,5	0,3	%		Contract Lab
sabinene	<=0,3	<0,3	%		Contract Lab
alfa-phellandrene	0,05 - 1,5	1,2	%		Contract Lab
limonene	0,05 - 15,0	6,7	%		Contract Lab
1,8-cineole	>=70,0	83,3	%		Contract Lab
Camphor	<=0,1	<0,1	%		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 solvens	ICH Q3C	Conform			Data Producer
Metallic residues	ICH Q3D	Conform			Data Producer

Quality: Excipient

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

Performed by: Lenka Morávková

Responsible: Ing. Pavel Mišák, QC
MVDr. Zdenka Borská, QP

Date: 24.06.2022

Conclusion: **APPROVED**

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