

Certificate of Analysis

Productname: Eucalypti etheroleum

Inspection No: I08130/1021/536
Batchnumber: 21117-T07-087092
Expiration date: 07.09.2024
Analysed according to: Ph.Eur.10.5
Original Manuf. Date: 8.9.2021

Sample Unit: 0 x
Batch Size: 107 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 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	CPMP/ICH/82 260/2006	Conform			Data Producer
Metallic residues	ICH Q3D on elemental impurities	Conform			Data Producer

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

The product conforms to Ph.Eur.10.5.

Performed by: Lucie Kubáňová DiS.

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



Date: 02.11.2021

Conclusion: I certify that the above-mentioned batch of pharmaceutical raw material has been manufactured and tested in accordance with the requirements of Marketing Authorization (License) and requirements of Good Manufacturing Practice.

This document has been produced electronically from our quality system and is valid without signature.

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