



Certificate of Analysis

Productname: Eucalypti etheroleum

Inspection No: J01056/0322/536

Batchnumber: 21K09-T07-093438

Expiration date: 13.10.2024

Analysed according to: Ph.Eur.10.5

Original Manuf. Date: 14.10.2021

Sample Unit: 1 x 1 ml

Batch Size: 63 x 100 ml

Identification of producer: V00201

Batch no. of vendor: 1280722

	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	1,460			Fagron CZ
Optical rotation	0 - +10	3,7	°		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	3,1	%		Contract Lab
beta-pinene	0,05 - 1,5	0,3	%		Contract Lab
sabinene	<=0,3	<0,1	%		Contract Lab
alfa-phellandrene	0,05 - 1,5	1,1	%		Contract Lab
limonene	0,05 - 15,0	7,8	%		Contract Lab
1,8-cineole	>=70,0	81,7	%		Contract Lab
Camphor	<=0,1	<0,1	%		Contract Lab
Microbiology	Conform	Conform			Contract Lab
TAMC	<=2 x 10 ³	<2 x 10 ³	CFU/g		Contract Lab
TYMC	<=2 x 10 ²	<2 x 10 ²	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

Quality: Excipient

Performed by: Ing. Petra Drábková

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

Date: 17.02.2022

Conclusion: **APPROVED**

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