

Certificate of Analysis

Productname: Eucalypti etheroleum

Inspection No: I09317/1221/536
Batchnumber: 21J26-T18-089571
Expiration date: 10.10.2024
Analysed according to: Ph.Eur.10.5
Original Manuf. Date: 11.10.2021

Sample Unit: 1 x 1 ml
Batch Size: 83 x 1 l

Identification of producer: V00201
Batch no. of vendor: 1281426

	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	+2	°		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	1,6	%		Contract Lab
beta-pinene	0,05 - 1,5	0,3	%		Contract Lab
sabinene	<=0,3	<0,05	%		Contract Lab
alfa-phellandrene	0,05 - 1,5	1,4	%		Contract Lab
limonene	0,05 - 15,0	7,6	%		Contract Lab
1,8-cineole	>=70,0	81,3	%		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	CPMP/ICH/82 260/2006	Conform			Data Producer
Metallic residues	ICH Q3D on elemental impurities	Conform			Data Producer

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Performed by: Lucie Kubáňová DiS.
Responsible: Ing. Pavel Mišák, QC
MVDr. Zdenka Borská, QA
Date: 07.12.2021
Conclusion: **APPROVED**

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