



Certificate of Analysis

Productname: Eucalypti etheroleum

Inspection No: M06833/0825/536
Batchnumber: 25E15-T15-122818
Expiration date: 05.05.2028
Analysed according to: ČL 2023, Ph. Eur. 11.0

Customer: FAGRON a.s.
Sample Unit: 1 x 200 ml
Batch Size: 34 x 30 ml

Batch no. of vendor: 1452042

	Requirement	Result	Unit	Standard remark
CHARACTERS				
Appearance	Colourless or pale yellow liquid.	Conform		
Odour	Reminiscent of 1,8-cineole.	Conform		
IDENTIFICATION				
Identification B	Conform	Conform		Chromatographic profile, GC
TESTS				
Relative density	0,906 - 0,927	0,913		
Refractive index	1,458 - 1,470	1,459		
Optical rotation	0 - +10	+2,2	°	
Solubility in alcohol	Conform	Conform		
Aldehydes	Conform	Conform		
Chromatographic profile	Conform	Conform		GC
alfa-pinene	0,05 - 10,0	2,81	%	
beta-pinene	0,05 - 1,5	0,48	%	
sabinene	<=0,3	<0,05	%	
alfa-phellandrene	0,05 - 1,5	0,71	%	
limonene	0,05 - 15,0	7,05	%	
1,8-cineole	>=70,0	81,3	%	
Camphor	<=0,1	<0,05	%	
Microbiology	Conform	Conform		
TAMC	<=2 x 10 ³	<10	CFU/g	
TYMC	<=2 x 10 ²	<10	CFU/g	
TSE/BSE	No contamination with TSE/BSE-risk materials.	Conform		
Residual solvents	ICH Q3C	Conform		
Elemental impurities	ICH Q3D	Conform		
Nitrosamines	Risk evaluation	Conform		

Quality: Excipient

Performed by: QC Fagron a.s. (CZ)

Responsible: Mgr. Kateřina Špičková, QC
Ing. Martina Zemanová,

Date: 14.10.2025

Conclusion: **APPROVED**

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

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